



**STAFF OPERATIONS
MANUAL**

Cooperative Studies Program

December 2007

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INTRODUCTION

The Cooperative Studies Program (CSP) Staff are guided in the conduct of their scientific and administrative responsibilities by the **CSP Staff Operations Manual**. This document supplements the **CSP Guidelines**; the **CSP Global SOPs**; and the **Research and Development in Medicine Manuals**, in particular sections M-3, Part I (General) and M-3, Part II (Medical Research Program). All CSP Staff should be familiar with these documents and the CSP Key Staff Directory and keep these references readily accessible.

Generally, it is understood that the CSP Coordinating Centers (CSPCC) are responsible for the management and conduct of a VA Cooperative Study. These responsibilities include: data collection and analysis; fiscal management; maintenance of study records; adherence to the study protocol; and overall scientific integrity of the study. For VA Cooperative Studies involving investigational drugs, medical devices, and/or biologic agents, the CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC) holds primary responsibility for these items. Additionally, the CRPCC is the primary liaison for all regulatory and safety aspects of VA Cooperative Studies. The Health Economics Resource Center (HERC) oversees economic data collection and analysis for all VA Cooperative Studies. All CSP Coordinating Centers report directly to CSP Central Office. CSP Staff are expected to promptly report all important matters to the appropriate leadership.

The **CSP Staff Operations Manual** details the procedures and special circumstances of the VA Cooperative Study. While the materials are intended to be applicable to all CSP Coordinating Centers, local circumstances may require exceptions and/or modifications. Additionally, VA Central Office may periodically issue guidance to reflect current VA policies. Center leadership and/or VA Central Office will provide further guidance to CSP Staff as necessary.

ROLES AND RESPONSIBILITIES

The following table lists the roles and responsibilities of CSP personnel.

Title	Responsibility
CSP CENTERS	
Center Director	<ul style="list-style-type: none"> • Organization and management of the Coordinating Center (CC) • Professional, scientific and visionary leadership • Communication with Central Office regarding Center and study issues • Center and program strategic planning • Quality Initiatives
Associate Center Director	<ul style="list-style-type: none"> • Scientific management of the Coordinating Center including studies and Center based research • Special projects assigned by the Center Director • Center strategic planning
Assistant Center Director for Administrative Operations/AO	<ul style="list-style-type: none"> • Administrative, fiscal and human resource management of the Coordinating Center • Center strategic planning
Assistant Center Director for Technical Operations	<ul style="list-style-type: none"> • Manages all information technology aspects of the Coordinating Center • Contributes to the development of CSP information technology needs • Technical management of the Coordinating Center
Health Economist	<ul style="list-style-type: none"> • Addresses economic issues assessed in a trial if appropriate • Member of Planning and Executive Committee
Study Biostatistician	<ul style="list-style-type: none"> • Provides methodological and statistical direction to a study • Member of Planning and Executive Committees • Manages CSSMRB submission • Manages study start-up • Monitors on-going studies for compliance, data collection issues, recruitment • Manages study analyses
Study Project Manager	<ul style="list-style-type: none"> • Organization and administrative management of studies • Member of Planning and Executive Committees • Tracks and manages all study budget costs • Coordinates start-up and ongoing issues at participating sites • Responsible for regulatory requirements for studies
Clinical Data Manager	<ul style="list-style-type: none"> • Performs data validation and quality control checks on study data to ensure protocol adherence • Produces and distributes site specific data quality control reports • Liaise between sites and Center on data related issues
Quality Assurance Specialist	<ul style="list-style-type: none"> • Assures compliance with GCP and CSP SOPs • Manages institutional and informed consent requirements for studies • Coordinate HRC activities • Notifies sites of upcoming regulatory expirations

CSPCRPCC	
Study Clinical Research Pharmacist (Pharmaceutical Project Director)	<ul style="list-style-type: none"> • Manages all the safety and regulatory aspects for drug/device studies in all phases • Oversees all study safety data • Member of Study Planning and Executive Committees
Pharmaceutical Project Manager	<ul style="list-style-type: none"> • Assists in developing pharmacy budgets during the study planning phase • Assists in managing the regulatory and safety aspects of studies in start-up and ongoing phases • Tracks and manages pharmacy study budgets
Adverse Event/Regulatory Specialist	<ul style="list-style-type: none"> • Manages all safety and regulatory aspects for studies in all phases • Oversees all study safety data • Member of Study Planning and Executive Committees
Adverse Event Program Manager	<ul style="list-style-type: none"> • Assists in developing Adverse Event budgets during the study planning phase • Assists in managing the regulatory and safety aspects of studies in start-up and ongoing phases • Tracks and manages regulatory study budgets
SITE MONITORING, AUDITING AND RESOURCE TEAM	
Good Clinical Practices Standards and Resources Group	<ul style="list-style-type: none"> • Develop study tools for GCP compliance • Provide GCP training programs • Perform study implementation visits and for cause audits
Good Clinical Practices Review Group	<ul style="list-style-type: none"> • Perform GCP periodic study site and closeout reviews • Perform as needed visits
Good Clinical Practices Monitoring Group	<ul style="list-style-type: none"> • Develop study monitoring plans for pivotal trials • Perform GCP study site initiation, routine, and close-out visits • Perform as needed GCP study visits
VA CENTRAL OFFICE	
Director, Clinical Science Research & Development	<p>General:</p> <ul style="list-style-type: none"> • Responsible for overall CSP direction and leadership <p>Specific:</p> <ul style="list-style-type: none"> • Responsible to VA/VHA leadership for CSP • Approves all CSP-related requests • Authorizes funding for CSP activities • Conducts performance evaluations for Center Directors and CSP CO personnel • Assigns duties as needed to CSP personnel <p>Note: Some responsibilities are delegated to the CSP Deputy Director and/or provides responses after review by CO staff</p>
Deputy Director, Cooperative Studies Program	<p>General:</p> <ul style="list-style-type: none"> • Manages CSP scientific, operational and financial activities <p>Specific:</p> <ul style="list-style-type: none"> • Primary point of contact for all CSP study activities • Primary point of contact for all CSP inquiries/requests • Primary point of contact for agreements with outside organizations <ul style="list-style-type: none"> ○ Includes CRADAs (industry) and Interagency Agreements (with NIH) • Reviews budget/funding and/or study-related requests

	<ul style="list-style-type: none"> • Oversees CSP Central Office activities • Responsible for all scientific review activities • Coordinates CSP communications (e.g., study initiation, publications, press releases) • Coordinates CSP policy efforts and related documents • Responsible to ORD leadership for CSP activities
Management Analyst (Finance), Cooperative Studies Program	<p>General:</p> <ul style="list-style-type: none"> • Manages all financial activities for CSP <p>Specific:</p> <ul style="list-style-type: none"> • Manages all CSP approved budget requests • Processes all CSP financial transactions to field sites (for studies and travel) • Reviews all VA-NPC study budgets and funding activities • Responsible to ORD for all CSP budget reporting • Coordinates and reviews yearly budget submissions • Analyzes the CSP Center and study budget submission for efficiency and implement necessary changes • Assigns funding for all CSP Central Office and field travel • Manages & processes Interagency Agreements (IAAs) and funding
CSR&D Administrative Officer	<p>General:</p> <ul style="list-style-type: none"> • Manages and directs VACP CSR&D/CSP administrative staff and other duties as assigned by Director, BLR&D/CSR&D and Deputy Director, CSP <p>Specific:</p> <ul style="list-style-type: none"> • Primary point of contact for VHA administrative policies and regulations <ul style="list-style-type: none"> ◦ Includes travel, IT, and contracting • Routes CSP assignments to appropriate administrative staff • Monitors tracking and request response rate. • Assists CSR&D/BLR&D Directors in implementation of national administrative policies. • Assists CSP Deputy Director in reviewing non-CRADA/CTAA contracts for contractual compliance. • Monitors and manages IT issues within VACO and communicates with coordinating centers and field stations on national IT issues.
CSP Program Analyst	<p>General:</p> <ul style="list-style-type: none"> • Management of CSP review activities, special projects and assists CSP Director <p>Specific:</p> <ul style="list-style-type: none"> • Management of LOI process • Primary backup point of contact for CSP-related outside queries • Coordination and organization of CSSMRB meeting • CSP Studies communications • Management of CSP website content • Generation of CSP stakeholders reports

CSP Program Specialist	<p>General:</p> <ul style="list-style-type: none"> • Manages CSP CO administrative functions & field communications <p>Specific:</p> <ul style="list-style-type: none"> • Receives and assigns all outside correspondence for CSP • Handles scheduling and event planning for CSP CO functions • Maintains calendars and contact info for CSP CO staff • Communications <ul style="list-style-type: none"> ○ Schedules CSP Directors and AO conference calls ○ Sends general announcements ○ Sends report reminders and collects responses • Maintains CSP CO records • Main point of contact for ePROMISE information requests from Coordinating Centers • Handles A/V and logistics for CSP CO meetings and events
CSR&D Program Specialist	<p>General</p> <ul style="list-style-type: none"> • Assists the CSP Financial Analyst and CSR&D/CSP Administrative Officer

LETTER OF INTENT

I. Overview

The submission of a Letter of Intent (LOI or Planning Request) by an eligible VA investigator to the Cooperative Studies Program is the first step in the CSP study development process. The investigator who submits the LOI to CO is designated as the Principal Proponent. The LOI is a detailed study proposal that describes the Principal Proponent's ideas for a multi-site trial with the goal of enhancing the care provided in the VA. The elements required in the LOI are those aspects critical to any clinical trial, as well as the study's relevance and feasibility to the VA. Upon receipt of the LOI, a review process is initiated to determine the appropriateness of the concept for a VA Cooperative Study.

II. Review Process

A. Processing of LOI

1. Letters of Intent are sent directly to the CSP Central Office. The CO staff is responsible for processing the LOI and overseeing its review process.
2. **Tasks:**
 - a. **CSP Program Analyst reviews the LOI to confirm contact information and all proper approvals from Principal Proponent's VA Medical Center (i.e., ACOS for R&D and VAMC Director) are provided.**
 - b. **CSP Program Analyst sends to Principal Proponent acknowledgement of receipt (Letter 1 - LOI Acknowledgement Letter)**
 - c. **Once all required information and signatures are obtained, the CSP Program Analyst records the following information in the LOI tracking database:**
 - name of Principal Proponent
 - study title
 - date LOI received
 - d. **CSP Program Analyst creates an LOI folder for both the CO files and the CO hard drive.**
 - **Personal identifiers (e.g., SSN) should be removed.**
 - e. **CSP Program Analyst prepares a folder for review by CSP Deputy Director containing a copy of the LOI (Suggested Reviewers List page flagged) and available biographical and publications information for Suggested Reviewers. Upon request, CSP Program Analyst will also prepare for CSP Deputy Director's consideration a list of additional reviewers and their biographical and publications information.**
 - Suggested reviewer information can be obtained from relevant internet sources (e.g., PubMed).

Reference: Checklist 1 – Letter of Intent Checklist Items 1-5

B. Administrative Review

1. An administrative review of the LOI is conducted to determine whether it is ready for external review for scientific and clinical merit.

2. **Tasks:**
 - a. **CSP Deputy Director reviews the LOI for completeness and appropriateness to the VA.**
 - Attention should be given to proponent eligibility, relevance to the VA, study feasibility / sample size calculations, and required elements of the LOI.
 - Additional information may be requested from the Principal Proponent if needed.
 - b. **CSP Deputy Director reviews the LOI with Director, CSR&D to determine if the review process should continue.**

Reference: Checklist 1 – Letter of Intent Checklist Items 6-7

C. External Review

1. If decision is made to continue the review of the LOI, external reviews are conducted by independent clinical and/or methodological experts knowledgeable of the topic and the conduct of clinical trials in the field.
2. **Tasks:**
 - a. **CSP Deputy Director determines a list of proposed reviewers for the LOI.**
 - b. **CSP Program Analyst contacts the proposed reviewers to determine their willingness to review the LOI and records date of initial contact in the LOI tracking database. (See **Letter 2** - Invite Letter for CSP LOI Reviewers)**
 - c. **If the proposed reviewer accepts, CSP Program Analyst sends to reviewer Reviewer Acknowledgement Letter (**Letter 3**); electronic version/hardcopy of the LOI, Principal Proponent's Curriculum Vitae, and Guidelines for Reviewing Planning Requests VA Cooperative Studies Program (CSP) (**Exhibit 1**), and records date these materials are sent in the LOI tracking database.**
 - A minimum of three reviewers should be obtained.
 - d. **If a review is not received within approximately one month after the LOI is sent to the reviewer (or by the submission date agreed upon), CSP Program Analyst sends a reminder to the reviewer.**
 - e. **Upon receipt of a review, CSP Program Analyst sends an acknowledgement to the reviewer; removes any identifiers from the review; saves an electronic version of the review in the appropriate CO hard drive folder; and enters date received in the LOI tracking database. (See **Letter 4** - Review Acknowledgement Letter)**
 - f. **When all reviews for the LOI are received, CSP Program Analyst creates a folder containing a copy of the LOI and all reviews and submits to CSP Deputy Director.**
 - g. **Based on the reviews, CSP Deputy Director may instruct CSP Program Analyst to send copy of the LOI to Director, CSPCRPCC and to Director, HERC. (See **Memo 5** – Notification of Possible Planning)**
 - h. **CSP Deputy Director evaluates reviewer comments and ratings and summarizes them for approval by/ further discussion with the Director, CSR&D.**

References:

- Exhibit 1 - Guidelines for Reviewing Planning Requests
- Checklist 1 – Letter of Intent Checklist Items 8-15

III. Notifications

A. Preparation

1. Once a decision is made to either approve or disapprove the LOI for further planning, CO staff prepare necessary notifications.
2. **Tasks for disapproved LOI:**
 - a. **CSP Program Analyst records disapproval in the LOI tracking database.**
 - b. **Director, CSR&D sends disapproval notification letter to Principal Proponent.**
 - This letter summarizes key points raised by the reviewers.

Reference: Checklist 1 – Letter of Intent Checklist Item 16

3. **Tasks for approved LOI:**
 - a. **CSP Deputy Director assigns CSP study number to the LOI.**
 - b. **CSP Deputy Director with Director, CSR&D determines appropriate CSP Coordinating Center for the LOI.**
 - c. **CSP Deputy Director records assigned CSP study number and Coordinating Center in LOI tracking database.**
 - d. **Director, CSR&D writes approval notification letter for Principal Proponent summarizing reviewer comments and indicating assigned CSP study number and CSP Coordinating Center.**
 - e. **CSP Program Analyst indicates assigned CSP study number on the reviews; makes six sets of copies of approval notification letter, reviewer comments; and LOI for distribution, and files original documents in the LOI's CO file.**

Reference: Checklist 1 – Letter of Intent Checklist Item 17

B. Distribution of Notifications

1. Notification letters and supporting materials are distributed accordingly.
2. **Tasks:**
 - a. **For a disapproved LOI, CSP Deputy Director sends disapproval notification letter by Director, CSR&D to Principal Proponent and his/her ACOS for R&D.**
 - b. **For an approved LOI, CSP Deputy Director sends approval notification packets to the following. (Unless otherwise noted, the approval notification packet is comprised of approval notification letter by Director, CSR&D, reviewer comments, and LOI.)**
 - **Principal Proponent (approval notification letter and reviewer comments only)**
 - **Principal Proponent's ACOS for R&D (approval notification letter only)**
 - **Assigned CSP Coordinating Center**
 - **Clinical Research Pharmacy Coordinating Center**
 - **Health Economics Resource Center**
 - **CSP DNA Bank**

Reference: Checklist 1 – Letter of Intent Checklist Items 18-19

Checklist 1 – Letter of Intent Checklist

<u>DATE</u>	<u>TASK</u>
	<u>Processing of LOI</u>
_____ 1	LOI reviewed by CSP Program Analyst to confirm all appropriate information received.
_____ 2	Letter 1 (LOI Acknowledgement Letter) sent to Principal Proponent.
_____ 3	Information recorded in LOI tracking database.
_____ 4	LOI folder created for both the CO files and the CO hard drive.
_____ 5	Folder prepared for review by CSP Deputy Director to include suggested reviewers.
	<u>Administrative Review</u>
_____ 6	CSP Deputy Director reviews LOI for completeness and appropriateness to the VA.
_____ 7	CSP Deputy Director reviews LOI with Director, CSR&D to determine if review process should continue.
	<u>External Review</u>
_____ 8	CSP Deputy Director determines list of proposed reviewers for the LOI.
_____ 9	Proposed reviewers contacted and dates recorded in LOI tracking database. See Letter 2 (Invite Letter for CSP LOI Reviewers)
_____ 10	If reviewer accepts, Letter 3 (Reviewer Acknowledgement Letter) and appropriate materials sent along with Exhibit 1 (Guidelines for Reviewing Planning Requests). Dates materials sent recorded in LOI tracking database. Minimum of 3 reviewers required.
_____ 11	Reminder sent to reviewer if review not received within one month.
_____ 12	When review received, Letter 4 (Review Acknowledgement Letter) sent to reviewer, identifiers removed from review, and date received entered in LOI tracking database.
_____ 13	When all reviews received, CSP Program Analyst creates folder with copy of LOI and reviews and submits to CSP Deputy Director.
_____ 14	Based on reviews, LOI may be sent to Director, CSPCRPCC and to Director, HERC. See Memo 5 (Notification of Possible Planning)
_____ 15	CSP Deputy Director evaluates reviewer comments and ratings and summarizes them for approval by/further discussion with the Director, CSR&D
	<u>Preparation of Notification</u>
	For disapproved LOI:
_____ 16	- Disapproval recorded in LOI tracking database - Director, CSR&D sends disapproval notification to Principal Proponent.
	For approved LOI:
_____ 17	- CSP study number assigned to LOI. - Selection of CSP Coordinating Center made to handle study. - CSP study number and Coordinating Center recorded in LOI tracking database. - Notification letter sent to Principal Proponent. - CSP Program Analyst makes copies of letter, reviewer comments and LOI for distribution and filing.

DATE

TASK

Distribution of Notifications

- _____ 18 For disapproved LOI:
 - Disapproval notification letter sent to Principal Proponent and his/her ACOS for R&D
- _____ 19 For approved LOI:
 - Approval notification packets sent out. See distribution list in Staff Operations Manual.

PROTOTYPE LETTER 1

LOI Acknowledgement
Letter

Dear Dr. [NAME]:

We have received your Letter of Intent entitled “[LOI TITLE]”. Your submission will now go through the LOI evaluation process.

Thank you for your interest in the VA Cooperative Studies Program.

Sincerely,

[NAME]
VA Cooperative Studies Program (125)
810 Vermont Avenue, NW
Washington, DC 20420

Ph: 202-254-0192
Fax: 202-254-0471

PROTOTYPE LETTER 2

Invite Letter for CSP LOI
Reviewers

Dear Dr. [NAME]:

The Department of Veterans Affairs Cooperative Studies Program (CSP) has received a Letter of Intent (LOI) from Dr. [NAME] entitled "[TITLE]". This Letter of intent is a request to CSP for approval and funding to plan a VA multi-site clinical trial. Given your expertise, we would like to determine your interest and availability in providing a review for the LOI.

The review would consist of a few written pages of your expert evaluation of the proposed study's concept, applicability, and feasibility, along with any major or minor concerns you might have. We also ask reviewers to provide a review within a month's time, but can accommodate if more time is needed. If you are willing and able to review this LOI, we will send it to you along with a review form.

[IF APPLICABLE]

Please note that Dr. [NAME] has also submitted your name as a potential planning committee member for the study if approved for planning. If the LOI is approved and you prefer to serve on this committee instead (i.e., you cannot provide a review because of a potential conflict), please let me know.

If you are unable to be a reviewer, any suggestions for reviewers would be greatly appreciated.

Thank you for considering this request.

Sincerely,

[NAME]

VA Cooperative Studies Program (125)
810 Vermont Ave NW
Washington DC 20420

Ph: 202-254-0192

Fax: 202-254-0471

PROTOTYPE LETTER 3

Reviewer Acknowledgement
Letter

Dear Dr. [NAME]:

We are glad you are available to review the Cooperative Studies Program Planning Request submitted by Dr. [NAME] entitled "[LOI TITLE]". I have attached copies of Dr. [NAME]'s Planning Request and Curriculum Vitae, and the review guidelines.

Please contact me if I can be of any service.

[NAME]
VA Cooperative Studies Program (125)
810 Vermont Avenue, NW
Washington, DC 20420

Ph: 202-254-0192
Fax: 202-254-0471

PROTOTYPE LETTER 4

Review Acknowledgement
Letter

Dear Dr. [NAME]:

Thank you for reviewing the VA Cooperative Studies Program Planning Request submitted by Dr. [NAME], entitled "[LOI TITLE]". Your help and effort are greatly appreciated as the VA and Cooperative Studies Program continue our mission of supporting high quality multi-site clinical trials to enhance the care we give to veterans.

Sincerely,

[NAME]
VA Cooperative Studies Program (125)
810 Vermont Avenue, NW
Washington, DC 20420

Ph: 202-254-0192
Fax: 202-254-0471

Memorandum

PROTOTYPE MEMO 5

Upon notification from
Director, Clinical Science
R&D of possible planning

Date:

From: Deputy Director, Cooperative Studies Program (125)

Subj: [title of LOI]

To: Director, CSPCRPCC (151-1)
Director, HERC (152 MPD)
Director, DNA Bank

1. Enclosed is an LOI of a study by [LOI Principal Proponent] entitled, “[LOI title]”.
2. This LOI is being provided for your information to assist with planning purposes and/or determining if resources need to be allocated for this study if approved for planning.
3. To date, approval for planning has not been given. If and when approval for planning is given, you will be notified along with the assigned CSP study number.
4. If you have any questions, please contact me at (202) 254-0252 or via e-mail at grant.huang@va.gov.

Grant D. Huang, MPH, Ph.D.

**GUIDELINES FOR REVIEWING PLANNING REQUESTS
VA COOPERATIVE STUDIES PROGRAM (CSP)**

In reviewing the enclosed proposal, please keep in mind that this is a request for planning support. This is the initial review in the planning process. If planning support is granted, the study will be assigned to one of the Cooperative Studies Program Coordinating Centers. The principal investigator and a biostatistician at the Center, together with the study's Planning Committee, will develop the final protocol. The Cooperative Studies Scientific Merit Review Board (CSSMRB) will then review the proposed research plan. Details such as specific inclusion/exclusion criteria, specific treatment regimens, follow-up techniques, data collection forms, sample size estimation, data processing procedures and statistical analyses need not be included in the investigator's proposal at this stage.

Please comment on the following:

1. DESCRIPTION

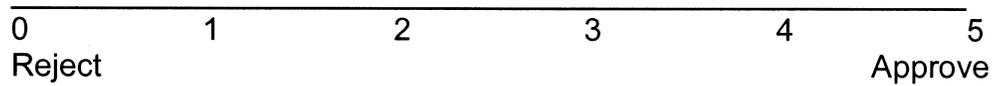
Briefly describe the proposed study and the specific objectives.

4. RECOMMENDATIONS

Keeping in mind that this is a request to plan a cooperative study, please indicate your overall assessment by typing your rating in the space provided using the scale below as a guide.

A score in the mid-range indicates a judgement that the study should be planned, but with specified modifications. Please add any additional comments.

RATING: _____



Comments:

PLANNING

I. Initial Startup of Planning Activities

A. Written Notification to Principal Proponent by CO

1. Planning activities start when CO approves a Letter of Intent, notifies the Principal Proponent and assigns the CSPCC, CSPCRPCC, and HERC in writing. If there is a DNA Bank component included, MAVERIC and Palo Alto should also be notified.
2. **Tasks:**
 - a. **Record date of this letter on the Planning Checklist**

Reference: Checklist 2 - Study Planning Checklist Item 1

3. The official study title will be the one given on the Letter of Intent. If the title is changed for the CSSMRB submission, the Proponent requests a change in writing to the CSPCC Director.

B. Initial Contact with Principal Proponent by CSPCC

1. The CSPCC initiates contact with the Principal Proponent to provide an introduction to CSP, an overview of planning stage activities, and to begin organizing a study planning team.
2. **Tasks:**
 - a. **The CSPCC Director sends Memo 6 to the Principal Proponent.**
 - This memo identifies the Biostatistician, Project Manager and other team members for the study. The Proponent is asked to identify a Planning Committee. The memo also requests that the Principal Proponent obtain the signatures of his/her ACOS/Research and Development, the Chief of Staff and the Medical Center Director, indicating that they have been informed and approve of the Principal Proponent's participation in the study. (See **Memo 7**)
 - b. **The CSPCRPCC Director sends Memo 8 to the Principal Proponent (if applicable).**
 - This memo identifies the Study Clinical Research Pharmacist and/or Adverse Event Specialist assigned to the study.
 - **Checklist 3** - CSPCRPCC Budget Requirements Checklist for items to be considered for inclusion in budget to be sent along with **Memo 8**.
 - c. **CSPCC Director or designee contacts the Principal Proponent by telephone.**
 - d. **CSPCC Director makes contact with the ACOS for R& D (Memo 9).**
 - This memo informs the ACOS for R&D that approval has been granted for the Principal Proponent to begin working on a cooperative study.
 - e. **Other CSP personnel make phone calls to Principal Proponent.**
 - After sufficient time has elapsed for **Memo 6** to reach the Proponent, the Biostatistician and Project Manager call to introduce themselves and to review some of the items referred to in **Memo 6**.

f. CSPCRPCC contacts Principal Proponent.

- After sufficient time has elapsed for **Memo 8** to reach the Proponent, the Study Clinical Research Pharmacist and/or Adverse Event Specialist will call to introduce themselves and to review some of the items referred to in **Memo 8. Checklist 3** - CSPCRPCC Budget Requirements Checklist will be discussed with the Principal Proponent during initial contact by the Study Clinical Research Pharmacist.

References:

- Checklist 2 - Study Planning Checklist Items 2 – 9
- Checklist 3 - CSPCRPCC Budget Requirements Checklist

C. Establishment of CSPCC and CSPCRPCC Central Study Files

1. The Central File serves to collect all key documents and approvals relevant to the study. It is important that the file structure be established according to standard operating procedures (see reference below).
2. **Tasks:**
 - a. **The CSPCC establishes a central study file to include all materials generated during the planning stage.**
 - Once the study has been approved and funded after CSSMRB, the complete central study file can be established.
 - **Checklist 4** - SMART Checklist should be utilized to complete tasks associated with monitoring.
 - b. **The CSPCRPCC establishes a central study file to include all pharmacy or regulatory materials generated during the planning state.**
 - Once the study has been approved and funded, the complete pharmacy and regulatory study files can be established.

References:

- CSP Global SOP - 3.2.0 - Central Monitoring - Attachment 2: Guidelines for Contents of the CSP Central Study File
- Good Clinical Practice: Consolidated Guidance (ICH-E6), Section 8 – Essential Documents for the Conduct of a Clinical Trial
- Checklist 2 - Study Planning Checklist Items 10–11
- Checklist 4 – SMART Checklist

D. Announcement of Study Planning to VA Sites

1. Once planning activity is approved, an announcement is made to the field by VACO. Interested sites will be asked to contact Principal Proponent (and/or Coordinating Center) if interested in participating in study.
2. **Task**
 - a. **CSP Deputy Director sends an email to the ACOS for R&Ds and posts relevant information on the CSP website.**

Reference: Checklist 2 - Study Planning Checklist Item 12

E. Formation of Planning Committee

1. The planning committee will be key to the development of the full study and writing the final proposal for review at CSSMRB.
2. Members of the Planning Committee include: the Principal Proponent, Biostatistician, Health Economist (if applicable), Clinical Research Pharmacist, Coordinating Center Director, Adverse Event Specialist, Project Manager, and Content Expert(s). Pharmaceutical Project Manager will be a non-voting member.

3. **Tasks:**
 - a. **The Principal Proponent will submit the names and contact information of all members nominated for the Planning Committee to the Project Manager.**
 - b. **The Project Manager will contact each member for their CV.**
 - c. **This material will be provided to the CSPCC Director for approval and then forwarded to the Director, Clinical Science R&D for concurrence/approval.**
 - d. **When the Planning Committee members have been approved, the Project Manager will initiate arrangements for the first Planning Committee meeting.**

References:

- CSP Guidelines, Chapter II, "Developing a CSP Study", Section C., "Planning a CSP Study: Participants", Part 5, "Planning Committee" for a comprehensive list of Planning Committee Members
- Checklist 2 - Study Planning Checklist Items 13 - 15

II. First Planning Meeting

A. Preparation for First Planning Meeting

1. The First Planning Meeting should be held within three months of the date that active planning is approved. If this cannot be done, the CSPCC Director will request additional time from the Director, Clinical Science R&D Service.
2. The First Planning Committee meeting will be held in the vicinity of VA Central Office, unless, permission is granted by the Director, Clinical Science R&D Service to hold the meeting elsewhere.
3. **Tasks:**
 - a. **Project Manager will contact all of the Planning Committee members and attendees to identify potential meeting dates.**
 - A minimum of 3 dates are to be identified.
 - b. **Set up e-mail groups as needed (e.g., Planning Committee members, Chairperson's Office, Study Team).**
 - c. **Administrative Officer (AO) or Project Manager will then contact the CSR&D Service (including CSP Deputy Director) with the proposed meeting dates.**
 - d. **CO will select the date of the meeting based on the availability of the CRADO, Director, Clinical Science R&D, CSP Deputy Director, and other CO personnel. Project Manager will initiate arrangements for First Planning Meeting.**
 - e. **Once CO has identified an agreeable date, the Project Manager will communicate this date to the Planning Committee members and attendees.**

References:

- Checklist 2 - Study Planning Checklist Items 16 - 21
- Additional instructions for the First Planning Meeting can be found in **Exhibit 2** – Guidance for CSP Study First Planning Meetings

B. Suggested Agenda

1. An agenda is prepared for the First Planning Meeting to include as many of the following topics as possible:

- Primary Hypothesis
- Secondary Hypothesis (if any)
- How to Communicate the Importance of the Study
- Treatment to be Studied
- Treatment Regimens
- Experimental Design
 - Patient Population
 - Inclusion Criteria
- Exclusion Criteria
- Baseline Criteria
- Follow-Up
- End Points – Primary and Secondary
- Sample Size Criteria
- Human Rights Issues
- CSPCRPCC Issues/Budget Checklist
- Economic Analysis (if any)
- Study Forms
- Budget Issues (to include info on study personnel and participating sites)
- Core Laboratories (if needed)
- Quality Assurance Issues
- Assessment of GCP Monitoring or Auditing Requirements
- Publications
- Participating Centers
- Collaboration with Non-VA Groups
- AE/SAE Safety Issues

2. Tasks

a. Prepare agenda for First Planning Meeting

Reference:
- Checklist 2 - Study Planning Checklist Item 22

C. Planning Materials Sent to Committee

1. Prior to the First Planning Meeting, materials are to be sent to the Planning Committee members in order to facilitate the meeting and ensure all individuals understand CSP activities.

2. Tasks

a. Project Manager will prepare and mail **Memo 10 with the following materials. See memo for distribution.**

- CSP Guidelines (noting that they should pay special attention to Chapter II, “Developing a CSP Study”, Sections A-D)
- CSP Brochure
- Planning Request - including relevant publications submitted by Principal Proponent
- Reviews of the preliminary proposal
- Response to reviewers’ criticisms by Director, Clinical Science R&D Service (if any)
- Detailed analysis of reviewers’ comments by Principal Proponent and/or Study Biostatistician including a point-by-point response to the reviewers criticisms.
- List of Committee members
- Agenda
- A review of the literature to provide the Planning Committee with a basis for design decisions (e.g., effect sizes, estimates of variability, outcome measures). It will be the responsibility of the Biostatistician to provide a “Concise Summary” of the extensive clinical literature relevant to the study. The purpose of this activity is to recognize potential duplicative (or nearly duplicative), completed, or ongoing trials so the Director, Clinical Science R&D Service can fully assess the unique scientific contributions of all new proposed CSP trials.
- Key items to establish a CSP budget (see **Checklist 5**)

References:

Resources for providing above information are:

- Cochrane Library (<http://www.cochrane.org>). You must subscribe to receive information from the Cochrane Library (approx. \$400). Abstracts only are provided.
- NIH trial database (<http://www.clinicaltrials.gov>). This NIH Clinical Trials database provides names of studies, recruitment status and also provides some preliminary information about a trial.
- CSP Guidelines, Chapter II, "Developing a CSP Study", Sections A-D.
- Checklist 2 – Study Planning Checklist Item 23
- Checklist 5 - Key Items to Establish CSP Budget

D. Travel/Meeting Details

1. Travel to and conducting the First Planning Meeting are the major activities of this phase. CSPCCs need to determine that these efforts represent a good use of CSP funds and that the meeting is organized to meet its goals.
2. **Tasks**
 - a. **The Travel Manager/Travel Coordinator will transmit estimates of travel costs via e-mail for all participants to the CSP Finance Officer and CSP Deputy Director, at least four weeks before the meeting (See Exhibit 3).**
 - No sleeping rooms should be included as part of hotel contract. **Exhibit 2** provides more information regarding hotel accommodations.
 - After Travel Authorization received from VA Headquarters, the Travel Manager/Travel Coordinator should provide copy to Administrative Officers at respective VA sites.
 - b. **The Project Manager will provide an attendee sign-in sheet for each day of the meeting. This sign-in sheet will be used to determine who actually attended this meeting.**
 - c. **After meeting is held, the Travel Manager/Travel Coordinator must inform the CSP Deputy Director and Management Analyst for Finance of who did not attend this meeting.**

References:

- Exhibit 2 – Guidance for CSP Study First Planning Meetings
- Exhibit 3 – CSP Meeting and Travel Information
- Checklist 2 – Study Planning Checklist Items 24 - 28

E. Deviations from Original LOI

1. If **significant deviations** from the originally stated letter of intent occur during planning, the Center Director must inform the Director, CSR&D and request approval for the changes. Significant deviations may require an administrative review by the Director, CSR&D and/or the consultants who reviewed the original Letter of Intent.
2. A significant deviation from originally stated intent is left to the judgment of the CSPCC Director.

III. Second Planning Meeting

A. Requirements to Hold Second Planning Meeting

1. Funding for Second Planning Meeting is contingent upon a satisfactory first meeting.
2. **Tasks:**
 - a. **Principal Proponent forwards an updated executive summary to the CSPCC Director.**

- b. **With the assistance of the CSPCC Director and Biostatistician, the Project Manager prepares a request to either continue or discontinue planning. This request is sent to the Director, CSR&D for the final decision on whether planning should be continued.**
- CSP policy requires that the Principal Proponent, with the assistance of the Biostatistician, conduct a **patient availability survey**. Include this information in the VACO request to continue planning. This survey is necessary before decisions can be made about the number of participating sites and years of patient intake that will be required to achieve the target sample. One approach is to search for patients with appropriate clinical profiles in utilization databases such as the Patient Treatment File (PTF), the Outpatient Care file (OPC), or the DSS National Data Extracts. Another approach is to informally survey providers at potential study sites, asking them to track patients over a defined period of time to determine how many meet the proposed inclusion and exclusion criteria. A less valuable alternative is for those providers to estimate the number of patients who will meet the criteria.
 - If the Director, Clinical Science R&D Service requests additional information to make this decision or disapproves continued planning, the information or any appeal to the disapproval must be submitted to the Director, Clinical Science R&D Service within 30 days of notification.
- c. **The Biostatistician and Project Manager prepare the Principal Proponent for the second meeting by sending **Memo 11** (unless contraindicated) along with a sample outline of a protocol.**
- d. **The CSPCC and CSPCRPCC will develop a draft budget for discussion at the Second Planning Meeting. See Section IV. Study Budget Development.**

References:

- CSP Global SOP 2.1.0 Developing, Approving and Amending Protocols. See Attachment 2 (pages 20-22) for Sample Table of Contents for Protocols
- Checklist 2 – Study Planning Checklist Items 29 - 32

B. Securing Drug/Device Supplies – Planning

1. When a study involves drugs or devices, negotiations will begin during planning with industry to secure commitments for the donation drug/device supplies for the study. This can be accomplished by the CSPCRPCC clinical research pharmacist, or in conjunction with the Principal Proponent or CSPCC. The clinical research pharmacist must attempt to secure a written commitment from each involved company during planning or at least prior to CSSMRB review. A formal contract delineating rights and privileges between the CSP and the involved company is not required during planning. But to facilitate the completion of a formal agreement during Kickoff, the clinical research pharmacist should, if possible, determine whether the company will require Intellectual Property be addressed in the final formal agreement.
2. In the event industry's support to a study will include funds to support the efforts of the CSPCRPCC for the study, the CSPCRPCC Director and the Director, Clinical Science R&D Service must become involved in the negotiations. In the event industry's support to a study is beyond the donation of drugs/devices and funds to support the CSPCRPCC's efforts (i.e., industry will donate funds to support non-drug/device aspects of the study), the appropriate CSPCC Director, the CSPCRPCC Director, and the Director, Clinical Science R&D Service, must become involved in the negotiations.
3. While a few mechanisms are available for enabling drug company provision of drugs/funds, the most common one will be the Cooperative Research and Development Agreement (CRADA) (see CSP Deputy Director for CRADA template). If the drug company requires agreements related to intellectual property, the use of a CRADA will be required. Central Office will provide the lead for all efforts involving any agreements, with the CSPCRPCC and CSPCC providing assistance.

Reference: Checklist 2 - Study Planning Checklist Item 33

C. Identifying Date for Second Planning Meeting

1. The Second Planning Meeting should be held within **six** months after the first planning meeting. If this cannot be done, the CSPCC Director should recommend to Director, Clinical Science R&D Service that planning be discontinued or petition for an extension.
2. **Tasks:**
 - a. **The Project Manager mails Memo 12 to all participants informing them of the meeting.**
 - It is obligatory that the second meeting be in the vicinity of the CSPCC to facilitate Human Rights Committee review and attendance by CSPCC staff. This will provide the opportunity for the Planning Committee and the Human Rights Committee to review the protocol together. Note that some Centers may choose to follow the “just-in-time” rule, therefore the Human Rights Committee Review may not be necessary until after approval by CSSMRB.
3. If additional planning meetings are required after the Second Planning Meeting is held, the CSPCC Director will contact the Director, Clinical Science R&D Service.

Reference: Checklist 2 - Study Planning Checklist Items 34 - 35

D. Preparation for CSSMRB

1. Planning activities are conducted to prepare for a protocol submission review to CSSMRB. Near the time of the Second Planning Meeting, preparations for this submission should begin.
2. **Tasks:**
 - a. **Shortly before the Second Planning Meeting, the CSPCC Director sends the Proponent Memo 13 (or comparable e-mail) which deals with the preparation of the submission to the Cooperative Studies Scientific Merit Review Board (CSSMRB).**
 - b. **Materials to be received from Principal Proponent, CSPCRPCC (if applicable) and HERC (if applicable).**

Reference: Checklist 2 - Study Planning Checklist Items 36 - 39

E. Travel/Meeting Details

1. Similar principles for travel and meeting apply as for the First Planning Meeting.
2. **Tasks:**
 - a. **The Travel Manager/Travel Coordinator will transmit estimates of travel costs via e-mail for all participants to the CSP Finance Officer and CSP Deputy Director at least four weeks before the meeting (See Exhibit 3).**
 - No sleeping rooms should be included as part of hotel contract. **Exhibit 2** provides more information regarding hotel accommodations.
 - After Travel Authorization received from VA Headquarters, the Travel Manager/Travel Coordinator should provide copy to Administrative Officers at respective VA sites.
 - b. **The Project Manager will provide an attendee sign-in sheet for each day of the meeting. This sign-in sheet will be used to determine who actually attended this meeting.**
 - c. **After meeting is held, the Travel Manager/Travel Coordinator must inform the CSP Deputy Director of who did not attend this meeting.**

References:

- Exhibit 2 – Guidance for CSP Study First Planning Meetings
- Exhibit 3 – CSP Meeting and Travel Information
- Checklist 2 – Study Planning Checklist Items 40 - 42

IV. Study Budget Development

A. Overall Process of Developing Final Study Budget

1. A draft study budget should be developed for discussion at the Second Planning Meeting. Based upon discussions of the draft budget provided, the framework for a final study budget will be assessed during the Second Planning Meeting.
2. Review of a budget proposal usually involves some negotiation with the Proponent or even with other members of the Planning Committee. Attention must be paid to cost control, but not to the extent that it in any way jeopardizes the success of the study. In the long run, it may be more serious to underfund a study than it is to overfund it in some marginal way. Final preparation is the responsibility of the Project Manager. **Exhibit 4** may be used as a tool for collecting this information from the Planning Committee.
3. It is important that the timeframe of the study be clearly identified. The budget in the CSSMRB submission contains cost estimates for each year of the study rather than fiscal year costs. It should include startup, ongoing, follow-up, and closeout periods. The budget must display personnel (FTE/FTEE and \$ costs), equipment to be purchased for the study and all other costs (AOC). Budget should reflect all anticipated costs and the period of time those costs cover.
4. In making your projection, you should allow for fringe benefits in an amount of **30%**. Annual cost-of-living increase of **5%** for personnel salary or anticipated step increases should be built in for future years. There should be no automatic increases in supplies (OOC) unless there is a complete justification. In most instances, an increase in supplies would only be reflected in the CSPCRPCC budget. See **Exhibit 5** for Sample CSSMRB Budget.
5. If consideration is being given to hiring personnel using an IPA, it should be noted that the agreement is for a four-year period. Terms of an IPA can be found at the following website: <http://www.opm.gov/programs/ipa/>.
6. All budget information should be submitted to the CSP Coordinating Center at least 8 weeks before CSSMRB submission.

References:

- Exhibit 4 – CSSMRB Budget Planning Tool
- Exhibit 5 - Sample CSSMRB Budget

B. Chairperson/Site Costs

1. Personnel costs are usually the largest budget item. In most instances, the CSP provides personnel support for the Principal Proponent's office and for each of the participating sites. The operating rule is to fund the Chair's Office no more than **three** months prior to the anticipated date of first patient intake and for **six** months after the date of last patient follow-up. Exceptions to this rule can be requested with the necessary justification in the CSSMRB submission. It is appropriate for the CSPCC Director to bring such requests to the attention of the Director, Clinical Science R&D Service and CSSMRB in his/her cover letter so that it can be approved or disapproved at the review meeting. Funding of personnel at the participating sites is usually authorized **one** month before the anticipated date of first patient intake and is terminated **one** month after the date of last patient follow-up. Travel costs and registration fees (if applicable) should also be included for the Chairperson's Office to cover costs associated with presentations at scientific conferences. Include costs for travel for up to two years after end of study.
2. The number of personnel (and grades) in the Chair's Office and participating sites, are decisions that have to be made on their own merit. Typically, the CSP funds one or two employees in the Chair's Office and one study coordinator at each site, but this is study dependent and should be decided on the basis of need. In discussing personnel for the Chair's Office, it is important to inform the Proponent of the considerable support provided by the staff of the CSPCC and the CSPCRPCC. Determining appropriate target grades is difficult because CSP staff and investigators are not experts in classifying position descriptions and they often have to consider such practical problems as recruiting term appointments in high cost areas.

3. Estimated personnel costs for Study Nurses and GS employees are based on the Chicago pay scales (considered to be the national average pay scale).
4. Include any miscellaneous expenses for such items as furniture, mail, office supplies, etc.

Reference:

- Pay rates can be found at: <http://vaww1.va.gov/ohrm/pay/payrate1.htm>.

C. Site Monitoring, Auditing and Resource Team Costs

1. A separate budget is developed for GCP support provided by SMART to include GCP Standards and Resources Group, GCP Monitoring Group, and GCP Resource Group. The budgets will include costs of SMART monitoring, auditing, and support personnel, contractor monitors and/or auditors, GCP training and tools, travel, and if applicable administratively coordinating the activities of monitors by industry or CSP Centers. **Exhibit 6** provides a definition of SMART and **Exhibit 7** describes the CSP SMART services available.

References:

- CSP Global SOP 6.1.0 – Pre-Study Site Monitoring, Section 1 (Planning Site Monitoring)
- Exhibit 6 – SMART Definitions
- Exhibit 7 – SMART Services

D. CSPCC Costs

1. Include all costs, both personnel, all other and travel, for the Coordinating Center. **Costs for the Coordinating Center should be based on startup (3-6 months before kickoff), ongoing, closeout (6 months after the date of last patient follow-up), and manuscript and publication preparation (12 months after closeout).**

E. CSPCRPCC Costs

1. Include all drug or device, personnel, vendor certification, travel, equipment, supply costs, laboratory, etc., for the CSPCRPCC. Drug or device costs are usually one of the largest amounts of the budget. However, in many cases these drug or device costs can be donated by industry. In the case of a drug or device donation, an estimated cost will be incorporated in the budget for documentation purposes. The CSPCRPCC may perform a vendor certification to determine acceptability of the drug or device vendor. **Costs for the CSPCRPCC should be based on startup (3 to 6 months before kickoff), ongoing, closeout (6 months after the date of last patient follow up), and analysis (12 months after closeout).** The additional 12 months is to provide support for manuscript and publication preparation and closeout of IND/IDE if applicable. If additional requirements are requested such as adding or terminating sites, the budget will need to be adjusted.
2. See **Checklist 3** - CSPCRPCC Budget Requirements Checklist for items to be considered for inclusion in budget.

F. Travel Costs

1. All costs for travel for the study should be budgeted for in the final CSSMRB submittal (**See Exhibit 5**). Projections should be calculated for the routine study meetings such as Study Group, Executive, DMC, Endpoints (if applicable), and any other related committee that may need to convene to review the study.
2. Travel projections for any professional conference that may be attended to present data from the study must also be included in the CSSMRB budget including any associated registration fee(s).

3. A separate justification for the presentations should be included in the "Budget Justification" section of the protocol. Provide the name(s) and/or study position if name unknown at this time, the type of conference and the reason for attending.
4. The travel projections should be based on \$900 per person for all study related and professional meetings plus applicable registration fees for conferences.

References:

- Checklist 3 – CSPCRPCC Budget Requirements Checklist
- Exhibit 5 - Sample CSSMRB Budget

G. Health Economic Costs

1. If there is a Health Economic Component to the study, then these costs, both personnel and all other, should be included.

H. Funding of Substudies

1. It is not unusual for a Planning Committee to include substudies or secondary objectives in the protocol and often there is considerable cost associated with these proposals. As a general rule, this tendency should be discouraged. The proposal (and costs) should be directed as the central objective of the study.

I. Equipment

1. The CSP may not fund equipment for the study if such equipment is already available and accessible at the participating sites. It does not fund routine laboratory studies that would be expected in normal patient care. Items of this type require special justification if they are to be included in the budget section.

J. Capitation Costs

1. Studies can be funded via capitation. Under this method, sites are funded according to predetermined criteria including the number of patients randomized or the number of procedures completed. These criteria need to be thoroughly indicated out and forecasted for the length of the study. Description of capitation schedule should be included in the budget justification.

K. Interagency Agreements

1. Interagency Agreements are conducted between federal agencies. The agreements need to clearly define the description of work, period of agreement, estimated costs, purpose of the agreement, positions to be supported, financial and technical reporting requirements, designation of responsible officials, and signatures from the appropriate individuals from both agencies. Interagency Agreements are reviewed by Central Office staff and signed by the appropriate contracting officer at both Central Office and the Chief, Acquisition and Materials Management at VACO or the respective CSP Coordinating Center. Typically these agreements cover a period greater than one year, and are reviewed or appended on a yearly basis.

L. Industry/Pharmaceutical Donations

1. Donations to the study can be of several types such as drug/device supplies, equipment, and/or financial support.
2. Individuals responsible for negotiations:
 - a. When industry support to a study will include only the donation of drug/device supplies, the negotiations can be accomplished by the CSPCRPCC clinical research pharmacist or in conjunction with the Principal Proponent or CSPCC.

- b. When industry support to a study will include funds to support the efforts of the CSP for the study, the CSPCC/CSPCRPCC Director, and the Director, Clinical Science R&D Service must become involved.
 - c. In the event industry support to a study is beyond the donation of drugs/devices and funds to support the CSPCRPCC's efforts (i.e., industry will donate funds to support non-drug/device aspects of the study), the appropriate CSPCC Director, the CSPCRPCC Director, and the Director, Clinical Science R&D Service, must become involved in the negotiations.
3. Any donation from industry or from a pharmaceutical company, including study costs to be supported by financial donations, and cost of donated drug/device supplies or equipment, should be listed as a separate line item(s) on the budget with an estimate of cost. This will be used by CO to determine budget impact should company pull its support.

Reference: Checklist 2 - Study Planning Checklist Item 43

V. Research Data Forms

A. Development of Research Data Forms

1. The development of adequate research data forms is time-consuming and often unfeasible to be completed during the actual planning stage. CSP personnel are experienced in what forms are necessary and what constitutes a good form, but they depend upon the Proponent or members of the Planning Committee for the content and specific details of the forms.
2. The Biostatistician should provide guidance on forms development at the first meeting or shortly thereafter so that the Proponent can prepare drafts of the forms for review at the final meeting. Adequate time must be provided on the agenda of Second Planning Meeting so that this can be accomplished. The objective is to provide the CSSMRB reviewers with a clear idea of the data collection items to be used in the study. If the actual form is not included in the CSSMRB submission, then it is important to include a list of forms to be used and a description/purpose for each form.

References:

- CSP Global SOP 2.5.0 – Developing and Approving Case Report Forms (CRFs)
- Checklist 2 - Study Planning Checklist Item 44

VI. Human Rights Committee Review

A. Materials Required for Human Rights Committee Review

1. An essentially complete, but not necessarily final protocol, must be available prior to the Second Planning Meeting so that the Project Manager can distribute this material to the Human Rights Committee for a valid review. Some Centers may choose to wait until after CSSMRB to have the protocol and informed consent (see **Checklist 6**) reviewed by the Human Rights Committee (identified as Just-in-Time review).
2. **Tasks:**
 - a. **Materials prepared for distribution to Human Rights Committee.**

References:

- CSP Global SOP 2.1.0 – Developing, Approving and Amending Protocols. See Attachment 2 (pages 20-22) for Sample Table of Contents for Protocol
- CSP Global SOP 7.1.0 – Conducting Review of Human Rights Committee (HRC) Consent Forms
- Checklist 2 – Study Planning Checklist Item 45
- Checklist 6 - Consent Form Checklist

B. Arrangements for Human Rights Committee Review

1. The AO or his/her designee is often responsible for making all arrangements for Human Rights Committee meetings.

3. **Tasks:**
 - a. **Members are contacted to determine the availability of regular or alternate members for the proposed meeting date. Materials are assembled and mailed two weeks prior to the meeting. Letters of Agreement (Letter 14) prepared for Director's authorization of payment.**

 - b. **Letter 15 is then sent to Human Rights Committee members which provides details regarding the next meeting with the Planning Committee.**

Reference: Checklist 2 - Study Planning Checklist Items 46 - 49

Checklist 2 - Study Planning Checklist

<u>DATE</u>	<u>TASK</u>
	<u>First Planning Meeting</u>
_____ 1	Record date study approved for planning on this checklist.
_____ 2	Memos 6 & 7 sent to Proponent from CSPCC. Memo identifies Biostatistician, Project Manager and other team members.
_____ 3	Proponent asked to identify a Planning Committee.
_____ 4	Proponent asked to obtain signatures of his/her ACOS for R&D, Chief of Staff and Medical Center Director, indicating that they have been informed and approved of Proponent's participation in the study.
_____ 5	Memo 8 to Principal Proponent from Director CSPCRPCC identifying Clinical Research Pharmacist and/or Adverse Event Specialist assigned to study. Checklist 3 to be sent along with Memo 8 .
_____ 6	Telephone Call to Proponent by CSPCC Director.
_____ 7	Memo 9 to ACOS for R&D from CSPCC Director.
_____ 8	Telephone Call to Proponent by Biostatistician and Project Manager.
_____ 9	Telephone Call to Proponent by CSPCRPCC. Checklist 3 will be discussed.
_____ 10	CSPCC and CSPCRPCC to establish central study files (see SOP 3.2.0 – Central Monitoring – Attachment 2); Checklist 4 should be utilized.
_____ 11	Establish electronic file system in O:/Admin drive (Perry Point only).
_____ 12	CSP Deputy Director sends an e-mail to the ACOS for R&Ds announcing a CSP study is in planning and posts relevant information on the CSP website.
_____ 13	Obtain list of nominated members of Planning Committee and their CVs from the Principal Proponent.
_____ 14	Once obtained, CSPCC will submit packet to CSP for approval.
_____ 15	CSPCC receive approval of committee nominees from CSP.
_____ 16	Initiate contact to Planning Committee Members to identify potential dates for first meeting.
_____ 17	Submits 3 sets of potential meeting dates to the Director, Clinical Science R&D..
_____ 18	Set up e-mail group(s), as needed.
_____ 19	Once a confirmed date has been identified, CO will inform CSPCC.
_____ 20	Project Manager to initiate arrangements for first planning meeting.
_____ 21	Once location has been determined, alert Planning Meeting attendees of meeting date and include relevant information as it relates to the meeting and to the travel, hotel and per diem reimbursements for both VA and non-VA attendees. NOTE: Additional instructions for the First Planning Meeting can be found in Exhibit 2 .

<u>DATE</u>	<u>TASK</u>
_____ 22	Develop agenda for First Planning Meeting
_____ 23	Memo (10) w/attachments to Planning Committee Members. Include Checklist 5 . Travel Coordinator sends meeting & travel info to the CSP Finance Officer and CSP Deputy Director – 4 wks prior to meeting. See Exhibits 2 and 3 .
_____ 24	Once travel authorization received from VA HQ, send copy to Administrative Officer at respective VA site.
_____ 25	Sign-in sheet to be used at First Planning Meeting.
_____ 26	Project Manager to inform CO of those who did not attend.
_____ 27	Record date First Planning Meeting held.
_____ 28	Establish study info in Filemaker, as needed (Perry Point only).
 <u>Final (or Second) Planning Committee Meeting</u>	
_____ 29	Proponent forwards updated executive summary to CSPCC Director.
_____ 30	Continuation of Planning Memo sent to Director, CSR&D.
_____ 31	Memo (11) to Principal Proponent by CSPCC.
_____ 32	CSPCC and CSPCRPCC develop a draft budget for discussion at Final Planning Meeting.
_____ 33	If study involves drugs or devices, negotiations should begin with industry to secure commitments for donation of drug/device supplies for study.
_____ 34	Memo (12) to Planning Committee Members.
_____ 35	AO contacts Human Rights Committee RE: Availability of Final Planning Meeting.
_____ 36	Memo (13) to Proponent by CSPCC.
_____ 37	Nearly final protocol from Principal Proponent.
_____ 38	Drug Info from CSPCRPCC, if applicable.
_____ 39	Info from Economic Analysis, if applicable. Travel Coordinator sends meeting & travel info to Asst. Director CSP/VACO – 4 wks prior to meeting. See Exhibits 2 and 3 .
_____ 40	Once travel authorization received from VA HQ, send copy to Administrative Officer at respective VA site.
_____ 41	Sign-in sheet to be used at First Planning Meeting.
_____ 42	Project Manager to inform CO of those who did not attend.
_____ 43	Develop study budget. See Exhibits 4, 5, 6 and 7 . See Checklist 3 .

DATE

TASK

- _____ 44 Develop study forms.
- _____ 45 Materials prepared for distribution to Human Rights Committee. See **Checklist 6**.
- _____ 46 LOAs to Human Rights Committee members (**Letter 14**).
- _____ 47 Packet sent to Human Rights Committee w/letter (**Letter 15**).
- _____ 48 Date 2nd or Final Planning Meeting held.
- _____ 49 Human Rights Committee minutes received.

Checklist 3 - CSPCRPCC Budget Requirements Checklist

1. Design - Length of enrollment
2. Design - Length of treatment for study and subjects
3. Design - Method of randomization and drug assignment
4. Design - Number of sites
5. Design - Number of treatment arms (drug, dose, frequency, route, titration y/n, device)
6. Design - Population to be studied and objectives
7. Design - Sample size
8. Design - Total length of study
9. Design - Type of sites (VA or not, international, etc.)
10. Design - Visit interval for dispensing
11. Drug/Device - Blinded or open label.
12. Drug/Device - Commercially bottled drug or bulk.
13. Drug/Device - Dosage form?
14. Drug/Device - Drug ID for method development.
15. Drug/Device - Drug source: donated, purchased, or PCC manufactured drug?
16. Drug/Device - How many drugs/devices will be supplied by the PCC?
17. Drug/Device - How will the drug be processed at PCC?
18. Drug/Device - IND or IDE for this study
19. Drug/Device - Is a device being used?
20. Drug/Device - Is the drug on the market or in Phase 1, 2, and 3 testing?
21. Drug/Device - Number of strengths needed – what are they?
22. Drug/Device - Returns – degree of processing required, expected quantities being returned
23. Drug/Device - Schedule of drug (DEA Schedule 2,3,4, or 5)
24. Drug/Device - Special storage requirements, warehouse, refrigerated, freezer, ultra-lo freezer
25. AE/SAE - Definition of what safety data will be collected in the study, (AEs, SAEs, related and non-related)
26. AE/SAE - Risk level for patients (determines need for full safety monitoring or partial monitoring)
27. GCP - GCP training will be at every kick off and repeated every 3 years
28. GCP - How frequently will study be monitored?
29. GCP - What level of GCP RISK?
30. IT - Clinical Trial Support Center (CTSC) used?
31. IT - Is an Interactive Voice Randomization System (IVRS) being considered?
32. IT - Is web technology being considered (i.e. randomization, termination, drug assignments, site inventory management)
33. Supply - Large contracts – contracting issues
34. Supply - New equipment or tooling required
35. Supply - Other technology being considered at this time
36. Supply - Will vendor certifications be needed?
37. Supply - Will we be procuring hardware to send to sites?
38. Manufacturing - Are we making a placebo?
39. Manufacturing - Capsule – what size or sizes
40. Manufacturing - Liquid filled capsule – what size or sizes?
41. Manufacturing - Over coating
42. Manufacturing - Over encapsulation – what size or sizes of capsules
43. Manufacturing - Tablet – Is tooling required
44. Manufacturing - What type of manufacturing will be done?
45. Manufacturing - Will manufacturing need to be done?

Checklist 4 - SMART Checklist

<u>DATE</u>	<u>TASK</u>
	<u>Study Planning Stage</u>
_____ 1	Notify SMART of all new studies in planning and request SMART to provide information on GCP for protocol inclusion.
_____ 2	Assure that SMART is notified of needs assessment of First Planning Meeting for monitoring and auditing.
	<u>Study Initiation Stage</u>
_____ 3	After funding is approved, send SMART a copy of the protocol, informed consent form, and Operations Manual. Also send request to SMART to provide GCP material for inclusion in Operations Manual
_____ 4	Communicate with SMART to schedule GCP training at kickoff meetings.
_____ 5	Provide SMART with a list of all approved sites.
	<u>Study Ongoing Stage</u>
_____ 6	Forward all approved protocol amendments, sub-protocols, and administrative updates that are made to the protocol and operations manual. (NOTE: Treat SMART as a participating site on the distribution list with respect to these items or any other items that must be submitted to the IRB, such as DSMB Summaries.)
_____ 7	Assist with scheduling GCP site visits if needed; provide copies of items from the central file as requested and other items that CSPCC wishes SMART to review while at a site.
_____ 8	Provide the periodic reports of screening and enrollment (paper and/or electric)
_____ 9	Notify SMART of any new sites added to study.
_____ 10	Notify SMART of early termination of site (include date of termination).

Checklist 5 - Key Items to Establish a CSP Budget Checklist

1. Length of enrollment
2. Length of follow-up
3. Number of sites
4. Type of sites (VA, University, International, etc.)
5. Length of startup (sites, Chair, lab(s), CSP Program Centers, etc.)
6. Length of closeout (sites, Chair, lab(s), CSP Program Centers, etc.)
7. Sample size
8. Determine personnel support and all other costs required at Chairman's (or Co-Chairman's) office(s)
9. What core laboratories will be required and obtain budget(s). If laboratory is not VA, then what will be required for contracting purposes?
10. Will sites be reimbursed on a capitation system or receive personnel support and all other funds?
11. Any required tests to be performed that are not standard of care
12. Subject payments or travel reimbursement required
13. What equipment is required for sites or Chairman's office?
14. Study website required?
15. Randomization system
16. Data collection process
17. Travel requirements for study related meetings/conferences
18. Industry or other Federal Agency collaboration

Checklist 6 – Consent Form Checklist

**WORKSHEET FOR VERIFYING REQUIRED ELEMENTS OF
INFORMED CONSENT**

CONSENT FORM CHECKLIST

Protocol: _____ Sponsor: _____
Protocol Version (No. and/or Date): _____
Consent Form Version (No. and/or Date): _____
Participating Site: _____

I. ELEMENTS OF INFORMED CONSENT REQUIRED IN VA RESEARCH*

**PRESENT
YES NO**

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Name of the Study. |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Name of the Principal Investigator. |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Statement that the study <u>involves research</u> . |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Explanation of the <u>purpose</u> of the research. |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. Expected <u>duration</u> of the subject's participation. |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. Description of the <u>procedures</u> to be followed. <i>For VA: Identify which procedures are done for research purposes.</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | 7. Identification of any procedures, which are <u>experimental</u> . |
| <input type="checkbox"/> | <input type="checkbox"/> | 8. Description of any reasonably foreseeable <u>risks or discomforts</u> . <i>For VA: this also includes privacy risks (legal, employment, and social).</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | 9. Description of any <u>benefits</u> to the subject or others, which may reasonably be expected from the research. |
| <input type="checkbox"/> | <input type="checkbox"/> | 10. Disclosure of appropriate <u>alternative procedures</u> or courses of treatment, if any, which might be advantageous to the subject. |
| <input type="checkbox"/> | <input type="checkbox"/> | 11. Statement describing the extent to which <u>confidentiality</u> of records identifying the subject will be maintained and noting the possibility that the sponsor (e.g., VA Cooperative Studies Program), the FDA [if applicable] and other Federal agencies; e.g., the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO), may inspect records; |
| <input type="checkbox"/> | <input type="checkbox"/> | 12. For research involving more than minimal risk, an explanation as to whether any <u>compensation</u> is available and an explanation as to whether any medical <u>treatments</u> are available <u>if injury</u> occurs and, if so, what they consist of, or where further information may be obtained. |

**All of these requirements apply to both VHA and CSP. CSP has one additional requirement concerning witnessing consent (see page 3).*

PRESENT

YES NO

13. An explanation of whom to contact for answers to questions about research and research subject's rights and whom to contact in case of research-related injury to subject. *For VA: At least one contact's name and phone number other than investigator or study personnel is required.*
14. Statement that participation is voluntary.
15. Statement that refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled.
16. Statement that subject may discontinue participation at anytime without penalty or loss of benefits to which subject is otherwise entitled.

II. ADDITIONAL ELEMENTS REQUIRED WHEN APPLICABLE

(Note: Seldom are these elements not applicable to a clinical trial)

PRESENT

YES NO NA

1. Statement that the particular treatment or procedure may involve risks to the subject (or to embryo or fetus, if subject is or may become pregnant), which are currently unforeseeable.
2. Anticipated circumstances under which subject's participation may be terminated by the investigator without regard to subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to subject.
6. Approximate number of subjects involved in the study.
7. If an FDA-regulated test article is involved, the FDA requires a statement that the FDA may choose to inspect research records that include the subject's individual medical records.
8. As appropriate, a statement regarding any payment the subject is to receive and how payment will be made.
9. A statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows:
- a. Certain veterans who are required to pay co-payments for medical care and services provided by VA. Suggested wording: "Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study."
 - b. Investigators need to note that charges will not be made for medical services, including transportation, furnished as part of a VA-approved research study.

PRESENT

YES **NO** **NA**

10. If the investigators believe that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, or if the specimens are to be retained after the end of the study, current VA policy and Veterans Health Administration (VHA) regulations must be followed. NOTE: *If genetic testing is to be done, VA requirements pertaining to genetic testing must also be met.*

III. ADDITIONAL ELEMENTS REQUIRED BY LOCAL IRB

PRESENT

YES **NO**

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

IV. OTHER VHA REQUIREMENTS CONCERNING CONSENT FORMS

1. VA Form 10-1086 must be used to prepare the consent form.
VA Form 10-1086 has been used. YES NO
2. IRB Stamp or pre-printed box on each page of the consent form indicating date of most recent IRB approval. YES NO
3. Signature lines provided on the form are to be consistent with VHA and CSP policy. VHA and CSP require that current forms be signed and dated by the subject (or subject's legally-authorized representative), a witness and the person obtaining the informed consent.
IRBs and Sponsors may have additional requirements for signatures, but at the minimum, VHA & CSP consent forms must provide:

- | | | |
|------------------------------|-----------------------------|---|
| <input type="checkbox"/> YES | <input type="checkbox"/> NO | Line for signature and date of patient or representative. |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO | Line for signature and date of person obtaining consent. |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO | Line for signature and date of witness*. |

*CSP requires that the witness not be part of the study team; VHA does not.

V. ELEMENTS OF PATIENT AUTHORIZATION REQUIRED BY THE HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA) OF 1996:

The following elements are required, either as part of an IRB-approved consent form or as a stand-alone HIPAA authorization document.

PRESENT			
YES	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. A description of the information to be used or disclosed,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. The identification of the persons or class of persons authorized to make the use or disclosure of the protected health information,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. The identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. A description of each purpose of the use or disclosure,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. An expiration date or expiration-triggering event,
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. The individual's signature and date, and
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. If signed by a personal representative, a description of his or her authority to act for the individual.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. A statement about the potential for the protected health information (PHI) to be subsequently disclosed by the recipient (disclosure of PHI to FDA is permitted under the rule, disclosure to business associates requires a written contract).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. A statement that the individual may revoke the authorization in writing (except to the extent that VHA has taken action in reliance on the consent), and either a statement regarding the right to revoke, and instructions on how to exercise such right.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. A statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule, or if conditioning is permitted by the Privacy Rule, a statement about the consequences of refusing to sign the authorization.

The HIPAA authorization elements listed above are:

- incorporated into the informed consent form.
- presented in a stand-alone HIPAA authorization form or addendum.

Reviewer

Date

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 6

Upon notification from
Director, Clinical Science R&D
initiating planning

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Approval for Planning CSP #[000], "[title]"

To: [Principal Proponent's name, medical center name (000/00)]

1. We have just been notified that the VA Cooperative Studies Program has given its approval to initiate planning of your cooperative study proposal entitled "[title]" ([000]). Our Cooperative Studies Program Coordinating Center (CSPCC) has been given the responsibility of working with you to develop the proposal to the stage where it is ready to submit to the Cooperative Studies Scientific Merit Review Board (CSSMRB) for review of scientific merit and recommendations for funding. If the study is ultimately approved for funding, the CSPCC will provide first line administrative, biostatistical and data processing support throughout the course of the study.

2. [Name] will be the Biostatistician for your study and [Name] will be the Project Manager. The three of you will have specific responsibilities and will share many others. Through [Study Biostatistician] and [Project Manager], the considerable resources of the CSPCC will be put at your disposal. They will call you within the next few days.

3. Your first task is to identify a Planning Committee. Normally, this committee would consist of yourself as Principal Proponent, [name] as Study Biostatistician and two or three investigators from other VA medical centers who in your judgment could contribute to the development of the proposal and who are likely to be involved in the study as Participating Investigators if the study is approved. An expert in economic analysis should be included when this is an objective of the proposed study. Also included would be the CSP Coordinating Center Director, CSP Project Manager, and Adverse Event Specialist. If drugs or devices are to be used in your study, a Clinical Research Pharmacist from the Cooperative Studies Program Clinical Research Pharmacy Coordinating Center in Albuquerque will be a member of the Planning Committee. It may be that because of the nature of your proposed study, your Planning Committee would be strengthened by a consultant in some special area not represented by the other members, or if you plan to use a central reference laboratory, you might need that kind of representation on the committee. You can work these details out with [Study Biostatistician]. Also, collaborate with [Study Biostatistician] and [Project Manager] to determine monitoring needs of the study and whether the Chief, Good Clinical Practices Review Group (GCPRG) or designee should participate in the Second Planning Meeting. Your nominations for the Planning Committee will be forwarded to the Director, Clinical Science R&D Service for approval.

4. The first planning meeting is held in Washington, DC, to make it possible for the Director, Clinical Science R&D Service to attend. It should be held within the next three months. As soon as you have formed your Planning Committee, work with [Project Manager]

2.

[Principal Proponent]

to choose some suitable dates. There are a few things you should do in preparation for the first meeting. It is useful to collect as much of the relevant literature as you can for distribution with a detailed outline of the proposal to the members of the Planning Committee prior to the meeting. [Study Biostatistician] will help you with the agenda because [he/she] knows what needs to be accomplished at this first meeting. If the major objectives of the first meeting are accomplished and it appears reasonable to assume that an approvable proposal can be produced, we will recommend that a second meeting be authorized.

5. Your second planning meeting must be held at or near the CSPCC within six months following the first meeting. It is not wise to schedule these two meetings too close together because usually there is considerable work that needs to be done before the second meeting can be effective. You are expected to have essentially a final draft of your proposal in the hands of your Planning Committee at least three weeks prior to the second planning meeting so that time can be spent on minor revisions, review by this Center's Human Rights Committee, and other issues such as the budget, generic job descriptions, and the like.

6. Although a great deal of effort on everyone's part goes into the development of a proposal for a cooperative study, it is important for you to recognize that the possibility for disapproval does exist and even approved studies may not be immediately funded. One must be willing to put forth this effort with this realization in mind, and with the hope that a successful review will be achieved.

7. Please prepare a memo for signature of your Medical Center Director that states that he/she approves of this planning activity. Include a signature block for the Chief of Staff and ACOS for Research and Development and address the memo to Director, Cooperative Studies Program Coordinating Center. A sample memo is attached for your convenience.

8. We have attached a cooperative studies proposal as a specimen for your guidance. We have also attached a copy of our **Guidelines for the Planning and Conduct of Cooperative Studies in the Department of Veterans Affairs** which contains a great deal of information that can be helpful to you.

[name]

Attachments (3)

(Guidelines)

(Specimen Proposal)

(Prototype Memo 7)

cc: ACOS for R&D, (name of medical center)
AO for R&D, (name of medical center)
Director, CSPCRPCC
Director, Clinical Science R&D Service (VACO)
Administrative Officer, CSPCC
Director, Health Economics Resource Center (if applicable)
Industry Sponsor (if applicable)

CSPCC NOTE: Blind copy to Study Biostatistician, copy for file.

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 7

Send with Memo 6

Date:

From: Medical Center Director, [medical center name] (#000/00)

Subj: CSP #[000], "[title]"

To: Director, Cooperative Studies Program Coordinating Center (000), [name of Center, i.e., Perry Point]

This is to confirm that our medical center has been informed and approves of the participation of [Principal Proponent name] as Principal Proponent in the planning of CSP #[000], "[title]."

DATE

MEDICAL CENTER DIRECTOR

APPROVED/DISAPPROVED

DATE

ACOS for R&D

APPROVED/DISAPPROVED

DATE

CHIEF OF STAFF

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

From: Director, [medical center name] CSPCRPCC (#000/00)

Subj: Approval for Planning CSP #[000], "[title]"

To: [Principal Proponent's name, medical center name (000/00)]

PROTOTYPE MEMO 8

Upon notification from
Director, Clinical Science
R&D initiating planning

1. We have been notified that the Cooperative Studies Program, has given approval to initiate planning of your cooperative study proposal on the "[name of trial]," (CSP #000).
2. Since your study may involve drugs or devices, the Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) at Albuquerque has been given the responsibility of working with you and the [Coordinating Center Name] Cooperative Studies Program Coordinating Center (CSPCC) to develop your proposal for submission to the Cooperative Studies Scientific Merit Review Board. The CSPCRPCC will assist you in:
 - a. developing the drug or device portion of your proposal;
 - b. dealing with the pharmaceutical or medical industry for the donation or purchase of drugs or devices;
 - c. assuring that we meet VA and federal regulation requirements concerning handling, and record keeping for the drugs or devices;
 - d. determining if an IND/IDE is required and, if so, completing this document for submission to the FDA;
 - e. formulating Drug or Device Handling Procedures;
 - f. developing and implementing a safety monitoring plan for adverse events;
 - g. drafting relevant sections of the protocol; and
 - h. addressing key pharmacy requirements (attached).
3. If the study is ultimately approved and funded, the CSPCRPCC Clinical Research Pharmacist will serve as a member of the study's Executive Committee and provide clinical research pharmacy support throughout the course of the study. On your behalf, the CSPCRPCC will be responsible for:
 - a. coordinating the acquisition or manufacturing of study drugs or devices;
 - b. assuring the quality control of study drugs or devices;

2.

[Principal Proponent's Name]

- c. providing for central control, distribution, retrieval, and accountability of study drugs or devices;
- d. registering all participating investigators under the study IND/IDE;
- e. coordinating amendments to the IND/IDE and annual reports to the FDA;
- f. monitoring and reporting of adverse reactions to the FDA (when applicable) and helping you solve any drug or device-related issues;
- g. providing for final disposition of any unused study drugs or devices upon completion of the study; and
- h. preparing a Final Drug or Device Accountability Report (FDAR).

4. [Pharmacist's Name] is the Clinical Research Pharmacist for your study and will be a member of your planning committee. Through [Surname of Pharmacist with Last Name], the considerable resources of the CSPCRPCC will be at your disposal. [Surname of Pharmacist with Last Name] will write or call you within the next few days.

[Name]
Director

Attachment: Checklist 3 – CSPCRPCC Budget Requirements Checklist

cc: Director, Clinical Science Research and Development
Deputy Director, CSP, VACO
Director, [Name, City, and State of CSPCC]
[Pharmacist's Name], CSPCRPCC, Albuquerque, NM

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: CSP #[000], "[title]"

To: ACOS for R&D (151) [Principal Proponent's medical center name (000)]

PROTOTYPE MEMO 9

Upon notification from
Director, Clinical Science R&D
Service initiating planning

Attached is a copy of a memo to [Principal Proponent] informing [him/her] that the VA Cooperative Studies Program has given its approval to initiate planning of [his/her] cooperative study. We will be working closely with [Principal Proponent] in the development of the proposal. Any administrative assistance you can give [him/her] during this process will be greatly appreciated. We will continue to keep you informed of our progress.

[name]

Attachment: (Prototype Memo 6)

cc: AO for R&D

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

From: Project Manager, [medical center name] CSPCC (#000/00)

Subj: First Meeting of the Planning Committee, CSP #[000]

To: [Each member of the Planning Committee including
Principal Proponent, medical center name (000/00)]

PROTOTYPE MEMO 10

Approximately 4 weeks before
1st Planning Meeting

1. The first meeting of the Planning Committee for the cooperative study entitled "[title]" ([#000]) will be held at the [place] in [city] on [date]. Attached please find a copy of the meeting agenda and a packet of relevant literature. In addition, I am attaching several documents including the **Guidelines for the Planning and Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs** (please pay special attention to Section II, "Developing a CSP Study", Sections A-D).
2. For VA employees, travel authority and advance travel funds will be forwarded to your medical center R&D office prior to your meeting from this Coordinating Center and VA Central Office. Adjustments (increase or withdrawal of balance) will be made subsequent to the trip upon notification of actual costs. Please file your travel voucher promptly.
3. For non-VA employees, you will receive a Letter of Agreement from this Coordinating Center prior to the meeting which will request your services at the meeting and will provide reimbursement of travel and per diem expenses.

[name]

Attachments [see attached list]

cc:

Site Personnel:

Principal Proponent (copy of memo & list of attendees)
ACOS for R&D (each medical center)
AO for R&D (each medical center)

VACO Personnel:

Director, Clinical Science R&D Service (VACO) (copy of memo & list of attendees)
CSP Deputy Director (VACO) (copy of memo & list of attendees)

CSP Personnel:

CSPCC Director (copy of memo & list of attendees)
Associate Director, CSPCC (copy of memo & list of attendees)
Administrative Officer, CSPCC (copy of memo & list of attendees)
Director, CSPCRPCC [if applicable]
Director, Health Economics Resource Center (if applicable)

LIST OF ATTACHMENTS TO MEMO 10

- **Guidelines**
- CSP Brochure
- Planning Request
- Reviews of the preliminary proposal
- Response to reviewers' criticisms by Director, Clinical Science R&D Service (if any)
- Detailed analysis of reviewers' comments by Principal Proponent and/or Study Biostatistician including a point-by-point response to the reviewers' criticisms.
- A review of the literature. This will include a "Concise Summary" of the extant clinical literature relevant to the study (prepared by Biostatistician).
- Key items to establish a CSP budget (see **Checklist 5** – Key Items to Establish a CSP Budget Checklist)
- List of Committee members
- Agenda

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date:

PROTOTYPE MEMO 11

From: Director, [medical center name] CSPCC (#000/00)

Approximately 4 weeks
before 1st Planning Meeting

Subj: Continuation of Planning CSP #[000], "[title]"

To: [Principal Proponent's name, medical center name (000/00)]

1. On the basis of your progress at the first planning meeting, I have recommended to the Director, Clinical Science R&D Service (VACO), that planning of your cooperative study be continued and am awaiting concurrence.

2. Usually there is a great deal of homework to be done before you can hold your second planning meeting. We must have a complete protocol, including research data forms, preliminary budget, position descriptions, and the consent procedures available for distribution to members of the Planning Committee and the Coordinating Center's Human Rights Committee at least three weeks prior to your second meeting or it will be necessary to reschedule. Having a complete protocol in essentially final form will permit a thorough Human Rights Review and will allow you to spend your time at your last meeting on final revisions, budget and other issues. Attached please find a sample Table of Contents for Protocols.

3. For this study, we are planning for a Cooperative Studies Scientific Merit Review Board (CSSMRB) review in [month] that means that the entire submission has to be available here at the CSPCC by [date]. You should work out the dates for your second planning meeting with this in mind. In any event, the second meeting must be held within the next six months.

4. [Study Biostatistician] will be in close contact with you as the protocol is developed and at some point other CSPCC staff members will be engaged in this effort. Please let us know if there is any way that the Center can be of assistance.

[name]

Attachment: (Sample Table of Contents)

Note: Some Coordinating Centers follow the "just-in-time" rule, therefore the Human Rights Committee review may not be necessary until after CSSMRB approval. If this is the case, amend paragraph 2 accordingly.

**SAMPLE TABLE OF CONTENTS
FOR PROTOCOLS***

(Refer to ICH Guideline for Good Clinical Practice, Section 6 - Clinical Trial Protocol
and Protocol Amendment(s))

	PAGE
Executive Summary	
Letters of Submittal	
Principal Proponent	
Cooperative Studies Program Coordinating Center	
Cooperative Studies Program Clinical Research Pharmacy Coordinating Center	
Planning Committee	
I. Introduction and Background	
II. Study Objectives	
A. Primary Objectives	
B. Secondary Objectives	
III. Study Outcome Measures	
A. Primary	
B. Secondary	
IV. Summary of Study Design	
V. Patient Population	
A. Inclusion Criteria	
B. Exclusion Criteria	
C. Recruitment and Screening	
VI. Human Rights Issues and Informed Consent	
VII. Evaluation Procedures	
VIII. Baseline Assessment	
IX. Stratification and Randomization	
X. Treatment Regimens	

*NOTE: This information was extracted from SOP 2.1.0 - Developing, Approving and
Amending Protocols (Attachment #2), pages 20-22

- XI. Follow-up Assessment
 - A. Follow-up Visits
 - B. Interim Visits
 - C. Monitoring Adverse Events
 - D. Unmasking the Study Treatment
 - E. Discontinuation of Treatment
 - F. Withdrawals from Study
 - G. Post Follow-up Procedures

- XII. Cost-Effectiveness
 - A. Overview and Perspective
 - B. Types of Costs Included in the Analyses
 - C. Methods of Direct Cost Data Collection
 - D. Estimating Costs
 - E. Discounting
 - F. Summary
 - G. Time Frame for Data Collection
 - H. Data Sources
 - I. Cost Estimation Methods

- XIII. Quality Control Procedures
 - A. Standardization/Validation of Measurements
 - B. Patient Management
 - C. Protocol Deviations
 - D. Masking
 - E. Site Performance Monitoring
 - F. Probation/Termination of Participating Centers

- XIV. Data Management

- XV. Good Clinical Practices
 (Note: Please insert attached description of Good Clinical Practices in the protocol)
 - A. Summary of Monitoring and Auditing Plans

- XVI. Biostatistical Considerations
 - A. Expected Treatment Effects
 - B. Sample Size/Power/Level of Significance
 - C. Power Considerations for Secondary Outcome Measures
 - D. Duration of Study/Number of Participating Sites
 - E. Statistical Analysis
 - F. Cost Analysis
 - G. Interim Monitoring
 - H. Criteria for Termination of Study
 - I. Procedure for Accounting for Missing, Unused and Spurious Data
 - J. Procedures for Reporting Any Deviation(s) From the Original Statistical Plan

- XVII. Study Organization and Administration

- XVIII. Publications
 - A. Publication Policy
 - B. Planned Publications

- XIX. References

Appendices

- A. Human Rights Considerations
 - 1. Human Rights Committee Minutes
 - 2. Consent Form
- B. Budget
 - 1. Budget Justification
 - 2. Budget
 - 3. Study Financing
 - 4. Insurance (if applicable)
- C. Curricula Vitae
 - 1. Principal Proponent(s)
 - 2. Study Biostatistician(s)
 - 3. Others attending CSSMRB
- D. Biostatistical and Research Data Processing
 - 1. Data Management
 - 2. Statistical Reports
- E. Research Data Forms
- F. Drug Treatment and Handling Procedures
- G. Drug Information
- H. Participation
 - 1. Estimates of Patient Availability
 - 2. Survey of Potential Sites/Investigators

PROTOTYPE MEMO 11

Attachment

Attachment to Sample of Table of Contents for Protocols. Please insert the paragraph below in the protocol as a standardized description of XV: Good Clinical Practices.

GOOD CLINICAL PRACTICES

This trial will be conducted in compliance with Good Clinical Practices. Monitoring of sites participating in the trial will be executed according to Cooperative Studies Program (CSP) Guidelines. A GCP Reviewer from the Site Monitoring, Auditing and Review Team (SMART) will visit all VA centers, at least once, during the course of the study. The purpose of these visits is to encourage and assess compliance with Good Clinical Practice requirements. Reviewers will examine patient study files including source documents in both the clinic files and the patients' official VA medical records and will also review regulatory/essential documents such as correspondence with the IRB and the Sponsor (CSP). Areas of particular concern will be patient informed consent issues, protocol adherence, safety monitoring, IRB reviews and approvals, regulatory documents, patient records, drug accountability and investigator supervision and involvement in the trial. Reports will be prepared following the visit and forwarded to the investigator, the Study Chair and CSPCC Director.

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date:

PROTOTYPE MEMO 12

From: Project Manager, [medical center name] CSPCC (#000/00)

Approximately 4 weeks before
2nd Planning Meeting

Subj: Second Meeting of the Planning Committee, CSP #[000]

To: [Each member of the Planning Committee including Principal Proponent, medical center name (000/00) and Chief, GCPRG (or designee) [if applicable]]

1. The second meeting of the Planning Committee for the cooperative study entitled "[title]" ([#000]) will be held at [place] in [city] on [date]. Attached you will find material to review prior to the meeting.
2. For VA employees, travel authority and advance travel funds will be forwarded to your medical center R&D office prior to the meeting from this Coordinating Center and VA Central Office. Adjustments (increase or withdrawal of balance) will be made subsequent to the trip upon notification of actual costs. Please file your travel voucher promptly.
3. For non-VA employees, you will receive a Letter of Agreement from the Coordinating Center prior to the meeting which will request your services at the meeting and will provide reimbursement of travel and per diem expenses.

[name]

Attachment

cc: **Site Personnel:**

Principal Proponent (copy of memo & list of attendees)
ACOS for R&D (each medical center)
AO for R&D (each medical center)

VACO Personnel:

Director, Clinical Science R&D Service (VACO) (copy of memo & list of attendees)
CSP Deputy Director (VACO) (copy of memo & list of attendees)

CSPCC Personnel:

CSPCC Director (copy of memo & list of attendees)
Associate Director, CSPCC (copy of memo & list of attendees)
Administrative Officer, CSPCC (copy of memo & list of attendees)

Director, CSPCRPCC [IF APPLICABLE]

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 13

4 weeks prior to
2nd Planning Meeting

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: CSP #[000], CSSMRB Submission

To: [Principal Proponent's name, medical center name (000/00)]

1. As [Study Biostatistician] has probably already informed you, your study protocol has been scheduled for scientific review by the Cooperative Studies Scientific Merit Review Board (CSSMRB). The review date is scheduled for [date]. In order for us to meet the [date] submission deadline, we will have to receive your final copy in its entirety by [date]. This will not be a problem if you can make all of the necessary changes at your final planning meeting on [date]. The actual CSSMRB review will take place in [month].

2. After your proposal has been reviewed at the Center and certified as ready for review, it will be reformatted and sufficient copies made for CSSMRB, the Planning Committee, and your own use. We will take full responsibility for this process and see that it reaches CSSMRB by its deadline.

[name]



DEPARTMENT OF VETERANS AFFAIRS
[INSERT ADDRESS OF MEDICAL CENTER]

PROTOTYPE LETTER 14

After contact with individual
committee members or 4 weeks
before 2nd Planning Meeting and HRC

[date]

000/00
CSP #000/00

[Human Rights Committee Members]
[title]
[address]
[city, state zip]

Dear _____:

Under authority USC 38, (Section 213), the Cooperative Studies Program Coordinating Center, Department of Veterans Affairs, requests your services on [date] at [time] for a meeting of the Human Rights Committee to be held at the [place]. The Committee will review the VA Cooperative Study "[title]" ([#000]).

For this service we can offer you the sum of [#] as remuneration in full covering travel and your fee. Payment will be submitted by this office after the service has been provided.

If the arrangement is agreeable to you, please sign the space provided below and return the original of this letter in the self-addressed envelope enclosed.

Sincerely,

[To be signed by appropriate person at CSPCC]

Social Security No. _____

AGREED: _____



**DEPARTMENT OF VETERANS AFFAIRS
[INSERT ADDRESS OF MEDICAL CENTER]**

PROTOTYPE LETTER 15
Two weeks before the meetings of the
2nd Planning Committee and HRC

[date]

000/00
CSP #000/00

[Human Rights Committee Members]
[title]
[address]
[city, state zip]

Dear _____:

This is to remind you that the Human Rights Committee will meet at the [place] in [city] at [time] [date] to review the cooperative study on "[title]" (#[000]). [name] from [place] is the Principal Proponent of this study and [name] is the Study Biostatistician.

This study is still in the planning stage and the upcoming meeting will be your first occasion to review the proposal. You will be meeting with the Planning Committee. In addition to the Principal Proponent and the Study Biostatistician we expect the following to attend:

[Name	Title	Institution]
-------	-------	--------------

Enclosed is an essentially final draft of the research proposal (and a copy of the Drug Information prepared by the CSP Clinical Research Pharmacy Coordinating Center). The informed consent procedures can be found on page(s) [] of the proposal. Please review these materials prior to the meeting and bring them with you to the meeting.

Sincerely,

[name], Director
Cooperative Studies Program
Coordinating Center

Enclosures: (Research Proposal)
(Drug Information)

GUIDANCE FOR CSP STUDY FIRST PLANNING MEETINGS

In accordance with the CSP Staff Operations Manual, CSP first study planning meetings are to be held in Washington, DC, unless permission is given by the CSR&D Director to hold the meeting elsewhere. The following provides specific guidance to help CSPCCs organize this meeting.

Meetings will be held in either a DC hotel or possibly a VACO conference room.

Scheduling

1. CSPCCs are to provide CSP Deputy Director and Program Specialist with some suggested dates (at least 3 options) based on consultation with the study team members.
2. Once dates are submitted, CSP CO will determine the CSR&D Director's availability to attend the meeting for at least the first day. Other CSP CO staff will attend as needed.
 - CO will also try to coordinate with the CRADO's calendar for his availability.
3. When the CSR&D Director's availability is confirmed, CSP CO will provide the CSPCC (via project manager and/or Assistant Director-Operations) with the finalized date.

NOTE: CSPCCs may inquire if a VACO conference room is available if it may potentially save on conference room costs.

Travel

1. Travel expenses will be covered by CSP CO through travel authorities (TWXs).
 - CSPCCs are to arrange for study team members hotel reservations and other travel arrangements as usual.
2. A list of hotels close in proximity to the meeting location is attached. A more complete list of hotels in Washington, DC can be accessed at www.washingtonhoteldirectory.org.
3. Washington-Reagan National Airport (DCA) is the closest airport and has Metro (subway) access to/from VA Central Office. Washington-Dulles International Airport (IAD) is also in the general vicinity, but requires a taxi/car to reach downtown Washington, D.C.

4. For Metro information, please see their website at:
<http://www.wmata.com/metrorail/default.cfm>

The VA Office of Research & Development (CSP Headquarters/meeting location) is closest to the Farragut West Station (Orange & Blue Lines) or the Farragut North Station (Red Line).

If additional information about these procedures is needed, please contact Kelli Potter at kelli.potter@va.gov or 202-254-0287.

HOTELS BY CSP HEADQUARTERS – WASHINGTON, DC

The following are hotels within walking distance to the meeting location. While they provide federal government rates, CSPCCs should confirm these rates with the hotel.

Capital Hilton
1001 16th St., N.W.
Washington, D.C. 20036
Ph: (202) 393-1000

Club Quarters
839 17th Street, NW
Washington, DC 20006
Ph: (202) 463-6400

Hay Adams Hotel
800 16th Street, NW
Washington, DC 20006
Ph: (202) 638-6600

Sofitel Lafayette Square
806 15th Street, NW
Washington DC 20005
Ph: (202) 730-8800

Additional hotels that are within a few miles of the meeting location.

Hilton Garden Inn
815 14th Street, NW
Washington, DC 20005
Ph: (202) 783-7800

Hamilton Crowne Plaza
14th & K Street NW
Washington, DC 20005
Ph: (877) 227-6963

EXHIBIT 3

CSP MEETING AND TRAVEL INFORMATION		COOPERATIVE STUDIES PROGRAM	
1. To: CSP, DVACO (151-I) cc:		2. Date:	
3. From CSP COORDINATING CENTER: <input type="checkbox"/> Boston <input type="checkbox"/> Hines <input type="checkbox"/> Palo Alto <input type="checkbox"/> Perry Point <input type="checkbox"/> West Haven <input type="checkbox"/> Central Research Pharmacy			
4. Study Number:		5. Study Name:	
6. MEETING INFORMATION			
6a. Meeting Purposes:			
6b. TYPES (Check Correct Combinations, if applicable) <input type="checkbox"/> Routine <input type="checkbox"/> Extra <input type="checkbox"/> Special		Date(s)	Hours
<input type="checkbox"/> Group KICK-OFF Meeting			
<input type="checkbox"/> Executive Committee			
<input type="checkbox"/> DMC w/Human Rights Committee <input type="checkbox"/> Yes <input type="checkbox"/> No			
<input type="checkbox"/> Annual Meeting			
<input type="checkbox"/> Data Analysis and Manuscript			
<input type="checkbox"/> HRC Site Visit			
<input type="checkbox"/> Site Visit			
<input type="checkbox"/> Training GCP			
<input type="checkbox"/> Study Planning Meeting <input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> Other			
<input type="checkbox"/> Study Subcommittee			
<input type="checkbox"/> Other: <input type="checkbox"/> PI Meeting <input type="checkbox"/> Program			
6c. Site(s) of Meetings: VA Cooperative Studies Program, Albuquerque, NM			
6d. Attendance Information:			
DVA: Number of DVA Attendees <u> 0 </u> Amount of DVA Funds <u> \$0.00 </u> SEE FOLLOWING PAGE(S) INDIVIDUAL DVA ATTENDEES			
LOA: Number of LOA Attendees <u> 0 </u> Amount of LOA Funds <u> \$0.00 </u> SEE FOLLOWING PAGE(S) INDIVIDUAL LOA ATTENDEES			
CONCURRENCE			
I have received the above-referenced, and attached, meeting and travel information. To the best of our knowledge, the Individuals listed will attend the meeting(s) and the travel estimates are accurate and final. These are ready to be processed by DVACO.			
_____		_____	
CSPCC / CSPCRPCC Certifying Official		Date	

EXHIBIT 3 (cont)

NAME OF AGENCY VHA, Washington, DC	PRECEDENCE ACTION: P INFO:	SECURITY CLASSIFICATION			
ACCOUNTING CLASSIFICATION	DATE PREPARED 10/31/2007	FILE			
FOR INFORMATION CALL					
NAME	PHONE NUMBER	TYPE OF MESSAGE			
Mavis Perry, Transportation Assistant	(203) 932-5711 ext. 3750	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%; text-align:center;">Single</td> <td style="width:33%; text-align:center;">Book</td> <td style="width:33%; text-align:center;">Multiple Address</td> </tr> </table>	Single	Book	Multiple Address
Single	Book	Multiple Address			
<i>THIS SPACE FOR USE OF COMMUNICATION UNIT</i>					

MESSAGE TO BE TRANSMITTED (Use double spacing and all capital letters)

TO:

00/151 BY DIRECTION OF DEPUTY UNDER SECRETARY FOR HEALTH, PROVIDED YOU CONCUR, DIRECTOR, CSR&D SERVICE APPROVES TRAVEL FOR **THE FOLLOWING INDIVIDUALS** TO ATTEND THE **CSP#[STUDY] ANNUAL MEETING ON [DATE], IN [PLACE]. BREAKFAST/LUNCH WILL BE PROVIDED M&IE REDUCED APPROPRIATELY.** FUNDING TO SUPPORT THIS DETAIL THROUGH PROGRAM 825 (CODES LISTED BELOW). IF FUNDING SOURCE INDICATES "COTBS", TDA TO FOLLOW; IF PYOS OR CYOS, USE FUNDS ALREADY ON STATION. ADJUSTMENT WILL BE MADE SUBSEQUENT TO THE TRIP UPON NOTIFICATION OF EXCESS FUNDING OR EXCESS COSTS TO **MS. MAVIS PERRY, (STA #689/151A), 203.932.5711 ext.3750.**

FUNDING CODES CYOS-CURRENT YEAR FUNDS ON STATION APPRO.368.90161.001 (.016) FY08

 PYOS-PRIOR YEAR FUNDS ON STATION APPRO.367.80161.001 (.016) FY07

 REIMBURSEABLE (REIMB)

 (COTBS)-CO DIRECTED FUNDS TO BE SENT

PY- (COTBS) APPRO.367.80161.001 (.016)

CY-(COTBS) APPRO.368.90161.001 (.016)

STATION NAME & # ("VAMC/VAHCS" NOT REQ'D)	PARTICIPANTS (VA)	AMOUNT	PYOS	CYOS	COTBS	NON-PROFIT
			(To Be Completed by RDCO)			
West Haven, CT (689)	Smith, Joan					

Timothy J. O'Leary, MD, PhD Director, Clinical Science Research & Development Service	PAGE NO. 1	NO. OF PAGES 3	SECURITY CLASSIFICATION
--	----------------------	--------------------------	-------------------------

CSP MEETING and TRAVEL INFORMATION
Individual DVA (VA) and LOA Attendance Information
[STUDY #], [TYPE OF MEETING], [PLACE MEETING HELD] AND [DATE]

Total for VA and LOA \$0.00

CSSMRB BUDGET PLANNING TOOL

Facility: Chairs Office MAVERIC Lab HERC CSPCRPCC Genomic Lab
 Central Lab CSPCC SMART Sites Other

Study Funding Source(s): VA _____ Other/Specify _____

Participating Sites: VA _____ Non-VA _____

1. Study Sample Size: _____

2. Length of Study: Start Up _____ (Years/Months) Patient Intake: _____ (Years/Months)
 Patient Follow-up: _____ (Years/Months) Close Out: _____ (Years/Months)
 Analysis: _____ (Years/Month)

Start up:

3. Personnel to be hired: YES NO Funds Required: 825 870 Other/Specify _____

Title: _____ Title: _____

Grade: _____ FTEE: _____ Grade: _____ FTEE: _____

4. Specific study equipment required (Non-IT items) (if yes; specify below): YES NO

5. IT equipment (if yes; specify below): YES NO

6. Specific Contracts (if yes; specify below): YES NO

7. Other:

8. Method of Data Collection:

9. Method of Randomization:

10. Lab:

Study test:

All Other:

11. Drug / Device

12. SAE Reporting

12. Subject Travel: Yes (if yes, specify below) No

13. Subject Reimbursement: Yes (if yes, specify below) No

14. Travel Requirements:

Number of Travelers per FY _____

Type of Travel: Exec Com. SMART DMC

Pre-Kickoff Annual/Kickoff HRC Other (please specify) _____

VA Cooperative Study #565 Budget for CSSMRB

EXHIBIT 5

	Start-Up	Year 1	Year 2	Year 3	Year 4	Year 5	Close-Out	Analysis	Total
Co-Principal Proponent's Office (Pittsburgh)									
Personnel:									
National Coordinator, GS 11/3 (FT 1.0)	18,200	76,500	80,300	84,300	88,500	92,900	48,800	-	489,500
Subtotal	18,200	76,500	80,300	84,300	88,500	92,900	48,800	-	489,500
All Other Costs:									
IT - Computer and printer	1,250	-	-	-	-	-	-	-	1,250
Misc. supplies, express mailings, etc.	500	2,000	1,500	1,500	1,500	1,500	1,000	-	9,500
Subtotal	1,750	2,000	1,500	1,500	1,500	1,500	1,000	-	10,750
Total	19,950	78,500	81,800	85,800	90,000	94,400	49,800	-	500,250
Co-Principal Proponent's Office (Phoenix)									
Personnel:									
Program Assistant, GS 6/3 (HT .50)	5,600	23,600	24,800	26,000	27,300	28,700	15,100	-	151,100
Subtotal	5,600	23,600	24,800	26,000	27,300	28,700	15,100	-	151,100
All Other Costs:									
IT - Computer and printer	1,250	-	-	-	-	-	-	-	1,250
Misc. supplies, express mailings, etc.	500	2,000	1,500	1,500	1,500	1,500	1,000	-	9,500
Subtotal	1,750	2,000	1,500	1,500	1,500	1,500	1,000	-	10,750
Total	7,350	25,600	26,300	27,500	28,800	30,200	16,100	-	161,850
Participating Medical Centers (30)									
Personnel:									
Study Coordinator, RN LII/3 (FTEE .70/50)	4,900	62,000	65,100	68,400	51,300	53,900	4,700	-	310,300
Subtotal	4,900	62,000	65,100	68,400	51,300	53,900	4,700	-	310,300
All Other Costs:									
Miscellaneous supplies, etc.	200	1,300	1,500	1,500	1,500	1,500	200	-	7,700
IT - Programmer/IRM Tech, database search fee	300	-	-	-	-	-	-	-	300
IT - Laptop Computer/printer/shipping & handling	1,625	-	-	-	-	-	-	-	1,625
Subtotal	2,125	1,300	1,500	1,500	1,500	1,500	200	-	9,625
Total for individual site	7,025	63,300	66,600	69,900	52,800	55,400	4,900	-	319,925
Total PMCs x 30	210,750	1,899,000	1,998,000	2,097,000	1,584,000	1,662,000	147,000	-	9,597,750
West Haven-CSPCC (P825 Funds)									
Personnel:									
Biostatistician, GS 14/4, (FTEE 0.50); 25% analysis	68,400	71,000	74,600	78,300	82,200	86,300	45,300	47,600	553,700
Co-Biostatistician, GS 14/3, (FTEE 0.25)	33,400	34,500	36,200	38,000	39,900	41,900	22,000	46,200	292,100
Research Coord, GS 11/3, (FTEE 1.0); 25% analysis	39,400	82,700	86,800	91,100	95,700	100,500	52,800	27,700	576,700
Project Manager, GS 11/4, (FTEE 1.0 in yr 1; .50 in yrs 2-5); 0% analysis	40,600	84,300	44,300	46,500	48,800	51,200	26,900	-	342,600
Subtotal	181,800	272,500	241,900	253,900	266,600	279,900	147,000	121,500	1,765,100
All Other Costs:									
General office supplies, express mailings, conference facilities, etc.	10,000	20,000	20,000	20,000	20,000	20,000	10,000	7,500	127,500
Subtotal	10,000	20,000	20,000	20,000	20,000	20,000	10,000	7,500	127,500
Subtotal for P825 Funds	191,800	292,500	261,900	273,900	286,600	299,900	157,000	129,000	1,892,600
West Haven-CSPCC (IT Funds)									
Personnel:									
Comp Specialist, GS 12/3 (FTEE 1.0); 50% analysis	47,200	98,000	102,900	108,000	113,400	119,100	62,500	65,600	716,700
Comp. Specialist, GS 12/6 (FTEE .50 yr 1; .25 yrs 2-5); 0% analysis	51,600	53,600	28,100	29,500	31,000	32,600	17,100	-	243,500
Subtotal	98,800	151,600	131,000	137,500	144,400	151,700	79,600	65,600	960,200
All Other Costs:									
IT - All Other Costs (maintenance, software, website, etc.)	3,000	5,000	5,000	5,000	5,000	5,000	3,000	5,000	36,000
IT - Computer Equipment (3 Desktop Computers)	3,300	-	-	-	-	-	-	-	3,300
Subtotal	6,300	5,000	5,000	5,000	5,000	5,000	3,000	5,000	39,300
Subtotal for IT:	105,100	156,600	136,000	142,500	149,400	156,700	82,600	70,600	999,500
Total for WH-CSPCC	296,900	449,100	397,900	416,400	436,000	456,600	239,600	199,600	2,892,100

VA Cooperative Study #565 Budget for CSSMRB

EXHIBIT 5

	Start-Up	Year 1	Year 2	Year 3	Year 4	Year 5	Close-Out	Analysis	Total
CSPCRPCC Albuquerque									
Personnel:									
See Attached for breakdown	63,230	250,009	260,136	269,458	218,253	222,304	82,358	19,347	1,385,095
IT Personnel	1,200	5,042	5,294	5,558	5,836	6,128	613	-	29,671
Subtotal	64,430	255,051	265,430	275,016	224,089	228,432	82,971	19,347	1,414,766
Operating Materials									
Supplies-packing materials/disposition/QC/shipping supplies	58,838	53,081	56,851	55,178	20,292	13,176	2,107	-	259,523
IT equipment	-	-	24,806	26,047	27,349	28,716	-	-	106,918
Drugs	610,241	75,722	743,146	157,356	-	-	-	-	1,586,465
Manufacturing Materials	261,849	267,591	518,203	544,113	-	-	-	-	1,591,756
Travel	3,600	2,700	2,700	2,700	2,700	2,700	2,700	900	20,700
Subtotal	934,528	399,094	1,345,706	785,394	50,341	44,592	4,807	900	3,565,362
Total	998,958	654,145	1,611,136	1,060,410	274,430	273,024	87,778	20,247	4,980,128
SMART									
Personnel: Standards & Resources Group(GCPSRG)	21,557	37,600	6,706	7,041	7,393	7,763	-	-	88,060
Training & Auditing Supplies (GCPSRG)	24,139	200	210	221	232	243	-	-	25,245
Travel	2,100	2,700	-	-	-	-	-	-	4,800
Contractor SRG	17,950	185,720	7,928	8,324	8,740	9,177	-	-	237,839
Subtotal for SMART	65,746	226,220	14,844	15,586	16,365	17,183	-	-	355,944
Personnel: Site Review Group (GCPRG)	4,209	16,837	92,633	35,618	102,128	107,234	29,336	-	387,995
Supplies (GCPRG)	-	500	525	551	579	608	319	-	3,082
Travel (GCPRG)	-	1,800	5,400	3,000	5,400	5,400	2,100	-	23,100
Contractor (GCPRG)	-	10,700	189,693	11,797	209,137	219,593	14,575	-	655,495
Subtotal for Site Review Group	4,209	29,837	288,251	50,966	317,244	332,835	46,330	-	1,069,672
Total for SMART	69,955	256,057	303,095	66,552	333,609	350,018	46,330	-	1,425,616
Combined Total for CSPCRPCC & SMART	1,068,913	910,202	1,914,231	1,126,962	608,039	623,042	134,108	20,247	6,405,744
MAVERIC									
Personnel: See attached for Breakdown	-	17,652	35,304	35,304	17,652	-	-	-	105,912
Supplies and Shipping	-	12,986	25,992	26,013	13,007	-	-	-	77,998
Storage Costs (Blood)	-	10,477	13,685	13,691	10,482	-	-	-	48,335
Storage Costs (Urine)	-	5,546	7,459	7,462	5,550	-	-	-	26,017
Supplies (Central Lab Creatinine Testing)	-	9,464	9,464	9,464	9,464	-	-	-	37,856
Total	-	56,125	91,904	91,934	56,155	-	-	-	296,118
CENTRAL CORE LAB									
Personnel:	-	-	-	-	-	-	-	-	-
AOC: (Estimated at \$3 per test)	-	5,550	12,390	18,900	19,530	18,540	-	-	74,910
Specimen Shipping Costs (\$32 per shipment)	-	49,920	49,920	49,920	24,960	24,960	-	-	199,680
Total	-	55,470	62,310	68,820	44,490	43,500	-	-	274,590
Travel (Annual/Executive/Initial Training & DMC)	74,700	76,940	80,250	82,630	85,080	87,600	90,190	48,000	625,390
Grand Total	1,678,563	3,550,937	4,652,695	3,997,046	2,932,564	2,997,342	676,798	267,847	20,753,792

Patient Intake 36 months (3 years)

Patient Follow-up 24 months (2 years)

Participating VA Centers = 30 1,850

Principal Proponents - 3 mths start up/6 months close out

PMC's - 1 month start up/ 1 months close out

WH-CSPCC - 6 mths start up/6 months close out/12 months analysis w/reduced staff

CSP#565 Estimated Travel Costs

EXHIBIT 5 (cont)

Type of Meeting	# of People	Start-Up	Year 1	Year 2	Year 3	Year 4	Year 5	Close-Out	Analysis	Total
Organizational/Annual Group	73	65,700	67,670	69,700	71,790	73,940	76,160	78,440	-	503,400
	0	-	-	-	-	-	-	-	36,000	36,000
Manuscript Meeting	10	-	-	-	-	-	-	-	9,000	9,000
Study Presentations..		-	-	1,000	1,000	1,000	1,000	1,000	3,000	8,000
Data Monitoring Committee	9 (estimated)	9,000	9,270	9,550	9,840	10,140	10,440	10,750	-	68,990
Endpoints Com.	5 (estimated)	-	-	-	-	-	-	-	-	-
Total		74,700	76,940	80,250	82,630	85,080	87,600	90,190	48,000	625,390
Chair's	4									
PMC	60									
WH-CSPCC	7									
Alb PCC	0	Included in their budget								
Alb SMART	0	Included in their budget								
HERC	0									
MAVERIC	1									
Central Lab	1									
Total	73									

DMC & Endpoints @ \$1,000 each
 All others @ \$900 each
 3% Adjustment per year

CSP#565 Budget Summary

EXHIBIT 5 (cont)

	Start-Up	Year 1	Year 2	Year 3	Year 4	Year 5	Close-Out	Analysis	Total	% of Total Cost
Co-Principal Proponent's Office (Pittsburgh)	19,950	78,500	81,800	85,800	90,000	94,400	49,800	-	500,250	2%
Co-Principal Proponent's Office (Phoenix)	7,350	25,600	26,300	27,500	28,800	30,200	16,100	-	161,850	1%
Participating Medical Centers (30)	210,750	1,899,000	1,998,000	2,097,000	1,584,000	1,662,000	147,000	-	9,597,750	46%
West Haven-CSPCC	296,900	449,100	397,900	416,400	436,000	456,600	239,600	199,600	2,892,100	14%
Albuquerque - CRPCC	126,868	310,832	349,787	358,941	274,430	273,024	87,778	20,247	1,801,907	9%
Drug & Manufacturing Materials	872,090	343,313	1,261,349	701,469	-	-	-	-	3,178,221	15%
SMART	69,955	256,057	303,095	66,552	333,609	350,018	46,330	-	1,425,616	7%
MAVERIC	-	56,125	91,904	91,934	56,155	-	-	-	296,118	1%
Central Core Laboratory	-	55,470	62,310	68,820	44,490	43,500	-	-	274,590	1%
Travel (Annual/Executive/Initial Training & DMC)*	74,700	76,940	80,250	82,630	85,080	87,600	90,190	48,000	625,390	3%
Total Study Costs	1,678,563	3,550,937	4,652,695	3,997,046	2,932,564	2,997,342	676,798	267,847	20,753,792	100%

Budget with Drug Donation	806,473	3,207,624	3,391,346	3,295,577	2,932,564	2,997,342	676,798	267,847	17,575,571
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*Albuquerque's travel estimates are included in their budget section.

SMART DEFINITIONS
(Site Monitoring, Auditing and Resource Team)

Definitions:

Auditing – an independent one-time examination of a participating site to determine whether the study is conducted in accordance with the protocol, Sponsor SOPs, GCP, and regulatory requirements. Visits are scheduled in response to specific concerns about the study or a participating site arising during the trial, e.g. requests generated by CSP Directors, monitors, chairmen, etc.

Monitoring – a program of recurring site visits by which the sponsor oversees the progress of the clinical trial at participating sites to ensure that the study is conducted in accordance with the protocol, Sponsor SOPs, GCP and regulatory requirements. Visits are scheduled in accordance with the Sponsor’s pre-defined monitoring plan as determined by the needs of the trial.

Site Reviews – a hybrid of auditing and monitoring. Like auditing, site reviews focus more on research practices than on data verification. Like monitoring, site reviews are conducted at regular intervals (at least annually) using a pre-defined site review plan prepared specifically for the trial.

[An audit provides a one-time snapshot of study conduct, site reviews provide periodic snapshots and monitoring provides a continual on-going overview of study conduct at the site]

SMART Services
(Site Monitoring, Auditing and Resource Team)

GCP Standards & Resources Group
(All Categories)

GCP Monitoring Group
(Category I)

GCP Review Group
(Category II & III)

- Develop Study Execution Materials**
- Study-specific CPRS procedures
 - Subject Casebooks for case report forms (CRFs)
 - Source document guidance, tools
 - Essential Documents Binders
 - Review plan and tools for Category II-IV trials
- Provide GCP Training Programs**
- GCP course for Researchers every 3 years
 - Site Reviewer Orientation & Training
 - GCP Site Initiation Visits (Category II-IV)
- Perform GCP For-Cause Site Audits**
- Requested by CSP Directors / Monitors
 - Identify problems, refer to CSP/Monitors

- Perform Site Monitoring for Pivotal Trials**
- Develop Monitoring Plan
 - Conduct monitoring visits
 - Initiation Visits
 - Routine Visits (frequency per monitoring plan)
 - Close-out Visits
 - PRN Visits

- Perform GCP Site Reviews for Non-Pivotal Trials**
- Periodic Review Visits (NLT annual)
 - Final Review Visits
 - PRN Visits

Study Risk Categories:	GCP Services:
Category I – High Regulatory Risk a. Drug/Device Studies with IND/IDE, intended for NDA/PMA Submission to FDA	Frequent monitoring visits, for-cause audits, GCP training & tools*
Category II – High regulatory and/or Patient Risk – Studies with issues that warrant additional evaluation b. Drug/Device Studies with IND/IDE, not intended for NDA/PMA Submission to FDA c. Drug/Device Studies without IND/IDE d. Surgical Studies e. Other Non-Drug, Non-Device, Non-Surgical Studies	Site Initiation visits, Review visits (frequency to be determined), For-Cause Audits, PRN visits, GCP training & tools*
Category III – Moderate Regulatory and/or Patient Risk b. Drug/Device Studies with IND/IDE, not intended for NDA/PMA Submission to FDA c. Drug/Device Studies without IND/IDE d. Surgical Studies	Site Initiation visits, Annual review visits, For-Cause Audits, PRN visits, GCP training & tools*
Category IV – Low Regulatory and/or Patient Risk e. Other Non-Drug, Non-Device, Non-Surgical Studies	Site Initiation visits, For-Cause Audits, PRN visits, GCP training & tools*

*GCP Tools consist of Essential Documents Binders, Subject CRF Binders and source documentation guidance.

COOPERATIVE STUDIES SCIENTIFIC MERIT REVIEW BOARD

I. Overview

The Cooperative Studies Scientific Merit Review Board (CSSMRB and formerly known as the Cooperative Studies Evaluation Committee (CSEC)) is an independent panel of clinicians, research methodologists, and statisticians who all have expertise in clinical trials. This group reviews the scientific merit of all new and ongoing CSP studies and makes funding recommendations to the Director, CSR&D. The CSSMRB is a Federal Advisory Committee Act (FACA) chartered committee appointed by the VA Under Secretary for Health. As a CSP hallmark, CSSMRB provides reviews of the highest standard and helps to ensure the continued excellence of the CSP.

II. CSSMRB Review Preparation - Central Office Procedures

A. Organizational Procedures

1. CSP CO is responsible for organization and oversight of all CSSMRB procedures. Communication among CO staff and the CSP centers is critical to ensuring CSSMRB meetings are held according to Federal and CSP standards.
2. It is the responsibility of the CSP Deputy Director to ensure that all tasks related to the organization of the CSSMRB Review are satisfactorily completed.
 - The CSP Deputy Director serves as the Designated Federal Officer for this FACA committee.
3. **Tasks:**
 - a. **If a meeting date was not finalized at the previous CSSMRB meeting, the CSP Deputy Director initiates steps with CSP CO staff to coordinate the next meeting date.**
 - b. **CSP Deputy Director checks with the Director, CSR&D on suitable meeting dates.**
 - CSP Program Specialist may be asked to assist with this effort.
 - c. **CSP Program Specialist determines availability of CSSMRB members using the CSP Meeting Coordination Survey (Exhibit 8)**
 - d. **Upon selection of the meeting dates, the Deputy Director notifies all CSP Centers.**

References:

- CSP Guidelines, Chapter III, "CSP Review Procedures", Section C. The Cooperative Studies Scientific Merit Review Board, Part 1. Committee Members
- Exhibit 8 – Cooperative Studies Program Meeting Coordination Survey
- Checklist 7 – CSSMRB Section Checklist Items 1-4

B. Administrative Procedures

1. Once a meeting date has been confirmed, the CSP Deputy Director coordinates and assigns preparatory activities with CSP CO staff. In order to allow for sufficient time, such efforts should begin about three months prior to the meeting.

2. **Tasks (three months prior to the meeting)**
 - a. **CSP Deputy Director confirms those studies to be reviewed at the meeting with CSP Centers Directors and reminds them of the meeting date.**
 - b. **CSP Deputy Director develops a list of reviewers and distributes review assignments to CSP CO staff.**
 - This list is comprised of CSSMRB members and any ad hoc reviewers.
 - Each proposal is typically assigned a minimum of two clinical reviewers and one biostatistical reviewer.
 - Discussions with the CSSMRB Chair should be held regarding final assignments.
 - c. **CSP Program Analyst creates meeting folders on the CSP hard drive and in the CSP filing cabinet.**
 - Subfolders may include ones for protocols, reviews, and administration.
 - d. **CSP Program Analyst sends reminder of meeting date and location (if available) to CSSMRB members.**
 - e. **CSP Program Specialist works with ORD personnel on identifying a meeting location.**

Reference: Checklist 7 – CSSMRB Section Checklist Items 5-9

3. Two months prior to the meeting, all proposals should be received from CSP Centers. Regular meetings among CO staff should be held to ensure timelines for the meeting are being met.
4. **Tasks (two months prior to the meeting)**
 - a. **CSP Program Specialist begins developing a meeting attendee list.**
 - This list should clearly indicate reviewers from study proponents.
 - b. **CSP Program Analyst prepares sets of assigned study proposal(s); CSSMRB Procedures and Reviewer Guidelines (Exhibit 9); and CSSMRB Clinical Review Guidelines (Exhibit 10) or CSSMRB Statistical/Methods Review Guidelines (Exhibit 10A) to be sent to the reviewers.**
 - Each set should be clearly marked with the assigned reviewer's name.
 - CSSMRB members receive copies of all study proposals. Ad hoc reviewers receive copies of assigned study proposal(s) unless otherwise indicated.
 - c. **CSP Program Specialist confirms the meeting location and starts preparing necessary travel documents for proponents and center staff.**
 - Documents include travel memos and TWXs.
 - d. **CSP Program Analyst starts preparing necessary travel documents for reviewers.**
 - Documents include travel letters, letters of agreement and vendorization forms.
 - e. **CSP Program Analyst drafts a meeting agenda and Federal Register notice for CSP Deputy Director approval.**

References:
 - Exhibit 9 – CSSMRB Procedures and Reviewer Guidelines
 - Exhibit 10 – CSSMRB Clinical Review Guidelines
 - Exhibit 10A – CSSMRB Statistical/Methods Review Guidelines
 - Checklist 7 – CSSMRB Section Checklist Items 10-14

5. **Tasks (six weeks prior to the meeting)**
 - a. **CSP Program Specialist and CSP Program Analyst ensure that reviewer packages are sent to all reviewers containing hard copies of study proposals, Travel Letter (Letter 16), Certification Form (Exhibit 11), ACH Vendorization Form (Exhibit 12), completed Letters of Agreement (LOAs) and Travel Authorities (TWXs), Travel Directions, and finalized.**
 - b. **CSP Program Analyst submits Federal Register notice to the White House Liaison's Office for concurrence and publication.**
 - **Federal Register notices must be published at least 15 days prior to the meeting.**
 - c. **CSP Program Specialist confirms study proponents who will attend the meeting with CSP Center Assistant Directors for Operations.**

References:

- Exhibit 11 – Certification Form
- Exhibit 12 – ACH Vendorization Form
- Checklist 7 – CSSMRB Section Checklist Items 15-17

6. **It is expected that once review materials are distributed, CSP CO staff hold weekly meetings to further discuss any updates or issues that have to be addressed. Ideally, CSP CO activities at this stage are dependent on CSSMRB reviewer communications.**
7. **Tasks (two weeks or less until meeting)**
 - a. **Two weeks prior to the meeting, CSP Program Analyst sends a reminder to reviewers regarding submission of reviews.**
 - b. **As reviews are received, CSP Program Analyst tracks receipt of reviews, standardize the format of reviews, and de-identifies reviews.**
 - **Reviewer confidentiality may be kept by use of an Author Key.**
 - c. **Upon receipt of all CSSMRB reviews, CSP Program Analyst creates a meeting materials CD with reviews and other details/materials. CSP Program Specialist distributes the CDs to all reviewers.**
 - **CSSMRB study proposals and reviews are made available at the meeting in both CD and hardcopy format.**
 - e. **One week prior to the meeting, the CSP Program Analyst and Specialist secure necessary meeting supplies (See Checklist 8 - CSSMRB Meeting Supplies Checklist).**
 - f. **No later than two days prior to the meeting, CSP Program Analyst emails de-identified reviews of respective proposals to CSP Center Directors.**

References:

- Checklist 7 – CSSMRB Section Checklist Items 18-22
- Checklist 8 – CSSMRB Meeting Supplies Checklist

III. CSSMRB Review Preparation - Study Center Procedures

A. Overview

1. CSSMRB reviews are held biannually in Spring and Fall. For those CSP Centers submitting a study proposal for funding consideration or undergoing mid-term study review by the CSSMRB, it is the responsibility of the CSPCC to ensure all elements required for CSSMRB submission are received by CO, and the proposal certified complete, accurate, and in acceptable form by the CSPCC Director, on or before the CSPCC and CO deadlines.
 - CO will communicate deadlines for CSSMRB submission.

B. CSSMRB Non-Submission

1. If CO submission deadline cannot be met, CSPCC Director will do the following tasks:
2. **Tasks:**
 - a. **Inform Principal Proponent that he/she must wait until next submission date, and request CO remove study from CSSMRB meeting agenda.**

Reference: Checklist 7 – CSSMRB Section Checklist Item 23

C. CSSMRB Submission

1. The CSPCC completes required procedures in preparation for proposal review at the CSSMRB meeting.
2. **Tasks:**
 - a. **CSPCC Assistant Director for Operations ensures availability of personnel, supplies and other required resources to meet submission deadlines.**
 - b. **CSPCC Assistant Director for Operations, Study Biostatistician, Project Manager and/or other appropriate CSPCC staff coordinate actual production of proposal.**
 - For Original Submission Checklist, see **Checklist 9**; for Special Submissions Checklist, see **Checklist 10 for Format for Mid-Term/Extension CSSMRB Review Budget, see Exhibit 13.**
 -
 - All personal identifiers should appear only on original proposal copy submitted to CSPCO, and redacted from all other copies.
- b. **CSPCC creates bound copies of CSSMRB submission using the following color scheme for all submission covers:**

Cover Colors:	
Boston.....	Charcoal
Hines.....	Navy Blue
Palo Alto.....	Forest Green
Perry Point	Light Blue
West Haven	Maroon
Seattle	Red

- All CSSMRB submissions must be bound.
 - Sequential numbering of pages throughout Volumes I and II must be adhered to beginning with first page after Table of Contents. See **Exhibit 14** – Format for CSSMRB Submissions.
 - See **Exhibit 14** – Format for CSSMRB Submissions for details regarding copying and tabbing and **Exhibit 14A** – CSSMRB Distribution Chart for dissemination of submissions.
- c. **CSPCC creates electronic version of proposal (pdf with bookmarks) and submits to CO in CD format.**
- d. **CSPCC Assistant Director for Operations sends tabbed bound copies of protocol to CO based on the number of reviewers.**
- CO will indicate number of bound copies needed.
- e. **CSPCC Assistant Director for Operations sends tabbed bound copies of protocol to Principal Proponent, Study Biostatistician, CSPCC Director, CSPCC Administrative Officer, and all consultants attending CSSMRB review.**
- f. **For proposal resubmission, CSPCC must include in their original submission to CO**
1. **Letter of Submittal summarizing changes made in response to CSSMRB evaluation, immediately followed by**
 2. **Copy of initial CSSMRB review, and**
 3. **Copy of letter from Director, CSR&D notifying Principal Proponent of CSSMRB review results.**
- g. **Two months prior to CSPCC CSSMRB submission deadline, Study Biostatistician prepares a one-page summary of study and sends it with copy of study proposal reference pages to CO to be used in selection of ad hoc CSSMRB reviewers.**
- h. **At least two weeks prior to CSSMRB review, Principal Proponent, Study Biostatistician, and Study Economic Consultant, if any, send a written copy of their oral CSSMRB presentations to the CSSMRB. CSPCC Administrative Officer or designee forwards these written copies to CO.**

References:

- CSP Guidelines, Chapter III, "CSP Review Procedures", Section C. The Cooperative Studies Scientific Merit Review Board, Part 2. The CSSMRB Review Process
- Exhibit 13 – Format for Mid-Term/Extension CSSMRB Review Budget
- Exhibit 14 – Format for CSSMRB Submissions
- Exhibit 14A - CSSMRB Distribution Chart
- Checklist 7 – CSSMRB Section Checklist – Items 24-32
- Checklist 9 – Original Submission Checklist
- Checklist 10 – Special Submissions Checklist

IV. CSSMRB Review

A. CSSMRB Review Procedures

1. The Principal Proponent, Study Biostatistician, Health Economist, and additional consultants, if any, appear before the CSSMRB and selected ad hoc reviewers for a

review of their study. The Study proponents make opening statements providing a concise summary of the research problem and why it should be supported by the VA. Based upon the success of an interactive discussion in which the Study proponents strive to satisfy questions and concerns, the CSSMRB renders a recommendation to approve/extend or disapprove/discontinue the study.

2. Tasks:

- a. **CSP Program Analyst takes the minutes for each proposal review.**
- b. **CSP Program Specialist handles all necessary meeting management and logistical arrangements.**
- c. **CSP Deputy Director summarizes for the Study proponents questions and concerns expressed by the Committee and ad hoc reviewers assigned to the study.**
- d. **CSP CO staff tabulates results of the voting for new proposals.**
- e. **Immediately after close of CSSMRB Executive Session, Director, CSR&D, informs Study Principal Proponent(s), Study Biostatistician, and CSPCC Director of CSSMRB recommendation.**

References:

- CSP Guidelines, Chapter III, "CSP Review Procedures", Section C. The Cooperative Studies Scientific Merit Review Board, Part 3. CSSMRB Recommendations
- Checklist 7 – CSSMRB Section Checklist – Items 33-37

V. Post CSSMRB Review

A. Post Review CO Activities

1. Tasks:

- a. **CSP Deputy Director and CSP Program Analyst draft minutes of CSSMRB Review and submits to CSSMRB Chair for approval.**
- b. **After the funding decision for a study is made by Director, CSR&D, the CSPCC, ACOS/R&D, VAMC Director, and ORD Communications Director are notified of the decision by Director, CSR&D.**
- c. **Director, CSR&D sends Principal Proponent written notification of official action on the proposed study with summary of the CSSMRB review.**
- d. **CSP CO staff meet 10 days post meeting to review the performance of the preceding CSSMRB meeting and determine ways to improve CO staff procedures for succeeding meetings.**
- e. **For disapproved studies, CSP CO staff files appropriate correspondence and transfer all folders for that study to inactive file.**

Reference: Checklist 7 – CSSMRB Section Checklist – Items 38-42

Checklist 7 – CSSMRB Section Checklist

<u>DATE</u>	<u>TASK</u>
_____ 1	Central Office Organizational Procedures CSP Deputy Director initiates steps with CSP CO staff to coordinate next meeting date.
_____ 2	CSP Deputy Director checks with the Director, CSR&D on suitable meeting dates.
_____ 3	CSP Program Specialist determines availability of CSSMRB members using the CSP Meeting Coordination Survey (Exhibit 8)
_____ 4	Upon selection of the meeting dates, the Deputy Director notifies all CSP Centers.
	Central Office Administrative Procedures (3 months prior to the meeting)
_____ 5	CSP Deputy Director confirms those studies to be reviewed at the meeting with CSP Directors and reminds them of the meeting date.
_____ 6	CSP Deputy director develops a list of reviewers and distributes review assignments to CSP CP staff.
_____ 7	CSP Program Analyst creates meeting folders on the CSP hard drive and in the CSP filing cabinet.
_____ 8	CSP Program Analyst sends reminder of meeting date and location to CSSMRB members.
_____ 9	CSP Program Specialist works with ORD personnel on identifying a meeting location.
_____ 10	Central Office Administrative Procedures (2 months prior to the meeting) CSP Program Specialist begins developing a meeting attendee list.
_____ 11	CSP Program Analyst prepares sets of assigned study proposal(s); CSSMRB Procedures and Reviewer Guidelines (Exhibit 9); and CSSMRB Clinical Review Guidelines (Exhibit 10) or CSSMRB Statistical/Methods Review Guidelines (Exhibit 10A) to be sent to the reviewers.
_____ 12	CSP Program Specialist confirms the meeting location and starts preparing necessary travel documents for proponents and center staff.
_____ 13	CSP Program Analyst starts preparing necessary travel documents for reviewers.
_____ 14	CSP Program Analyst drafts a meeting agenda and Federal Register notice for CSP Deputy Director approval.
	Central Office Administrative Procedures (6 weeks prior to the meeting)
_____ 15	CSP Program Specialist and CSP Program Analyst ensure that reviewer packages are sent to all reviewers containing hard copies of study proposals, Travel Letter (Letter 16), Certification Form (Exhibit 11), ACH Vendorization Form (Exhibit 12), completed Letters of Agreement (LOAs) and Travel Authorities (TWXs), Travel Directions and finalized.
_____ 16	CSP Program Analyst submits Federal Register notice to the White House Liaison's Office for concurrence and publication.
_____ 17	CSP Program Specialist confirms study proponents who will attend the meeting with CSP Center Assistant Directors for Operations.

<u>DATE</u>	<u>TASK</u>
_____ 18	Central Office Administrative Procedures (two weeks or less until meeting) CSP Program Analyst sends a reminder to reviewers regarding submission of reviews.
_____ 19	CSP Program Analyst tracks receipt of reviews, standardize the format of reviews, and de-identifies reviews.
_____ 20	Upon receipt of all CSSMRB reviews, CSP Program Analyst creates a meeting materials CD with reviews and other details/materials. CSP Program Specialist distributes the CDs to all reviewers.
_____ 21	One week prior to the meeting, the CSP Program Analyst and Specialist secure necessary meeting supplies (See Checklist 8).
_____ 22	No later than two days prior to the meeting, CSP Program Analyst e-mails de-identified reviews of respective proposals to CSP Center Directors.
_____ 23	Study Center Procedures – CSSMRB Non-Submission Inform Principal Proponent that he/she must wait until next submission date, and request CP remove study from CSSMRB meeting agenda.
_____ 24	Study Center Procedures – CSSMRB Submission CSPCC Assistant Director for Operations ensures availability of personnel, supplies and other required resources to meet submission deadlines.
_____ 25	CSPCC Assistant Director for Operations, Study Biostatistician, project manager and/or other appropriate CSPCC staff coordinate actual production of proposal.
_____ 26	CSPCC creates bound copies of CSSMRB submission.
_____ 27	CSPCC creates electronic version of proposal and submits to CO in CD format.
_____ 28	CSPCC Assistant Director for Operations sends tabbed bound copies of protocol to CO based on the number of reviewers.
_____ 29	CSPCC Assistant Director for Operations sends tabbed found copies of protocol to Principal Proponent, Study Biostatistician, CSPCC Director, CSPCC Administrative Officer, and all consultants attending CSSMRB review.
_____ 30	For proposal resubmission, CSPCC must include in their original submission to CO: Letter of Submittal summarizing changes, copy of initial CSSMRB review and copy of letter from Director, CSR&D notifying Principal Proponent of CSSMRB review results.
_____ 31	Two months prior to submission deadline, Study Biostatistician prepares a one-page summary of study and sends it along with copy of study proposal reference pages to CO to be used in selection of ad hoc CSSMRB reviewers.
_____ 32	Two weeks prior to CSSMRB review, Principal Proponent, Study Biostatistician, and Study Economic Consultant send a written copy of their oral CSSMRB presentations to the CSSMRB. CSPCC Administrative Officer or designee forwards these written copies to CO.
_____ 33	CSSMRB Review Procedures CSP program Analyst takes the minutes for each proposal review.

DATE

TASK

- _____ 35 CSP Deputy Director summarizes for the Study proponents questions and concerns expressed by the Committee and ad hoc reviewers assigned to the study.
- _____ 36 CSP CO staff tabulates results of the voting for new proposals.
- _____ 37 Immediately after close of CSSMRB Executive Session, Director, CSR&D, informs Study Principal Proponent(s), Study Biostatistician, and CSPCC Director of CSSMRB recommendation.
- Post Review CO Activities**
- _____ 38 CSP Deputy Director and CSP Program Analyst draft minutes of CSSMRB Review and submits to CSSMRB Chair for approval.
- _____ 39 After the funding decision for a study is made by Director, CSR&D, the CSPCC, ACOS/R&D, VAMC Director, and ORD Communications Director are notified of the decision by Director, CSR&D.
- _____ 40 Director, CSR&D sends Principal Proponent written notification of official action on the proposed study with summary of the CSSMRB review.
- _____ 41 CSP CO staff meet 10 days post meeting to review the performance of the preceding CSSMRB meeting and determine ways to improve CP staff procedures for succeeding meetings.
- _____ 42 For disapproved studies, CSP CO staff files appropriate correspondence and transfer all folders for that study to inactive file.

Checklist #8 - CSSMRB Meeting Supplies Checklist

- 1. **Name tents**
- 2. **Name tags**
- 3. **Folders with information**
- 4. **Meeting Agenda copies**
- 5. **Voting cards**
- 6. **Hard copies of reviews**
- 7. **Hard copies of proposals**
- 8. **CD version of reviews and proposals**
- 9. **Lap top computer**
- 10. **Printer**
- 11. **FACA folder**
- 12. **VA meeting sign for display**
- 13. **Tape recorder, tapes and batteries**
- 14. **Note pads**
- 15. **Pens**
- 16. **Pencils**
- 17. **Pencil sharpener**
- 18. **Stapler & staples**
- 19. **PostIt notes**
- 20. **Tape**
- 21. **Basket**
- 22. **Backup copies of all Letters of Agreement (LOAs)**

Checklist 9 - Original Submission Checklist

(Study Name and Number)

- I. Due by CSPCC deadline:
 - A. Final study proposal from Proponent
 1. ___ Study protocol
 2. ___ Informed consent procedures
 3. ___ Research data forms (or list/description of forms to be used)
 4. ___ C.V.'s
 5. ___ Description of Responsibilities
 6. ___ Justification of budgetary items
 7. ___ All other appendices including cost effectiveness protocol when appropriate
 8. ___ CSPCC Director cover letter
 - B. Material from Central Pharmacy:
 1. ___ Cover letter form CSPCRPCC Director (if needed)
 2. ___ Drug handling protocol
 3. ___ Drug Information
 4. ___ PCC and SMART budget
 5. ___ Forms
 6. ___ Issues Letter (letter used to clarify budget or document any sensitive issues that may be pending)
 - C. Material from biostatistician
 1. ___ Statistical sections for protocol
 2. ___ BRDP
 - D. Materials from Project Manager
 1. ___ Final Budget (to include CSPCC costs)
 2. ___ Final Informed Consent
 3. ___ Human Rights Committee Minutes (if applicable)
 - E. Materials from Health Economics (including budget if applicable)
 - F. Materials from SMART
- II. Review of proposal completed by biostatistician
- III. Review of proposal completed by CSPCC Director
- IV. Preparation of submission
 - A. ___ Typed
 - B. ___ Duplicated/collated
 - C. ___ Reviewed by biostatistician
 - D. ___ Bound
 - E. ___ Tabbed (at least all mailed copies should be tabbed)
 - F. ___ Proposals mailed to VACO and CSSMRB members
 - G. ___ Copies to Planning Committee, Proponent, Central Pharmacy and others as necessary
 - H. ___ Biostatistician prepares summary of proposal and copy of the pages of references to VACO for information when selecting reviewers (due six weeks before submission)

NOTE: All personal identifiers, such as SS# should appear only on the original of each proposal for research funding submitted to VACO. This information should be redacted (i.e., either removed or stricken) on all copies of proposal.

Checklist 10 - Special Submission Checklist

(Study Name and Number)

Mid Term - One Volume

- _____ 1. Table of Contents
- _____ 2. Executive Summary/Abstract (from Annual Report)
- _____ 3. Director's Summary Statement
- _____ 4. Letters of Submittal (if necessary)
- _____ 5. Letters of Understanding (if necessary)
- _____ 6. Progress Report
- _____ 7. Previous CSSMRB Reports
- _____ 8. Data Monitoring Committee Minutes
- _____ 9. Executive Committee Minutes
- _____ 10. Human Rights Committee Minutes and
Site Visits Reports
- _____ 11. Bibliography of Study Publications
- _____ 12. Budget (See **Exhibit 13**)
 - _____ original
 - _____ actual
 - _____ extension budget (if necessary)
- _____ 13. Original Protocol - (include original protocol only if
modification of protocol is requested)

Tabs for every section

Note: All personal identifiers, such as SS# should appear only on the original of each proposal for research funding submitted to VACO. This information should be redacted (i.e., either removed or stricken) on all copies of the proposal.



**CLINICAL SCIENCE RESEARCH & DEVELOPMENT SERVICE
COOPERATIVE STUDIES SCIENTIFIC MERIT REVIEW BOARD**



PROTOTYPE MEMO 16

Travel Letter with Meeting
Instructions for Reviewers

Date: **[DATE]**

From: Director, Clinical Science Research & Development Service

Subject: Cooperative Studies Scientific Merit Review Board Meeting: **[DATE]**

To: Cooperative Studies Program Staff and Study Presenters

**PLEASE READ THE FOLLOWING INFORMATION CAREFULLY
NOTING HOTEL LOCATION AND RESERVATION INFORMATION**

1. The CSSMRB meeting to review CSP Study Proposals is scheduled for **[DATE]**.
2. The meeting will be at the **[MEETING LOCATION]**
 - o The closest airport will be **[INSERT]**. Metro (subway) service is readily available. Travel directions to the hotel and meeting will be provided.
 - o You should plan to arrive on **[INSERT DATE AND/OR TIME OF ARRIVAL]**
3. A rooming block for the Department of Veterans Affairs has been reserved at **[INSERT HOTEL, ADDRESS]**. Please confirm your hotel reservation by **[INSERT DATE]** with your personal or government issued credit card as soon as possible to ensure that you receive the special government rate of **[INSERT]** per night. Confirm your reservation by **directly calling [INSERT]**.
 - o It is imperative that you confirm your reservation upon receipt of this letter. There is a 48-hour cancellation policy on reservations. Should you have any problems confirming your reservation, please call **[INSERT NAME]** at **[PHONE]**.
4. Each attendee will be responsible for paying room and any miscellaneous hotel charges. Authorized hotel and travel expenses incurred will be reimbursed upon submission of your receipts. **Please save all receipts.**

- 4.a. For VA Employees – Your VA Medical Center will determine whether you or they will make your travel arrangements, and will submit your expense receipts to us for reimbursement. Reimbursements go directly to your VA Medical Center. The TWX is the official mechanism for this process.
- 4.b. For Non-Government Employees – Travel processes are to be handled by your CSP Center and in accordance to the details of your Letter of Agreement. The Federal Government expects all travelers to handle their travel in a reasonable and prudent manner and will reimburse accordingly.
5. Enclosed please find copies of meeting materials (i.e., proposals, review assignments, agenda), along with a Review Certification Form for your review, signature and return to **[ADDRESS]**.
6. If you have questions or require further assistance please contact **[NAME]** at **[PHONE]**.

Timothy J. O'Leary, M.D., Ph.D.

cc: CSP Central Office

Attachments

Cooperative Studies Program Meeting Coordination Survey

Dear Cooperative Studies Scientific Merit Review Board Member:

To coordinate a meeting date for the review, please indicate your availability below. While **{insert the number of days for the meeting}** be needed. Further details will be provided immediately when available. The meeting location will be in Washington, D.C.

Reviewer Name: _____

Option #1

{Insert date} ___ Yes ___ No

If no, available by conference call? ___ Yes ___ No

Option #2

{Insert date} ___ Yes ___ No

If no, available by conference call? ___ Yes ___ No

Option #3

{Insert date} ___ Yes ___ No

If no, available by conference call? ___ Yes ___ No

Other available dates for the months of **{Insert month}**:

Please return completed forms by e-mail or fax to:

{Insert Program Specialist Name}

CSP Program Specialist

Email: **{email address}**

Fax: 202-254-0471

Phone: **{phone #}**

Based on responses, we will notify you of the selected meeting dates or try to coordinate other suitable times.

Thank you again for your willingness to participate in this important review for the CSP.

COOPERATIVE STUDIES SCIENTIFIC MERIT REVIEW BOARD PROCEDURES AND REVIEWER GUIDELINES

The Cooperative Studies Scientific Merit Review Board

The Cooperative Studies Scientific Merit Review Board (CSSMRB) reviews new and ongoing CSP studies and makes recommendations to the CRADO regarding the scientific merit of the studies.

Committee Members

Members of CSSMRB are appointed by the Secretary of the Department of Veterans Affairs upon recommendation by the CRADO. There are members representing many medical specialties as well as representatives from the FDA, the fields of epidemiology and biostatistics, and from health services research. All members have had extensive experience in clinical research and in the conduct of clinical trials. Members are appointed for a four-year term. Two members of CSSMRB, usually a biostatistician and a clinician, are assigned primary responsibility for reviewing each protocol. In addition, for new proposals, the Committee is augmented by an *ad hoc* member knowledgeable in the particular subject matter of the protocol being reviewed. The Chairperson of CSSMRB is nominated by the CRADO. The responsibilities of the Chairperson are to conduct the meeting and to summarize the deliberations of the Committee. The CRADO and his staff serve as coordinators for the meetings.

Written Ad Hoc Reviews for Cooperative Studies Scientific Merit Review Board

Once CSP/VA Headquarters receives the proposal, it is reviewed to ensure that all the required information is included. Copies of the proposal are then sent to *ad hoc* reviewers who provide written critiques to the Cooperative Studies Scientific Merit Review Board. These written critiques are available to the Principal Proponent, Study Biostatistician, and Study Clinical Research Pharmacist prior to the meeting.

Reviewers are asked to comment on the importance of the project, its feasibility, the clarity and achievability of its objectives, the adequacy of the plan of investigation, the correctness of the technical details, the adequacy of safeguards for the welfare of the patients and any other pertinent features of the proposal. The biostatistical reviewer also is asked to comment on the character and definition of response variables, measurement, data collection, frequency of observations, sample size, plans for data processing and analysis and any other relevant features.

The CSSMRB Review Process

The Principal Proponent and the Study Biostatistician appear before the Committee. If the proposal includes an economic analysis component, the consultant appears as well.

At the meeting, the Principal Proponent will be asked to make an opening statement not to exceed ten minutes, followed by a five-minute statement from the Study Biostatistician. If there are Co-Proponents present, only one will make a formal statement. If there is an economic component, the individual responsible for preparing that protocol will also be expected to make a five-minute statement. At the request of the Principal Proponent and with the concurrence of the CRADO, additional consultants may be available to answer questions and may make a five-minute statement. These statements should be based on written documents that are distributed to CSSMRB members prior to the meeting. They should provide a concise summary of the research problem and state why it should be supported by VA.

The Principal Proponent and the Study Biostatistician should take relevant notes at the meeting since in-depth reports of the CSSMRB proceedings are usually not provided.

After the formal statements, the *ad hoc* reviewer, the CSSMRB primary reviewers and the remaining CSSMRB members question the proponents on problems and issues they have identified. The proponents defend the protocol in an interactive discussion.

After the open session, the proponents are excused for the CSSMRB Executive Session. The *ad hoc* reviewer remains and participates as a voting member in this closed session, during which the Committee formulates recommendations.

CSSMRB Recommendations

Generally one of four actions is taken:

- Unconditional approval. The study is approved without changes and is recommended for funding.
- Conditional approval. The Committee approves the study with the understanding that the Principal Proponent and the Study Biostatistician will make certain changes or additions to the protocol. When the changes are made and are approved by the CRADO, the Chairperson of CSSMRB, and the CSSMRB primary reviewers, the study will be recommended for funding.
- Reject or defer consideration of the study with recommendation for resubmittal. In unusual circumstances the Committee finds the study worthwhile, but in need of major revisions. In this case, should the investigator choose to submit a revised protocol, the CRADO may waive the requirement for an initial planning request and review.
- Reject the study. The Principal Proponent will have an opportunity to review the CSSMRB report. If the Principal Proponent wants to resubmit the proposal to the CSP, a new request for planning must be sent to the CRADO.

The Principal Proponent(s), the CSPCC Director, and the Study Biostatistician are informed of the CSSMRB recommendation immediately after the close of the Executive Session.

For new studies that are approved, CSSMRB assigns a numeric rating of the scientific merit of the proposal. This rating is from 10 to 50 with 10 as the best rating. Approval of a proposal by CSSMRB does not ensure funding. Action by this Committee constitutes a recommendation to the CRADO. Written notification by the CRADO constitutes the official action on the proposed study. Studies approved but not funded are reviewed on a continuing basis and will be dropped from the awaiting funding list if the CRADO determines that funding will not become available within 18 months after CSSMRB approval. If the Principal Proponent then chooses to resubmit a proposal, a new request for planning must be sent to the CRADO.

Abbreviations

CSSMRB	Cooperative Studies Scientific Merit Review Board
CSP	Cooperative Studies Program
CSPCC	Cooperative Studies Program Coordinating Center
CRADO	Chief Research and Development Officer – Dr. Stephan D. Fihn
CRP	Clinical Research Pharmacist
FDA	Food and Drug Administration
VA	Veterans Affairs

CSSMRB CLINICAL REVIEW GUIDELINES

VA Cooperative Study # _____

Title _____

Reviewer _____

General Critique

- A. Brief Synopsis

- B. Overall Review

- C. Major Concerns

- D. Minor Concerns

- E. Facilities, Equipment, and Resources/Budget

- F. Summary Recommendation/Enthusiasm

CSSMRB STATISTICAL / METHODS REVIEW GUIDELINES

VA Cooperative Study # _____

Title _____

Reviewer _____

Statistical Critique

- A. Brief Synopsis

- B. Study Design and Methods Evaluation

- C. Major Concerns

- D. Minor Operational/Methodological Concerns

- E. Facilities, Equipment, and Resources/Budget

- F. Summary Recommendation/Enthusiasm

EXHIBIT 11

**DEPARTMENT OF VETERANS AFFAIRS REVIEW CERTIFICATION FORM
REGARDING CONFLICT OF INTEREST, CONFIDENTIALITY, AND NON-DISCLOSURE OR INFORMATION FOR
REVIEWERS OF COOPERATIVE STUDIES PROGRAM PROPOSALS**

Merit Review Board: Cooperative Studies Scientific Merit Review Board

Date(s) of Review: [DATE]

A. Confidentiality and Non-disclosure: I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials to the evaluation; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting outside of that meeting or with any other individual except as authorized by the Portfolio Manager (PM) or other VA designated official; (3) not to disclose procurement information prior the award of a contract; and (4) to refer all inquiries concerning the review to the PM or other designated VA official.

B. Conflict of Interest for Non-Federal Reviewers: This is to certify that in the review identified above, I did not participate in an evaluation of any application or proposal: (1) from any applicant institution or offeror where I am a full-or part-time salaried employee or where I am negotiating for such employment; (2) from any applicant institution or offeror where I have received or could receive a direct financial benefit in relation to the application or proposal under review or have received or could receive a financial benefit from the applicant institution or offeror or principal investigator valued at \$10,000 or more per year that is unrelated to the application or proposal under review; (3) submitted by a close personal relative, a member of my household, or professional associate, or if such person receives financial benefits from or provides financial benefits to an applicant or offeror. (4) If there was an appearance or real conflict of interest, or any application submitted by my former (within the past year) employer I recused myself from the review of the application/proposal or was granted an appropriate waiver.

C. Conflict of Interest For Federal Reviewers: This is to certify that in the review identified above, I did not participate in an evaluation from (1) any applicant institution where I have an outside activity; (2) any applicant institution where I serve as an officer, director, trustee or partner; (3) any applicant institution where I am seeking employment; (4) any applicant institution in which I, my spouse, and my minor child hold, in aggregate, more that \$15,000 worth of stock; (5) any applicant institution where my spouse is employed; (6) any application submitted by a close personal relative, a member of my household, a colleague with whom I have a business or other contractual relationship, the employer of my spouse, parent, or child, or (7) any application submitted by my former (within the past year) non-federal employer. If there was an appearance or actual conflict of interest, I recused myself from the review of the application/proposal or was granted an appropriate waiver.

CERTIFICATION

Under penalty of perjury (US Code Title 18 Chapter 47 section 1001), I fully understand the confidential nature of the review process and agree to confidentiality and non-disclosure (paragraph A) and certify that in the review above I did not participate in an evaluation of any application or proposal with which I knowingly had an interest (paragraph B or C).

Printed Name

Signature

Vendorizing Coversheet Continued

Station #: _____ Station Contact Name: _____

Contact Phone #: _____ Contact Fax #: _____

What type of payment is being made?

Agent Cashier

Benefit (Explain): _____

Bowel and Bladder Care

Child Support

Coast Guard

Construction

Employee Education Payment (Paid to school)

Employee Education Reimbursement (Paid to employee)

Garnishment

Honorarium

Insurance Refund

LGY

Research Study

Settlement

Vocational Rehabilitation & Education

Travel Reimbursement

 VA Employee PCS

 VA Employee TDY

 Veteran Benefit

 Non-VA Employee TDY - Paid through an E-Travel system

 Non-VA Employee TDY - Paid as a Certified Payment

Other (Explain): _____

FSC Information:

Vendorizing Team may be contacted by vendors or stations for information pertaining to the FMS vendor file or 1099s.

Phone Number (512) 460-5049

Fax Number (512) 460-5221

Email vafscvendot@va.gov or VAFSC Vendorizing Team in Global Address Book

Hours of Operation 6:30 AM through 5:00 PM Monday through Friday

Customer Support Help Desk may be contacted by vendors and stations for information pertaining to payments and VIS.

Vendor Phone Number (877) 353-9791

Station Phone Number In 2005, a phone number was created solely for station calls to help identify them as priority over vendor calls. For this number, stations may email Customer Support Help Desk, refer to FSC News Flash FY-05-Issue 23-Customer Support Help Desk Toll-Free Phone Number, or refer to Station SOP on Vendorizing Submissions. Please do not distribute this phone number to vendors to avoid an unnecessary increase in wait time.

Email vafscshd@va.gov or VAFSC CSHD in Global Address Book

Hours of Operation 7:15 through 4:15 PM Monday through Friday

FOS Regions (Payment Resolution) may be contacted by stations for information pertaining to payments.

Region 1 Phone Number (512) 460-5544

Region 2 Phone Number (254) 297-5495

Helpful websites are provided at <http://www.fsc.va.gov/vis.htm>

This site lists links to Vendor Inquiry System (VIS) (including links to registration and training), Electronic Data Interchange (EDI), Treasury Offset Program (TOP), general payment information, Payroll, Payment Advice Internet Delivery (PAID) (a service offered by Treasury), and Facility Locators.

Vendorizing Coversheet Instructions

Page 1 Instructions

Header information - Please print

- Station # = 3 digit station number as used in Purchase Order numbers
- Station Contact Name = Name of station contact submitting the form
- Contact Phone # = Phone number of station contact submitting the form, including extension if applicable
- Contact Fax # = Fax number of station contact submitting the form

Vendor Type

- Vendor types are single letter characters used to identify the vendor in FMS. FMS uses this information to make payments timely and to accrue information for 1099 reporting. Select the type of vendor whose information will be on the SF 3881 that accompanies the Vendorizing Coversheet. Descriptions of each letter code are given immediately to the right of the letter code.
- Arrows (▶) indicate important additional information that is required to process forms for some vendor types. The information indicated by the arrows at the bottom of the first page explain the additional information that is needed and what it is used for. Answers should be indicated to the right of the areas marked with arrows by circling the appropriate choice, if a choice is given.
- If all information required (as explained in section ▶) has been provided to indicate a vendor that should be exempt from Prompt Pay Act (PPA), an "X" will be placed in the Prompt Pay Type field on the vendor file for the vendor information provided on the SF 3881 that accompanies the Vendorizing Coversheet. This will exempt from PPA all certified payments. Matched payments will not be exempt because the receiving report overrides the Prompt Pay Type field on the vendor file. To have matched payments exempt from PPA, follow instructions provided by FOS Regions 1 & 2 and the Customer Support Help Desk.
- If a vendor's contract states that payments must be made within a certain number of days that falls outside of PPA for purposes of meeting discount terms or receiving discounted rates from the vendor, annotate this information on the invoice before submitting. This exemption must be input at the time the payment is made, so it is important that this is known ahead of time. If you have questions on this process, please contact Customer Support Help Desk.
- If a VA employee would like to have his/her travel reimbursement paid to the same account used by Payroll, circle "Yes" at section ▶▶. If "Yes" is circled, no SF 3881 need be submitted.
- Section ▶▶▶ explains the difference between personal and professional services provided by individuals. This is used by Vendorizing to set up individuals in such a way that Payment personnel are easily able to tell which payments should be PPA exempt. This type of exemption must be applied to each payment as it is entered, so it is important to correctly identify personal and professional services to ensure that payments are made in accordance with PPA.
- Vendors from countries outside the U.S. may have a vendor code established in FMS if they have a federal tax id number (TIN). This is an absolute must, as VA is required to report valid tax id numbers and names to IRS for each vendor who receives a payment. Vendors who do not have a TIN on file with IRS may not be established in FMS and must be paid as a miscellaneous foreign vendor by the method described in ▶▶▶▶.

Station Comments to Vendorizing

In this section, the station should provide any special instructions regarding the type of action to be taken by Vendorizing. This should include Customer Account Number for LGY vendors and any other information the station believes important.

Page 2 Instructions

Header information is required again in case pages are separated when faxed.

Type of payment

- Type of payment is required to ensure proper set up of vendor file. This information will help us determine whether the correct vendor type was circled on page 1. If vendor type is inconsistent with type of payment, we will ignore the vendor type circled on page 1 and use the correct vendor type for the type of payment specified on page 2.
- If you are unsure of the payment type or if the correct type of payment is not available, circle Other and describe the payment on the blank provided. It may or may not be necessary for someone to contact the submitter for more information.
- FSC Information is provided at the bottom of page 2. This includes contact information and helpful websites.

For more detailed instructions, please refer to the Station SOP on Vendorizing Submissions

**ACH VENDOR/MISCELLANEOUS PAYMENT
ENROLLMENT FORM**

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

AGENCY INFORMATION

FEDERAL PROGRAM AGENCY U.S. Department of Veterans Affairs – Financial Services Center		
AGENCY IDENTIFIER: 111036183	AGENCY LOCATION CODE (ALC): 36001200	ACH FORMAT: <input type="checkbox"/> CCD+ <input type="checkbox"/> CTX
ADDRESS: P.O. Box 149971 Austin, TX 78714-8971		
CONTRACT PERSON NAME: Customer Support Help Desk – Vendorizing Team		TELEPHONE NUMBER 1-877-353-9791
ADDITIONAL INFORMATION Fax completed form to (512) 460-5221		

PAYEE/COMPANY INFORMATION

NAME	SSN NO. OR TAXPAYER ID NO.
ADDRESS	
CONTACT PERSON NAME:	TELEPHONE NUMBER: ()

FINANCIAL INSTITUTION INFORMATION

NAME:	
ADDRESS:	
ACH COORDINATOR NAME:	TELEPHONE NUMBER: ()
NINE-DIGIT ROUTING TRANSIT NUMBER:	
DEPOSITOR ACCOUNT TITLE:	
DEPOSITOR ACCOUNT NUMBER:	LOCKBOX NUMBER:
TYPE OF ACCOUNT: <input type="checkbox"/> CHECKING <input type="checkbox"/> SAVINGS <input type="checkbox"/> LOCKBOX	
SIGNATURE AND TITLE OF AUTHORIZED OFFICIAL: (Could be the same as ACH Coordinator)	TELEPHONE NUMBER: ()

Standard Form (SF) 3881 Instructions

Note: All information on the SF 3881 is required. Vendorizing Coversheet must be attached at the time of submission. Any submission missing information will be returned to the sender for completion. Forms are processed in the order of receipt.

Agency Information

1. Vendor must select the preferred ACH format for direct deposit. Check the corresponding box for either CCD+ or CTX format. If no choice is made, this defaults to CCD+.

Payee/Company Information

1. Name
 - A. This must be the legal name for the vendor as on file with IRS.
 - B. If invoice billing or remit to name is different from the legal name, also provide this name as a doing business as (DBA) name.
2. SSN No. or Taxpayer Id No.
 - A. This must be the legal social security number (SSN), federal employer id number (EIN), or federal taxpayer id number (TIN).
3. Address
 - A. This is the correspondence mailing address to include city, state, and zip code. Please do not abbreviate city names.
4. Contact Person Name
 - A. This is the name of the vendor's contact person.
5. Telephone Number
 - A. This is the phone number of the vendor's contact person. Please be sure to include area code. This person may be contacted by VAFSC Vendorizing Team to answer questions related to the vendor's file with VA.

Financial Institution Information – VAFSC does not have wire capability. ACH Direct Deposit is used to make payments.

1. Name
 - A. This is the name of the bank being used for direct deposit.
2. Address
 - A. Address of bank, to include city, state, and zip code. Please do not abbreviate city names.
3. ACH Coordinator Name
 - A. Banks have ACH Coordinators who can answer questions for vendors regarding the process. VAFSC does not use this name. It is for your information only.
4. Telephone Number
 - A. This is the phone number of the bank or ACH Coordinator. This can be useful information if payments reject.
5. Nine-Digit Routing Transit Number
 - A. This number identifies the bank when direct deposits are made.
 - B. This number should begin with 0, 1, 2, or 3.
 - C. Take this number from a *check*, not a deposit slip.
 - (1) Deposit slip routing numbers are internal numbers for bank use only.
 - (2) If you cannot locate your routing number, contact your bank and ask for the routing number for direct deposit.
6. Depositor Account Title
 - A. This is the name on the account.
7. Depositor Account Number
 - A. This is the account number.
8. Lockbox Number
 - A. Lockbox numbers are treated as checking accounts. Please include the lockbox number if there is one.
9. Type of Account
 - A. Please select the type of account used (checking, savings, lockbox). Again, lockboxes are treated as checking accounts.
10. Signature and Title of Authorized Official
 - A. Signature is required on all SF 3881 submissions. The signature must be the owner of the account in cases of individuals or a company official (with title) in cases of companies.
11. Telephone Number
 - A. This is the phone number of the individual or company official who signed the form.

Submit forms by fax to (512) 460-5221 or by mail to PO Box 149971 Austin, TX 78714-8971.

FORMAT FOR MID-TERM/EXTENSION CSSMRB REVIEW BUDGET

CSP #_ BUDGET SUMMARY

	Personnel	All Other Costs	Total
Original Budget Prepared for (date) CSSMRB Review			

Actual and Projected Budget

FY	825 Personnel	870 Personnel	Subtotal	OOB	CSPCC Costs	CSPCRPCC Costs	Contracts/ Special Labs	Total

NOTE: Use footnotes in appropriate fiscal years to explain increases/decreases from originally approved budget.

	Personnel	All Other Costs	Total
Original Budget Prepared for (date) CSSMRB Review			
Actual and Projected			
Difference			

FORMAT FOR CSSMRB SUBMISSIONS

First Submission

Volume I

Table of Contents
 Letters of Submittal/Understanding
 Executive Summary/Abstract
 Protocol
 Cost Analysis/Effectiveness Protocol (when appropriate)
 Human Rights: (includes Procedures and Ethical
 Issues [when appropriate], Consent Documents,
 Committee Minutes)
 Good Clinical Practices Information
 Budget (includes cost effectiveness budget when
 appropriate)
 C.V.'s (4 page limit) - Required for Principal Proponent & Study
 Biostatistician. If protocol contains economic analysis component,
 include C.V. of person responsible for that component. Also, if a
 consultant or other member of the Planning Committee will appear
 before CSSMRB, include their C.V.

Volume II*

Table of Contents (duplicate)
 BRDP
 Research Data Forms
 Drug Handling Protocol
 Drug Information
 Participation

*Other supplemental material may be included in Volume II.

The first page of Volume II, after the copy of the Table of Contents, should be numbered sequentially following the last page of Volume I.

Tab each section listed above.

Note: All personal identifiers, such as SS# should appear only on the original of each proposal for research funding submitted to VACO. This information should be redacted (i.e., either removed or stricken) on all copies of the proposal.

EXHIBIT 14A

CSSMRB Protocol Distribution Chart

	<u>First Submission</u>		<u>Midterm Review</u>
	<u>Vol. I</u>	<u>Vol. II</u>	
CSSMRB Members (approx. 12 members)	1 ea	1 ea	1 ea
CSP/VACO	8	8	8
Principal Proponent/Chairman	1	1	1*
Planning Committee Members (approx. 8-10 members)	1 ea	1 ea	-
Albuquerque	1	1	1
Clinical Research Pharmacist	1	1	1
AE/Regulatory Specialist	1	1	1
Pharmaceutical Project Manager	1	1	1
SMART (if applicable)	1	1	1
CSPCC Staff:			
Director	1	1	1
Study Biostatistician	1	1	1
Administrative Officer	1	1	1
Project Manager	1	1	1
Computer Assistant	1	1	1
Statistical Programmer	1	1	1
Database Programmer	1	1	1
Total Copies Required (approximate)	40	40	40

*Please review with the Biostatistician exactly which portions of the three-year review/midterm should be sent to the Chairman.

STUDY STARTUP / INITIATION

I. Introduction

Once VACO determines that a study will be funded or initiated, ORD Communications will issue a press release. Study Initiation/Startup begins for the CSPCC when CSSMRB approval and funding approval are received from VA Central Office and ends after the first DMC meeting. During this phase of the study you will have much communication with the study chair and other study group members to do such tasks as revising the protocol, identifying members for the Executive Committee and Data Monitoring Committee (DMC), identifying and selecting sites, initiating the contract process for study medications and/or devices, arranging a pre-kickoff meeting, sending and obtaining necessary documentation from participating sites, creating and distributing the study operations manual, obtaining approval for data collection forms, organizing meetings for study kickoff, the Executive Committee, and DMC and finally ensuring that documentation is received prior to starting a site. Some tasks for this process may occur simultaneously and others are dependent on completion of previous tasks.

II. Preparation and Organization

A. Notification from VACO

1. Study initiation begins once CSSMRB approves the study and approval of funding from CO is received.
2. **Tasks:**
 - a. **Record date of CSSMRB Notification.**
 - b. **Record date of official letter of approval of funding from VACO.**
 - c. **File approval letters.**

Reference: Checklist 11 – Study Startup/Initiation Checklist Items 1-3

B. Contact Study Chair

1. The Project Manager notifies Study Chair that funding was approved.
2. **Tasks:**
 - a. **The Project Manager sends Memo 17 to the Study Chair.**
 - This memo informs the Study Chair that the study has been approved for funding. The memo also requests that the Study Chair address CSMRB issues/comments and update protocol, make the final selection of participating medical centers, nominate an Executive Committee, and nominate a Data Monitoring Committee.
 - b. **The Project Manager, on behalf of the Study Chair, sends Memo 18 thru the CSPCC Director to the Director, CSR&D.**
 - This memo identifies the final selection of participating medical centers.
 - c. **The Project Manager, on behalf of the Study Chair, sends Memo 19 thru the CSPCC Director to the Director, CSR&D.**
 - This memo identifies the nominees for Executive Committee.

- d. **The Project Manager, on behalf of the Study Chair, sends Memo 20 thru the CSPCC Director to the Director, CSR&D.**
 - This memo identifies the nominees for Data Monitoring Committee.
- e. **The CSPCC Director sends Memo 21 to the Study Chair.**
 - This memo asks for permission to use the study protocol as a specimen for other proponents to use in planning proposals.
- f. **The Study Chair and Biostatistician updates protocol based on CSSMRB recommendations.**
- g. **Identify sites/SI to be surveyed or reconfirm interest in participation if surveyed as part of CSSMRB submission.**
- h. **Identify members of the Endpoint Committee or any other committees as dictated by the protocol.**

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section A, "CSP Study Management and Monitoring", Part 2, "Executive Committee" and Part 3, "Data Monitoring Committee" for description of committees
- Checklist 11 – Study Startup/Initiation Checklist Items 4 – 11.

C. Site Survey

1. Potential sites are surveyed and evaluated to determine whether they are suitable for participating in the study. The survey should reflect criteria listed in the protocol and include questions regarding facilities and 5/8ths status of the prospective Site Investigator (SI). **Exhibit 15** is provided as a tool to collect information on study personnel.
2. **Tasks:**
 - a. **Check FDA Sanctions to ensure sites are eligible to participate in the research.**
 - b. **Check DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listings.**
 - c. **If the prospective SI is less than 5/8ths then you must seek the appropriate waiver from the Clinical Science R&D Office. The request should originate from the ACOS for R&D along with a recommendation from the Study Chair. When this is received, the CSPCC Director sends Memo 22 to the Director, CSR&D for approval.**

References:

- http://www.fda.gov/ora/compliance_ref/debar/default.htm
- http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm
- http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
- <http://silk.nih.gov/public/cbz1bje.@www.orilist.html>
- Exhibit 15 – Requirements for Study Personnel
- Checklist 11 – Study Startup/Initiation Checklist 12 – 13.

D. Contact Other Groups

1. Once the Study Chair has been notified of funding approval, other key groups also need to be contacted in order to get them started on their respective responsibilities. These groups include: the CSP Clinical Research Pharmacy Coordinating Center (CSPCRPCC); the GCP Standards and Resource Group, GCP Monitoring Group, and GCP Review Group; the Health Economics Resource Center (HERC); and other agencies who may be collaborating on the study.

2. Tasks

- a. **The Project Manager contacts the Study Clinical Research Pharmacist to develop a timeline for the study drug donation or study device distribution. If the study does not have drugs or devices, the Project Manager will notify the Adverse Event Specialist. The Study Clinical Research Pharmacist or Adverse Event Specialist will then notify SMART.**
 - This timeline will determine when to fund the Study Chair's office and participating sites.
- b. **The Project Manager will forward the Director of SMART the revised protocol, list of study sites and operations manual when available.**
- c. **Securing Drug/Device Supplies – Kickoff**
 - After study approval and funding, but prior to Kickoff, it is necessary that a formal agreement delineating rights and privileges between the CSP and the involved company be drafted and signed by both parties. The form of this agreement will be determined by the requirements of the company to have Intellectual Property (IP) addressed in the agreement. If IP must be addressed, then the agreement between CSP and the company must be in the form of a Cooperative Research and Development Agreement (CRADA). If IP is not an issue, then a Clinical Trial Agreement (CTA) can be used. CO guidance should be sought if it is uncertain how to proceed.
 - The individual(s) responsible for generating the formal agreement will depend on the nature of the donations (drug/device with or without financial donations). The CSPCRPCC Clinical Research Pharmacist, along with VACO, will be responsible for generating the agreement when donations involving only drug/device supplies and funding to support the CSPCRPCC. When donations involve drug/device supplies and financial support for the study beyond support of the CSPCRPCC efforts, or when the company requests access to study data during or after the study (IP), then the responsibility for generating the agreement will fall to a designated individual from the CSPCC, the CSPCRPCC Clinical Research Pharmacist, and VACO.
 - Regardless of the type of agreement (CRADA or CTA), financial support provided by industry should be handled through the local non-profit corporation of the CSPCRPCC or CSPCC.
- d. **Study monitoring needs assessed with SMART**
 - The Project Manager, Study Chair and Study Biostatistician work with the Chief SMART to implement the monitoring needs of the study as determined during the planning phase.
- e. **The Project Manager notifies the Health Economist that the study is funded.**
 - The Health Economist is advised to review his/her section of the protocol to ensure no further changes need to be made.
- f. **Program Manager or AO/ADO contacts CSP Deputy Director to discuss plans for developing Interagency Agreements or CRADAs for industry agreements (review Planning Section – III. B. Securing Drug/Device Supplies – Planning).**

References:

- CSP Global SOP 1.3.0 Good Clinical Practice (GCP) Education and Training
- Checklist 11 – Study Startup/Initiation Checklist Items 14 – 19.

E. Pre-Kickoff Meeting

1. This meeting serves to clarify any outstanding CSSMRB issues and begin preparations for the study start up and Kickoff meeting. The meeting is organized by the Project Manager and is held at the CSPCC.

2. Attendees include:
 - Study Chair
 - Study Biostatistician
 - Project Manager
 - National Study Coordinator
 - Study Clinical Research Pharmacist (if applicable, drug or device)
 - Pharmaceutical Project Manager
 - Adverse Event Specialist (if applicable, no drug or device)
 - Study Health Economist (if applicable)
 - Representatives from Data Management group

3. A sample agenda would include:
 - Review of CSSMRB comments, questions, and requests
 - Review of Informed Consent
 - Data Security and IT Issues
 - Site Performance Measures
 - Patient Accrual
 - Site selection issues
 - Executive and DMC Committee nominations
 - Adverse Event (AE)/Serious Adverse Event (SAE) reporting
 - a. Case Report Form (CRF) development
 - b. Patient walk-through
 - c. Kickoff meeting location, date, and agenda
 - d. Operations and training manuals
 - e. Finalize study budget and change “Year” column headings to actual Fiscal Year (FY) format.
 - f. PCC issues
 - g. HERC issues
 - Drug/Device Handling

4. Human Rights Committee (HRC) Review - If the CSPCC uses the “just in time” HRC review then an HRC meeting needs to be arranged. A “just in time” review occurs after the study is approved by CSSMRB and funded by CO rather than reviewing the study before CSSMRB. The Project Manager works with the CSPCC Assistant Director or designee to arrange the meeting.

5. **Tasks:**
 - a. **Organize Pre-Kickoff meeting visit.**
 - b. **Organize HRC review (in conjunction with Pre-Kickoff meeting).**
 - c. **Project Manager finalizes nominations for necessary committees.**
 - The Project Manager prepares the Executive Committee, DMC, and participating site nomination and approval memos for the Study Chair and Director, CSPCC, to sign. CVs and a signed Statement of Disclosure from each person nominated to serve in the Executive Committee and the DMC needs to be included with the nomination memo.
 - d. **Once the approved memos are received from CO, the Project Manager prepares Memo 23 for each DMC member and Memo 24 for each member of the Executive Committee.**

References:

- CSP Staff Operations Manual, Planning Section, VI, “Human Rights Committee Review”
- CSP Guidelines, Chapter III “CSP Review Procedures,” Section A, “The CSPCC Human Rights Committee”
- CSP Global SOP 2.1.0, “Developing, Approving, and Amending Protocols”
- Checklist 11 - Study Startup/Initiation Checklist Items 20 – 24.

F. Update Protocol and Finalize Budget

1. During the Pre-Kickoff meeting the protocol should be updated based on CSSMRB and HRC recommendations.
2. **Tasks:**
 - a. **CSPCC Director sends the updated protocol and a memo describing the changes made based on recommendations from CSSMRB and HRC to CO for approval by the Director, CSR&D.**
 - b. **The Project Manager works with the CSPCC Assistant Director of Operations (ADO) and other study members to revise the study budget if necessary. Revisions may be based on recommendations by CSSMRB and CO or changes in costs of supplies or other items.**
 - c. **The finalized (recast) budget and Memo 25 describing the changes are prepared and approved by the CSPCC ADO and forwarded to CO for approval by the Director, CSR&D..**

References:

- CSP Global SOP 2.1.0, "Developing, Approving, and Amending Protocols"
- Checklist 11 - Study Startup/Initiation Checklist Items 25 – 27.

III. Study Documents

A. Materials Sent to the Sites and SMART

1. After the approvals of participating sites, updated protocol, and final budget are received from CO, the Project Manager will prepare and send the following information to the participating sites. Please pay particular attention to the "cc" on the memos as multiple personnel at each site receive the information.
2. **Tasks:**
 - a. **The CSPCC Director sends Memo 26 to the ACOS for R&D at each participating site.**
 - This memo informs the ACOS that the Site Investigator is interested in participating and describes the necessary documentation. Three copies of the protocol are sent with this memo (or centers may choose to send a pdf version and one hard copy). If the study is capitated, prepare **Memo 26A** instead of **Memo 26**. Please note that the protocol sent to sites should include only the site budget, not the overall budget.
 - b. **The ACOS-R&D sign and return the prepared Memo 27 to the Project Manager.**
 - This memo is a request for site funding. Once information is received, Project Manager will review and forward to VACO for approval. If the study is capitated, the Project Manager will prepare a memo requesting the initial front-load for the site after IRB and R&D approval is received (**Memo 27A**).
 - c. **The CSPCC Director sends Memo 28 to the Site Investigator.**
 - This memo describes what documentation is needed in order for the study to be approved to start. It also describes the Investigator Study File (**Exhibit 16**) and SMART documents Attached to memo is a Statement of Disclosure (**Exhibit 17**) and a Site Investigator Agreement (**Exhibit 18**) that need to be signed and returned to the Project Manager. A copy of the *Cooperative Studies Program Guidelines for Planning and Conduct of Cooperative Studies in the Office of Research and Development Department of Veterans Affairs* and a copy of the protocol are also enclosed. If the study is capitated, prepare

Memo 28A instead of **Memo 28**. This memo contains further explanation about capitation rates.

- d. **The Investigator's brochure and Drug Information Report (DIR) should also be included with the protocol.**
- e. **Suggested recruitment material and/or drafts of patient letters should be included for submission to the IRB.**
- f. **Electronic copies of the informed consent forms, inclusive of HIPAA requirements, should be sent to the site for ease of modifying.**
- g. **If a central lab is being used then you should also send the lab certificates with the Site Investigator materials, as these will need to be submitted with the IRB application with copies to be filed in the Investigator's Essential Document Binder.**
- h. **A copy of the updated protocol and list of study sites should be sent to the Director of SMART.**

References:

- Exhibit 16 - Investigator Study File
- Exhibit 17 – Statement of Disclosure
- Exhibit 18 – Site Investigator Agreement
- Checklist 11 - Study Startup/Initiation Checklist Items 28 – 34.

B. Materials Needed from Sites

1. Before sites can begin their participation in the study, critical documents are needed. It is the Project Manager/Pharmaceutical Project Manager's responsibility to ensure that the following items are received from the sites and filed in the central study file.
CSPCC Responsibilities
 - Site Investigator Agreements (if applicable)
 - Statement of Disclosure
 - Good Clinical Practice (GCP) and Human Subjects Protection (HSP) Training certificates
 - Lab certifications (if applicable)
 - Normal lab ranges
 - Site Investigator CVs
 - IRB and R&D approval (Note: Approvals must be sent to CRSPCRPCC within a day)
 - Approved informed consent formsCSPCRPCC Responsibilities
 - FDA Form 1572 from CSPCRPCC (if applicable)
2. Participating sites may not be funded until this documentation is received. See **Checklist 12** for a comprehensive list of items required before kickoff.
3. **Tasks:**
 - a. **Create a database or spreadsheet to track IRB and R&D approvals and other necessary information.**
 - b. **The Project Manager will review each approved consent form for FDA, VA and CSP requirements. He/she will also review content for accuracy and will work with the site on any modifications that need to be made prior to starting. See **Exhibit 19 - Informed Consent Review** for monitoring of informed consents as they are received at the CSPCC.**

References:

- Exhibit 19 - Informed Consent Review
- Checklist 11 - Study Startup/Initiation Checklist Items 35 – 36.
- Checklist 12 - Material Required Prior to Study Kickoff Checklist

C. CSP Websites

1. The CSP websites serve as key primary sources of information for all CSP studies. It is critical that Project Managers ensure the accuracy of this information.
2. **Tasks:**
 - a. **Project Manager will update the study profile on the CSP website on a quarterly basis at a minimum (See Exhibit 33 in Coordinating Center Responsibilities section for details). Updates can be done two ways:**
 - Option 1: If your CSPCC has a database interface with the Albuquerque website, you may request your IT system administrator to perform a data transfer or “data dump” from the CSPCC to the website.
 - Option 2: Go to the CSP website at <https://vaww.csp.research.med.va.gov> and follow the study profiles link. You will need a password to modify study information. To obtain a password, email the CSP webmaster at webmaster@csp.research.med.va.gov
 - ORD policy requires that all clinical trials are registered on the National Library of Medicine’s clinicaltrials.gov. Updating information on the CSP website will ensure that registration processes are completed. Please refer to **Exhibit 20**, “Selection of CSP Study Keywords”, and **Exhibit 20A**, “Keyword Listing” for information on key word selection.

Reference:

- Exhibit 20 - Selection of CSP Study Keywords
- Exhibit 20A – Keyword Listing
- Exhibit 33 – CSP Center Reports Summary (can be found in Coordinating Center Responsibilities section)
- Checklist 11 - Study Startup/Initiation Checklist Item 37.

D. Study Operations and Training Manuals

1. The study operations manual is used by study staff at each participating medical center to ensure that study procedures are followed uniformly. It is helpful to use the operations manual from another study at your CSPCC as a template as it contains the “boilerplate” information.
2. The following study team members are all primarily responsible for creation of this manual:
 - The Study Chair
 - Study Biostatistician
 - Study CRP or AE Specialist
 - Project Manager
 - Pharmaceutical Project Manager
 - Data Manager
 - National Study Coordinator
 - SMART
 - Other study team members as required
3. The manual contains information on:
 - Responsibilities of study staff
 - Budget
 - Data collection and flow

- AE/SAE reporting
 - Study procedures
 - Pharmacy procedures
 - Instructions for investigational or study supplies
 - Research ethics and GCP
 - Materials or space requirements
4. Other training materials, such as videotapes or demonstrations may need to be prepared for the Kickoff meeting. It will be up to the study group to decide what is necessary.
 5. SMART will work with CSPCC and the Chairperson's Office to develop source documentation procedures and patient study file organizers for each trial.
 6. Each version of the Operations Manual needs to be approved by the Study Chair, Study Biostatistician, CSPCC Director and Pharmacist (if applicable).

Reference: CSP Global SOP 2.3.0 – Preparing and Approving Operations Manuals for sample Table of Contents and other information related to the operations manual

E. Distribution of Study Operations Manual

1. When the Study Operations Manual is complete and approved, it is distributed to all key personnel involved in the study.
2. **Task:**
 - a. **The Project Manager sends out the Study Operations Manual and other Kickoff meeting materials to:**
 - Each member of the study team (Project Manager, Study Biostatistician, Study Data Manager, Study Programmer, Study Chair, National Study Coordinator, Clinical Research Pharmacist, Pharmaceutical Project Manager and Health Economist)
 - Director of SMART
 - Site Investigator
 - Study Coordinator at each site

Reference: Checklist 11 - Study Startup/Initiation Checklist Item 38.

F. Forms Approval and Printing

1. On occasion, Case Report Forms need to be approved by VHA Forms, Publications, and Records Management Office (191E). Research data forms require Office of Management and Budget (OMB) approval if the subject matter is politically sensitive (e.g. Persian Gulf War, Agent Orange, Vietnam War, or Operation Iraqi/Enduring Freedom).
2. **Tasks (applicable for politically sensitive topics only):**
 - a. **The Project Manager and study biostatistician prepare a 100 word abstract of the protocol which describes the purpose of the study and the study participants.**
 - This abstract is sent to the CSP Deputy Director for a determination of the need for full OMB approval.
 - b. **The CSP Deputy Director will communicate with the VHA Forms, Publications, and Records Management Office to determine whether a full approval process is required.**
 - VHA (191E) will provide an exemption and form numbers, if needed.
 - c. **Study Biostatistician, Project Manager, and Data Manager initiate OMB Form 83-I (Paperwork Reduction Act Submission) (See Exhibit 21). This form must be accompanied by a Supporting Statement.**

- Only one OMB 83-I and one Supporting Statement are needed for cooperative studies where forms are related to one research project.

References:

- Checklist 11 - Study Startup/Initiation Checklist Item 40 - 41
- Exhibit 21 - Paperwork Reduction Act Submission

NOTE: VHA approval and form numbers are required before data forms can be printed and used. The operating rule is that forms included in the VHA Forms, Publications and Records Management Office (191E) should, to the best of your ability, be in final form. **The approval process takes considerable time and should be completed as soon as possible.**

IV. Funding Decisions

A. Coordination of Funding Activities

1. To ensure funding activities are properly coordinated and meet needed timeframes to initiate study activities in a timely manner, the Project Manager needs to obtain certain information from various groups and coordinate with several groups.
 - a. Sites will be funded after IRB and R&D approval is granted and approved informed consent forms are received by CSPCC.
 - b. Study must be registered with the National Library of Medicine before funding can be provided. Updating information on the CSP website will ensure that registration processes are complete.
2. **Tasks**
 - a. **The Project Manager works with CSPCC Assistant Director - Operations and the CSP Deputy Director to determine a rough timeline for funding requirements.**
 - The timeline developed with the Study CRP will be used for the funding timeline.
 - b. **The CSPCC Director sends Memo 29 to the Study Chair.**
 - This memo contains information about the Funding Chairperson's Office and the start of funding dates. It also gives a tentative personnel start date and the first patient intake date.
 - c. **The ACOS for R&D Office sends Memo 30 to the CSPCC Director.**
 - This memo identifies the amount of funds requested for support of the Chairperson's Office.
 - d. **CSPCRPCC will request funding for the pharmacy from VACO (thru assigned CSPCC) after approval and availability of drug/device is provided. CSPCRPCC will also request funding from VACO for SMART and/or AE/SAE support (when applicable) thru assigned CSPCC.**
 - e. **Site funding request (Exhibit 22) sent to VACO via e-mail.**

References:

- Exhibit 22 – Funding Request Form
- Checklist 11 - Study Startup/Initiation Checklist Items 42 – 45.

V. Investigational Device Exemption (IDE) and Investigational New Drug (IND)

A. IDE / IND Sponsor

1. IDE or IND sponsorship is a key part of many clinical trials and has important regulatory implications. Usually, the CSP is designated as the sponsor of the IDE/IND and the Study CRP/AE Specialist will be the CSP representative to the FDA.
2. **Tasks:**
 - a. **The Study Clinical Research Pharmacist/AE Specialist contacts appropriate groups (i.e., FDA) to determine whether an IDE or IND is needed and to obtain needed guidance for FDA submissions and approvals.**
 - b. **The Pharmaceutical Project Manager/AE Program Manager will work with Study CRP/AE Specialist to assist in the distribution of information to the participating sites and collection of documentation from sites.**
 - c. **The Pharmaceutical Project Manager/AE Program Manager will forward copies of regulatory documents to the CSPCC Project Manager.**

References

- CSP Guidelines, Chapter IV "Initiating a CSP Cooperative Study," Section H, "Investigational New Drug (IND) Application and Investigational Device Exemption (IDE)"
- Checklist 11 – Study Startup/Initiation Checklist Items 46 – 48.

VI. Kickoff Meeting

A. Purpose

1. The Kickoff Meeting is a three to four day meeting of the study group. The purpose of the meeting is to review the study protocol, procedures and data forms to ensure that study personnel understand all critical information involved with the study. The meeting also includes a one-day GCP training by the GCPRG and a meeting of the Executive Committee.

B. Organization

1. It is the responsibility of the Project Manager to document daily attendance via sign-in sheet at the Kickoff Meeting. The following study personnel need to attend the meeting:
 - a. Study Chair
 - b. Study Biostatistician
 - c. CSPCC Director
 - d. Project Manager
 - e. Study Data Manager
 - f. Study Programmer
 - g. National Study Coordinator
 - h. Site Investigator(s)
 - i. Site Coordinator(s)
 - j. SMART Personnel
 - k. Study Clinical Research Pharmacist or AE/SAE Specialist
 - l. Pharmaceutical Project Manager or AE Program Manager
 - m. Executive Committee Members
 - n. Other attendees as required by the study and as determined by the Study Chair, Study Biostatistician and Project Manager
 - o. VA Central Office should be invited, but their attendance is not essential.

2. **Tasks:**
 - a. **Study Team nominates locales and dates for Kickoff Organizational Meeting.**
 - b. **Project Manager and Travel Manager estimate travel costs for three locations and logistics for Kickoff Meeting.**
 - c. **ADO/AO makes recommendation to CSP Deputy Director who then approves final location.**
 - d. **The Project Manager sends out Memo 31 to all meeting participants.**
 - This memo informs the meeting participants about the date, time, and location of the meeting.
 - The Project Manager will work with the CSPCC Travel Coordinator to arrange this meeting. Once travel authorization received from VA HQ, the Travel Coordinator will send a copy to the Administrative Officer at respective VA sites.
 - Project Manager will provide an attendee sign-in sheet for each day of the meeting.

References:
 - CSP Global SOP 2.2.0 Study/Training Meetings, Attachment 3 (pages 11–12)
 - Checklist 11 - Study Startup/Initiation Checklist Items 49 - 52

3. The Kickoff Meeting agenda is developed by the study team. Agenda items may include:

<u>Item</u>	<u>Presenter</u>
• Welcome	• Study Chair or Center Director
• History of CSP	• Center Director or Designee
• History of the Study	• Study Chair
• Study Design and Patient Walkthrough	• Study Chair or Designee
• Administrative and Regulatory Issues	• Project Manager, Pharmaceutical Project Manager or AE Program Manager
• SAE Reporting/Monitoring	• Clinical Research Pharmacist or AE Specialist
• Biostatistical Issues	• Study Biostatistician
• Data Collection	• Study Data Manager
• Pharmacy Issues	• Clinical Research Pharmacist
• Health Economics	• Health Economist
• Data Form Training	• Study Data Manager, Biostatistician, and National Study Coordinator
• GCP Summary for Investigators	• SMART Personnel

Reference: CSP Global SOP 2.2.0 Study/Training Meetings, Attachment 2 (pages 9-10)

C. Good Clinical Practice Group

1. The Good Clinical Practice Resource Group will provide a one-day GCP training for study personnel one day prior to the Kickoff Meeting.
2. In-person training is mandatory for all study coordinators and strongly encouraged for site investigators. For those sites who do not have study coordinators at the time of kickoff, or have a change in coordinators during the course of the study, the Project Manager should work with SMART to determine when and where the next GCP training will be held so these new coordinators may attend. Those coordinators unable to attend the meeting or join the trial after the kickoff meeting must take the GCP course available on the ORD website (<http://www1.va.gov/resdev/programs/pride/training/gcp-hsp.cfm>) and must attend the SMART training within 90 days of joining the trial.

3. **Task:**
 - a. **The Project Manager notifies SMART to schedule GCP training at Study Kickoff meeting, anticipated date, AV and other logistical needs.**

Reference: Checklist 11 - Study Startup/Initiation Checklist Item 53

D. Executive Committee

1. It is important that the Executive Committee meet at the Kickoff Meeting to decide on and/or finalize study and management details.
2. **Tasks**
 - a. **The Project Manager will work with the CSPCC Travel Coordinator to arrange this meeting.**
 - b. **CSPCC Travel Coordinator will prepare Letter of Agreement (LOA) for non-VA Executive Committee members, which details the stipend, per diem (\$200 per day and \$100 for preparation), and other reimbursements.**

Reference: Checklist 11 - Study Startup/Initiation Checklist Item 54

E. Revisions to the Operations Manual, Protocol and Data Forms

1. Decisions during the Executive Committee and Kickoff Meetings may result in changes to the Operations Manual, Protocols and/or Data Forms.
2. **Task:**
 - a. **The Project Manager coordinates any revisions to the Operations Manual, Protocols and Data Forms as a result of any decisions made.**

References:

- CSP Global SOP 2.1.0 - Developing, Approving, and Amending Protocol
- CSP Global SOP 2.3.0 - Preparing and Approving Operations Manual
- Checklist 11 – Study Startup/Initiation Checklist Item 55.

VII. DMC Meeting

A. Purpose

1. The DMC is responsible for monitoring, evaluating, and making recommendations concerning all aspects of the ongoing study. The first meeting is held about the same time as the Kickoff Meeting or shortly thereafter. The Committee provides a continuing critical and unbiased evaluation of the study's progress and formulates operational policy consistent with the best biomedical operating practice. The major responsibilities of the DMC are:
 - a. Determining whether or not a study should continue, based on patient accrual, overall study progress, treatment efficacy, adverse effects and patient safety.
 - b. Assess performance at each participating site and make recommendations regarding continuation, probationary status, or termination.
 - c. Review and provide recommendations regarding protocol changes and substudies.
 - d. Review BRDP for future reports.

Reference: CSP Guidelines, Chapter V, "Conducting a CSP Study," Section A, "CSP Study Management and Monitoring," Part 3, "Data Monitoring Committee"

B. Preparation

1. Tasks:

a. Four weeks prior to the first DMC meeting, the Project Manager prepares and sends Letter 32 to the members.

- This letter confirms the date and location of the meeting and summarizes the flow and objectives of the meeting.

b. Two to four weeks before every meeting, the Project Manager or CSPCC Travel Coordinator will prepare and send Letter 33 to members.

- This also confirms the date and location of meeting. Enclosed with this memo is a Letter of Agreement (LOA), which details the stipend, per diem, and other reimbursements.

Meeting

"In-person" meetings
Conference Call

Stipend

\$200 per day and \$100 for preparation
\$100 per call and \$50 for preparation

References:

- CSP Global SOP 5.2.0 – Data Monitoring Committee
- Checklist 11 – Study Startup/Initiation Checklist Items 56 – 59.

Agenda

1. The DSMB agenda is developed by the Study Biostatistician and the Project Manager. Agenda items for the first meeting may include:

<u>Item</u>	<u>Presenter</u>
Welcome	CSPCC Director
Selection of DMC Chair	CSPCC Director
Overview of Study Progress	Study Chair
Review of Summary Tables	Study Biostatistician
Record Recommendation of DMC	Study Biostatistician
Decide Date for Next Meeting	DMC Chair
Executive Session (optional)	DMC Chair
Safety Regulatory Issues	CRP/AE Specialist

Reference: CSP Global SOP 5.2.0 Data Monitoring Committee, Attachment 3, "Sample DMC Agenda" (page 14)

2. Additional agenda items for future DMC meetings will include:

<u>Item</u>	<u>Presenter</u>
Convene Closed Session if appropriate to present unblinded data (Safety and Regulatory Issues)	Study Biostatistician Study CRP/AE Specialist
Combined DMC and HRC Meeting	DMC Chair

D. Prototype Tables

1. Tasks

a. The Study Biostatistician will present prototype tables and charts that summarize safety and efficacy data.

- These tables are developed during the planning phase of the trial and are incorporated into the protocol.

Reference: Checklist 11 – Study Startup/Initiation Checklist Item 60.

VIII. Pre-Randomization Activities

A. Master Case Report Forms (CRF)

1. After the Data Forms (Case Report Forms) have been revised, the Project Manager will work with the Study Data Manager to create a Master Case Report Form Binder for each participating site, the Study Chair, the Data Manager, the Project Manager, and the Study Biostatistician.
2. The Master CRF Binder will contain a printed “master” and an electronic copy of the study CRFs. The CRFs may be organized individually or grouped by study visit.
3. Participating sites may not start randomizing patients until they have the Master CRF Binder.

B. Updated Operations Manual

1. Once completed, the Operations Manual will serve as the key study document that all sites will follow. In preparation of pre-randomization activities, this manual should be finalized and distributed.

Task:

- a. **The revised version of the Study Operations Manual is copied and sent to the participating sites and other members of the study team.**

Reference: Checklist 11 - Study Startup/Initiation Checklist Item 61

Checklist 11 - Study Startup/Initiation Checklist

<u>DATE</u>	<u>TASK</u>
_____ 1	CSSMRB Notification received
_____ 2	Record date of official letter of approval of funding from VACO.
_____ 3	File approval letters in the Central Study File.
_____ 4	Memo 17 to Study Chair from Project Manager
_____ 5	Memo 18 for Study Chairs to sign and send back (send with Memo 17)
_____ 6	Memo 19 for Study Chairs to sign and send back (send with Memo 17)
_____ 7	Memo 20 for Study Chairs to sign and send back (send with Memo 17)
_____ 8	Memo 21 for Study Chairs to sign and send back (send with Memo 17)
_____ 9	Update protocol based on CSSMRB recommendations (in conjunction with Pre-Kickoff meeting).
_____ 10	Identify sites/SI to be surveyed or reconfirm interest in participation.
_____ 11	Identify members of Endpoint Committee or any other committees as dictated by protocol. Check FDA sanctions listings: http://www.fda.gov/ora/compliance_ref/debar/default.htm http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
_____ 12	Check DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listings: http://silk.nih.gov/public/cbz1bj.e.@www.orilist.html
_____ 13	Utilize Exhibit 15 as a tool to collect information on study personnel. Check to see if SI has a 5/8 th appointment with the VA. If not, must seek waiver from Cooperative Studies R&D (Memo 22).
_____ 14	Develop timeline for drug donation and/or device distribution.
_____ 15	Director of SMART notified that study is funded and final protocol, list of sites, and ops manual will be forthcoming.
_____ 16	Secure Drug/Device Supplies. Determine if CRADA or CTA will be required.
_____ 17	Study monitoring needs assessed with SMART.
_____ 18	Health Economist to review his/her section of protocol to ensure that no further changes are required.
_____ 19	Program Manager contacts CSP Deputy Director to discuss plans for developing Interagency Agreement or CRADA for industry agreements (if applicable).

<u>DATE</u>	<u>TASK</u>
_____ 20	Organize Pre-Kickoff meeting visit.
_____ 21	Organize HRC review (in conjunction with Pre-Kick off meeting).
_____ 22	Forward Executive Committee, DMC and site nominees to VACO for approval. CVs and a signed Statement of Disclosure from each person nominated to serve on the Executive Committee and the DMC needs to be included with the nomination memo.
_____ 23	Once VACO approves DMC members, send Memo 23 to potential DMC Members
_____ 24	Once VACO approves Executive Committee members, send Memo 24 to potential Executive Committee Members.
_____ 25	Memo describing changes and final protocol sent to CO for approval by Director, CSR&D.
_____ 26	Project Manager works with CSPCC ADO to revise study budget.
_____ 27	Final budget and memo describing any changes sent to CO for approval.
_____ 28	Send Memo 26 or 26 to ACOS at participating sites (Enclose Memo 27 or 27A for their use).
_____ 29	Send Memo 28 or 28A to Site Investigator. Include Exhibit 16 (Investigator Study File), Exhibit 17 (Statement of Disclosure) and Exhibit 18 (Site Investigator Agreement).
_____ 30	Investigator's brochure and Drug Information Report (DIR) should be included with protocol.
_____ 31	Suggested recruitment material and/or drafts of patient letters should be included for submission to the IRB.
_____ 32	Electronic copies of the informed consent forms, inclusive of HIPAA requirements, should be sent to the site for ease of modifying.
_____ 33	If a central lab is being used, send the lab certificates with the Site Investigator materials, as these will need to be submitted with the IRB application with copies to be filed in the Investigator's Essential Document Binder.
_____ 34	Send copy of protocol and list of study sites to Director of SMART.
_____ 35	Create database or spreadsheet to track IRB and R&D approvals and other necessary information. See Checklist 12 for a comprehensive list of items required before kickoff.
_____ 36	Project Manager will review each approved consent form for FDA, VA and CSP requirements. Project Manager will also review content for accuracy and will work with the site on any modifications that need to be made prior to starting. See Exhibit 19 .
_____ 37	Update Study Profile on CSP website. (See Exhibit 20, Exhibit 20A and Exhibit 33). Note: Exhibit 33 can be found in the Coordinating Center Responsibilities Section.
_____ 38	Operations manual and other Kickoff meeting materials prepared and distributed.
_____ 40	For politically sensitive topics, case report forms must be approved by VHA Forms, Publications and Records Management Office in VACO. If this is the case, the Project Manager and Study Biostatistician will prepare an abstract and send to the CSP Deputy Director to determine if the forms will need full OMB approval.
_____ 41	If full OMB approval is required, initiate OMB Form 83-I (See Exhibit 21).

DATE

TASK

- _____ 42 Project Manager works with CSPCC ADO and CSP Deputy Director to determine timeline for funding requirements.
- _____ 43 **Memo 29** to Study Chair with prototype **Memo 30** attached (funding requests).
- _____ 44 CSPCRPCC will request funding for pharmacy, SMART and AE/SAE support from VACO thru assigned CSPCC.
- _____ 45 Site funding request (**Exhibit 22**) sent to VACO via e-mail.
- _____ 46 Study Clinical Research Pharmacist/AE Specialist contacts appropriate groups (i.e., FDA) to determine whether an IDE or IND is needed and to obtain needed guidance for FDA submissions and approvals.
- _____ 47 Pharmaceutical Project Manager/AE Program Manager will work with Study CRP/AE Specialist to assist in the distribution of information to the participating sites and collection of documentation from sites.
- _____ 48 Pharmaceutical Project Manager/AE Program Manager will forward copies of regulatory documents to the CSPCC Project Manager.
- _____ 49 Study team nominates locales and dates for Kickoff Organizational Meeting.
- _____ 50 Project Manager and Travel Manager estimate travel costs and logistics for Kickoff.
- _____ 51 ADO/AO makes recommendations to CSP Deputy Director who then approves final location.
- _____ 52 Send **Memo 31** to all meeting participants.
- _____ 53 Contact SMART to schedule GCP training at Study Kickoff Meeting and anticipated date. Determine AV and other logistical needs.
- _____ 54 Project Manager will work with the CSPCC Travel Coordinator to arrange Executive Committee Meeting which typically meets during the Kickoff Meeting. The CSPCC Travel Coordinator will also prepare LOAs for non-VA Executive Committee members.
- _____ 55 Revision of Operations Manual, Protocols, and Data Forms post Kickoff Meeting.
- _____ 56 Send **Letter 32** to DMC members.
- _____ 57 Study team, in coordination with Travel Manager, decide upon locale and date of 1st DMC meeting.
- _____ 58 Send **Letter 33** regarding 1st DMC meeting.
- _____ 59 Date of first DMC meeting.
- _____ 60 Study Biostatisticians will present prototype tables and charts summarizing safety and efficacy data.
- _____ 61 Send Master CRFs and revised Study Operations Manual to participating sites and other site personnel.

Checklist 12 – Material Required PRIOR to Study Kickoff

Site Name: _____

Site Number: _____

Investigator Name: _____

Contact Number: _____

	<i>Item Requires</i>	<i>Pertinent Attachments Provided</i>	<i>Date Received</i>
1.	Investigator's CV		
2.	Investigator's SSN (last 4 digits only)		
3.	Confirm that site has FWA Number		
4.	Documentation of IRB Approval <i>This documentation is required annually.</i>		
5.	Documentation of R&D Approval <i>This documentation is required annually.</i>		
6.	Approved Site Consent <i>This documentation is required annually.</i>	IRB Stamp required on consent.	
7.	Site specific HIPAA Form <i>May be imbedded within consent – but this must be confirmed.</i>		
8.	IRB approval of HIPAA Waiver		
9.	Contact Information for Investigator		
10.	Contact Information for Coordinator		
11.	Documentation of SI GCP Training <i>Must be completed within 1 year- this documentation is required annually.</i>		
12.	Documentation of Study Coordinator GCP Training <i>Must have been completed within 1 year- this documentation is required annually.</i>		
13.	Documentation of SI Human Subjects Training <i>Must have been completed within 1 year- this documentation is required annually.</i>		
14.	Documentation of Study Coordinator Human Subjects Training - <i>Must have been completed within 1 year- this documentation is required annually.</i>		
15.	Signature Log– <i>Must be updated as personnel become involved in the study.</i>		
16.	Signed Investigator's Agreement		
17.	Signed Statement of Disclosure		
18.	Albuquerque CSPCRPCC Requirements	Refer to directives from CSPCRPCC	

Note:

1. Each site should be provided with the list of material required to be maintained in the Investigator's Study File ---- provided by SMART.
2. The Investigator should also be instructed to work with his Research Office to prepare the Project Data Sheet and/or other VA required material.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Approval for Study Initiation CSP #[000], "[title]"

To: Chairperson's name, [medical center name (000/00)]

PROTOTYPE MEMO 17

When we are told by CSP
that the study will be funded.

1. The Cooperative Studies Program has approved funding of your study in the near future. There are several kinds of activity that should be initiated without delay. Perhaps the highest priority should be given to any changes in the proposal that need to be made in response to suggestions or recommendations made by CSSMRB. If you have not already done so, work closely with [Study Biostatistician] on these changes and if necessary, we will duplicate a new set of revised proposals for you.
2. If you have not already made the final selection of your participating medical centers, would you give this your immediate attention and send your nominations to me. In making your selection you should take into consideration the criteria listed in the **CSP Guidelines** (Chapter IV, "Initiating a CSP Cooperative Study", Sections B and C). Remember that to be eligible to serve as a Site Investigator, an individual must be at least 5/8 VA time or judged to be eligible by the VACO Eligibility Panel. As soon as we receive your list of medical centers, we will forward it to the Director, CSP for approval. We will initiate the R&D review procedure when we receive approval on the sites. Please remember that your study will need to be reviewed initially by your site's R&D Committee and the Human Studies Subcommittee/IRB, and then on an annual basis thereafter. Minutes of these reviews must be provided to the Coordinating Center also.
3. You should nominate your Executive Committee and inform me in writing of your choice. The size and composition of the Committee varies from study to study, but [Study Biostatistician] can advise you in this regard. You should also nominate your Data Monitoring Committee. See the **CSP Guidelines** (Chapter V, "Conducting a CSP Study", Section A, "CSP Study Management and Data Monitoring", Parts 2 and 3) for instructions regarding both the Executive Committee and Data Monitoring Committee. You must nominate two individuals for each position on the Committee. It is important that you not contact your Data Monitoring Committee nominees directly prior to our communication with them.
4. After receipt of your final site selection and committee nominations, I will complete the appropriate memos for you to approve and I will forward to VACO.
5. Sometime soon, we will ask you to travel to the CSPCC to spend some time working with various members of our staff on final issues of protocol changes, forms design, database management, the Operations Manual and study administration. After this meeting, the CSPCC will initiate approval of the research data forms by VACO. As soon as form numbers are received, we will duplicate a sufficient quantity for the study, including the training activity.
6. I have attached three sample memos. One (**Prototype Memo 18**) is to indicate your choice of participating medical centers and the others are to let me know about your Executive Committee (**Prototype Memo 19** and Data Monitoring Committee nominations (**Prototype Memo 20**). Project Manager for this study, [Name], can assist you in completing these memos.

[name]

Attachments (3) (Prototype Memos 18, 19 and 20)

cc: ACOS for R&D [medical center]
AO for R&D [medical center]

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 18

With Prototype Memo 17

Date:

From: Study Chairperson, [medical center name] CSPCC (#000/00)

Subj: Selection of Participating Medical Centers, CSP #[000]

To: Director, [medical center name] CSPCC (#000/00)

I have nominated the following medical centers for participation in Cooperative Study #[000], "[title].

[name]
[list number of 8th's appointment, e.g., must be at least 5/8's appointment]
[site investigator]
[location]

[Name]

CSPCC NOTE: Once this memo is received from Study Chairperson, it should be forwarded to Director, Clinical Science R&D Service (VACO) for approval. Place an APPROVAL/DISAPPROVAL line at bottom of page for Director's signature (Note: When the listing has been approved, please send a copy to CSPCRPCC). However, before it is sent, the sanctions listings located below should be checked to make sure that the Site Investigator's name does not appear:

FDA Listings:

Debarment Listing: http://www.fda.gov/ora/compliance_ref/debar/default.htm
Disqualified/Restricted/Assurances: http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm
Disqualified/Totally Restricted List: http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm

DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listing:
<http://silk.nih.gov/public/cbz1bje.@www.orilist.html>

Also, before this memo is forwarded to VACO for approval, check to make sure each center's HSS/IRB has a FWA with the VA.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 19

With Prototype Memo 17

Date:
From: Study Chairperson, [medical center name (000/00)]
Subj: Nomination for Executive Committee, CSP #[000]
To: Director, [medical center name] CSPCC (#000/00)

Subject to approval I have selected the Executive Committee for Cooperative Study #[000], "[title]".

Name

Location

[chairperson]
[study biostatistician]
[site investigator]
[site investigator]
[clinical research pharmacist]
[heads of any central labs]
[health economist] (if applicable)
[MAVERIC] (If applicable)

[name]

CSPCC NOTE: Once this memo is received from Study Chairperson, it should be forwarded to Director, Clinical Science R&D Service (VACO) for approval. Place an APPROVAL/DISAPPROVAL line at bottom of page for Director's signature (Note: When the listing has been approved, please send a copy to CSPCRPCC).

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 20

With Prototype Memo 17

Date:

From: Study Chairperson, [medical center name (000/00)]

Subj: Nomination of Data Monitoring Committee, CSP #[000]

To: Director, [medical center name] CSPCC (#000/00)

The following individuals are my nominations for membership on the Data Monitoring Committee for Cooperative Study #[000], "[title]. I have nominated two individuals for each position.

[name, mailing address, telephone number
two for each position, e.g.,
surgeon, nutritionist, biostatistician, etc.]

[name]

CSPCC NOTE: Once this memo is received from Study Chairperson, and after Letter 22 is sent to prospective DMC members and CVs received, then the nominations and CVs should be forwarded to the Director, Clinical Science R&D Service (VACO) for approval. Place an APPROVAL/DISAPPROVAL line at bottom of page for Director's signature (Note: When the listing has been approved, please send a copy to CSPCRPCC).

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 21

Anytime after CSSMRB Approval

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Permission to Use Your Protocol as a Specimen

To: [Chairperson's name, medical center name (000/00)]

1. As you may recall, when your study began its planning we sent you a specimen protocol to use as a guide to prepare your proposal for the Cooperative Studies Scientific Merit Review Board (CSSMRB) submission. We would now like permission to use your protocol as a specimen for other proponents to use in planning their proposals.
2. Please indicate your approval/disapproval and return this letter in the enclosed self-addressed envelope.

[name]

APPROVE/DISAPPROVE

Signature

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 22

As needed

Date:

From: CSPCC Director, [medical center name] CSPCC (#000/00)

Subj: Eligibility Waiver for CSP [#000] Site Investigator

To: Director, Clinical Science R&D Service, VACO

1. Attached is request from the ACOS, Research and Development Service, at [medical center] to waive the 5/8th eligibility requirement for the CSP [#000] site investigator, [name of SI]. Also attached is the Study Chairman's recommendation of approval for the waiver. The site's status is [insert status]. [Provide additional information regarding **justification** of request for waiver].

2. We support the waiver request for [name of SI] with the understanding that this waiver will only apply to [name of SI]'s participation on CSP [#000].

[Name]

Attachments (2)

APPROVED/DISAPPROVED

[Name]

Director, Clinical Science R&D Service

cc: CSPCC AO [Name of CSPCC]
CSP Deputy Director, VACO (125A)
Study Chair
Project Manager [Name of CSPCC]
Biostatistician [Name of CSPCC]



DEPARTMENT OF VETERANS AFFAIRS
[INSERT ADDRESS OF MEDICAL CENTER]

PROTOTYPE LETTER 23

Upon receipt of memo
nominating DMC candidates

[date]

000/00
CSP #000/00

[Prospective DMC Members]
[Address]

Dear Dr. [Enter Name]:

Your name has been suggested for service on the Data Monitoring Committee for a recently funded cooperative study, CS #[000], "[title]." This cooperative study which will begin patient intake in [date], is chaired by [name and location of principal proponent].

Please find enclosed a summary of the study. Should you wish to receive a copy of the study protocol, please contact our office (000-000-0000) and we will send you one. The Data Monitoring Committee functions as a monitoring committee during the ongoing phase of the study. It, along with the Human Rights Committee connected with our Coordinating Center, reviews the data and recommends the course of the study, i.e., whether the study should continue, be terminated, or be modified, taking into account such aspects as patient accrual, overall study performance, treatment efficacy, and occurrence of adverse effects. The Committee also assesses the performance of each participating hospital. Enclosed is a copy of the **Guidelines for the Planning and Conduct of Cooperative Studies in the Department of Veterans Affairs** (See Section V, "Conducting a CSP Study", Section A, "CSP Study Management and Monitoring", Parts 2 and 3), explains in more detail the duties and responsibilities of the Committee. The **Guidelines** also provide an operational overview of cooperative studies as they are conducted within the Department of Veterans Affairs.

The Data Monitoring Committee for the study will consist of [# of members]. At this point, we would like to determine your interest and availability for serving as the [type of] member. If you are interested in being considered, please mail a copy of your curriculum vitae to me in the self-addressed envelope enclosed; the C.V. will be used to support your nomination. Our office will be in contact with you in approximately two weeks to determine your willingness to serve and/or if you would like additional information. I look forward to receiving your C.V.

Thank you for your consideration.

Sincerely yours,

[name]
Director, CSPCC

Enclosures: (study summary)
(Guidelines)
(self-addressed envelope)

cc: Principal Proponent
CSP Deputy Director (VACO)



DEPARTMENT OF VETERANS AFFAIRS
[INSERT ADDRESS OF MEDICAL CENTER]

PROTOTYPE LETTER 24
After nominations of Executive
Committee are approved.

[date]

000/00
CSP #000/00

[Member of Executive Committee]
[title]
[street address]
[city, state zip]

Dear Dr. [Enter Name]:

As I mentioned to you some time ago, I would like you to serve on the Executive Committee of Cooperative Study #[000], "[title]". Your appointment to that committee was recently approved by VA Central Office. I have enclosed a description which details the duties of the Executive Committee. The first meeting will take place in [place] on [date] in conjunction with the study investigators and nurses meeting. The members of the Executive Committee are as follows:

[name title institution phone #]

Thank you very much for agreeing to serve. If you have questions or concerns, please don't hesitate to contact me.

Sincerely,

[name], Director
Cooperative Studies Program
Coordinating Center

Enclosure (Excerpt from Guidelines)

[Enclosure for Letter 24 - Excerpted from Guidelines (Chapter V, "Conducting a CSP Study", Section A, "CSP Study Management and Monitoring", Part 2, "Executive Committee")]

Executive Committee

The Executive Committee, chaired by the Study Chairperson, consists of six to ten members and includes the Study Chairperson, the Study Biostatistician/Epidemiologist, the CSPCC/ERIC Project Manager, the Study Health Economist (if any), the Study CRP, the head(s) of any special central support unit(s) related to the study, the National Study Coordinator, study coordinator from the Chairperson's Office, two or three Site Investigators, and selected consultants when necessary. If there are no more than five investigators, they may all be members of the Committee. This Committee acts as the management group and decision-making body for the operational aspects of the study. It decides on all proposed changes in the study and on any subprotocols/substudies or use of the study data, on publications of study results, and recommends actions on medical centers whose performance is unsatisfactory. All major alterations in protocol design or operation of the study recommended by the Executive Committee must have the appropriate approvals as discussed in Section V. D. Protocol Changes. As with the Study Group, the interim results of blinded portions of the study will not be presented to this group.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 25

As needed

Date:

From: CSPCC Director, [medical center name] CSPCC (#000/00)

Subj: Approval for FY (Recast) Budget for CSP [#000]

To: Director, Clinical Science R&D Service, VACO

1. The CSSMRB study budget for CSP [#000], ["Study Title"] has been recasted to the fiscal year format. The budget for the duration of the study is projected to be [insert amount]. The proposed startup date is [date]. **[List any changes made to the budget based on CSSMRB recommendations, etc.]**
2. We are requesting your approval of the attached study budget.

[Name]

Attachment (Recast Study Budget)

APPROVED/DISAPPROVED

[Name]

Director, Clinical Science R&D Service

cc: CSP Deputy Director, VACO (125A)
Study Chair
CSPCC AO [Name of CSPCC]
Project Manager [Name of CSPCC]
Biostatistician [Name of CSPCC]

Memorandum

PROTOTYPE MEMO 26

Upon receipt of
participation list

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Initiation of CSP [#000], "[title]"

To: ACOS for R&D (151), [S.I.'s medical center name (000)]

1. The VA Cooperative Studies Program has received approval to initiate CSP #[000] "[title]." [Site Investigator] has expressed interest to the Study Chairperson in participating in the study, but others at your medical center share responsibility for deciding whether or not to participate.
2. We would appreciate the earliest possible review of the proposal by your R&D Committee and Institutional Review Board (IRB). We are tentatively planning to fund participating centers on [date] and initiate patient intake on [date] but these dates are contingent on how long the approval process takes by all participating medical centers.
3. One purpose of the R&D review is to decide if the study is feasible at your medical center. Every study has its own unique requirements in terms of support from the local pharmacy, the clinical laboratory, the Research Office, or other services. Each protocol also specifies requirements to allow monitors access to patient medical records for data verification purposes. Your decision to participate implies that these requirements are available and that the medical center has made a commitment to the Cooperative Studies Program.
4. In order for a center to participate in the [name of study], documentation of the initial IRB/R&D review and approval must be submitted to the Coordinating Center within **one** month of the review. Documentation required will consist of either:
 - a. minutes of the IRB and R&D (if appropriate) meeting where the initial review was conducted, **and a copy of the consent form reviewed by the IRB (to include committee approval date and informed consent expiration date recorded on form), or**
 - b. a letter signed by the IRB/R&D Chairperson (on Chairperson's official stationery) stating:
 1. that participation in the study is approved,
 2. date of the IRB/R&D review,
 3. period of review,
 4. a description of any action or problems that the IRB/R&D noted, and
 5. a copy of the consent form reviewed by the IRB (to include committee approval date recorded on form).

2.

[ACOS for R&D (151)]

The letter could be as simple as: "The IRB/R&D of (facility name) met on (date) and approved (SI's name) participation in the [name of the study]. There were no problems or major concerns noted by the IRB/R&D."

Please keep in mind that these two committees must review the study on an annual basis and provide documentation of their approval/disapproval to the Coordinating Center.

5. In addition to the protocol and consent forms, we have included other materials to be reviewed by your local IRB. Suggested patient letters, recruitment ads, as well as (list other materials that a patient may use or see such as patient diaries or workbooks) need to be submitted to the IRB.
6. The Site Investigator has been instructed to notify the Coordinating Center once the review dates have been scheduled.
7. We welcome constructive comments about the proposal by your R&D or IRB, and if suggestions for improvements are made promptly, the Study Chairperson will give them serious consideration.
8. If the study is approved at your facility you can request funds using the format of the attached sample memo. The dollar amounts are based on the assumption that you will be funded beginning [date]. The grade levels of personnel have been approved by VACO and are not to be changed although dollar amounts may have to be adjusted later. Please be sure you specify the professional status of the person being hired, as funding for R.N.'s will be sent in Program 870 funding. All other personnel dollars will be sent in Program 825 funding. Please remember that funding can only be requested after the Coordinating Center receives the site's IRB/R&D approval and approved informed consent. **Please note, if the site investigator has not received research funding before, please enter Investigator Data - Page 18 - information into the PROMISE system).**
9. We have attached three copies of the protocol for your use in the review. If you need more, write or call me at (insert phone number) and I will supply them.
10. The following information is provided for your project data entry into the "PROMISE" system:
Project Number: CSP #___; Study Chairman: (name, degree); and Medical Center Number: _____.

[name]

Attachments (3 Protocols)
(Prototype Memos 27 or 27A, 28 or 28A)

cc: AO for R&D [each medical center]
Study Chair
Site Investigator
[Project Manager name], CSPCC

Memorandum

PROTOTYPE MEMO 26A

(For Capitated Studies)
Upon receipt of
participation list

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Initiation of CSP [#000], "[title]"

To: ACOS for R&D (151), [S.I.'s medical center name (000)]

1. The VA Cooperative Studies Program has received approval to initiate CSP #[000] "[title]." [Site Investigator] has expressed interest to the Study Chairperson in participating in the study, but others at your medical center share responsibility for deciding whether or not to participate.
2. We would appreciate the earliest possible review of the proposal by your R&D Committee and Institutional Review Board (IRB). We are tentatively planning to fund participating centers on [date] and initiate patient intake on [date] but these dates are contingent on how long the approval process takes by all participating medical centers.
3. One purpose of the R&D review is to decide if the study is feasible at your medical center. Every study has its own unique requirements in terms of support from the local pharmacy, the clinical laboratory, the Research Office, or other services. Each protocol also specifies requirements to allow monitors access to patient medical records for data verification purposes. Your decision to participate implies that these requirements are available and that the medical center has made a commitment to the Cooperative Studies Program.
4. In order for a center to participate in the [name of study], documentation of the initial IRB/R&D review and approval must be submitted to the Coordinating Center within **one** month of the review. Documentation required will consist of either:
 - a. minutes of the IRB and R&D (if appropriate) meeting where the initial review was conducted, **and a copy of the consent form reviewed by the IRB (to include committee approval date and informed consent expiration date recorded on form)** , or
 - b. a letter signed by the IRB/R&D Chairperson (on Chairperson's official stationery) stating:
 1. that participation in the study is approved,
 2. date of the IRB/R&D review,
 3. period of review,
 4. a description of any action or problems that the IRB/R&D noted, and
 5. a copy of the consent form reviewed by the IRB (to include committee approval date recorded on form).

2.

[ACOS for R&D (151)]

The letter could be as simple as: "The IRB/R&D of (facility name) met on (date) and approved (SI's name) participation in the [name of the study]. There were no problems or major concerns noted by the IRB/R&D."

Please keep in mind that these two committees must review the study on an annual basis and provide documentation of their approval/disapproval to the Coordinating Center.

5. In addition to the protocol and consent forms, we have included other materials to be reviewed by your local IRB. Suggested patient letters, recruitment ads, as well as (list other materials that a patient may use or see such as patient diaries or workbooks) need to be submitted to the IRB.
6. The Site Investigator has been instructed to notify the Coordinating Center once the review dates have been scheduled.
7. We welcome constructive comments about the proposal by your R&D or IRB, and if suggestions for improvements are made promptly, the Study Chairperson will give them serious consideration.
8. This is a capitated study. Sites will be reimbursed up to (\$total dollars) per patient which will be allocated as follows: (\$amount) at randomization, (\$amount) for each follow-up visit. A site that randomizes and achieves its target of (#number) of patients will be reimbursed a total of (\$amount). Each site will be advanced funds to cover the start-up period and the first quarter of recruitment. As soon as your site has reached a reimbursement level greater than the advance funds due to study activity, you will be reimbursed based on the capitation rates above. Sites may enroll over the target amount of (#number) of patients. Please remember that funding can only be requested after the Coordinating Center receives the site's IRB/R&D approval and approved informed consent. **Please note, if the site investigator has not received research funding before, please enter Investigator Data - Page 18 - information into the PROMISE system).**
9. We have attached three copies of the protocol for your use in the review. If you need more, write or call me at (insert phone number) and I will supply them.
10. The following information is provided for your project data entry into the "PROMISE" system:
Project Number: CSP #___; Study Chairman: (name, degree); and Medical Center Number ____.

[name]

Attachments (3 Protocols)
(Prototype Memos 27 or 27A, 28 or 28A)

cc: AO for R&D [each medical center]
Study Chairman
Site Investigator
[Project Manager name], CSPCC

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 27

With Prototype Memo 26

Date:

From: ACOS for R&D, [medical center name (000/00)]

Subj: Request for Cooperative Study Funding, CSP #[000]

To: Director, CSPCC [(000/00)]
[address]

1. Our local R&D Committee fully endorses the conduct of Cooperative Study #[000], "[title]," at this facility. Official minutes of the R&D Committee and Human Studies Subcommittee/IRB will be sent within one month of the review.
2. We understand that funding will not be released until we provide CSPCC [Center Name] with the IRB approval, R&D approval, stamped approved informed consent and HIPAA authorization.
3. [name] requests the following funds for support of the study at this facility assuming a funding date of [00/00/00]. [name] is eligible to receive research funding as Site Investigator.

	1st Quarter FY__	2nd Quarter FY__	3rd Quarter FY__	4th Quarter FY__	Total
PERSONNEL:					
Job Title, Grade/Step, FTE	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___
Job Title, Grade/Step, FTE	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___
SUBTOTAL	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___
EQUIPMENT	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___
ALL OTHER COSTS	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___
TOTAL	\$ ___	\$ ___	\$ ___	\$ ___	\$ ___

[name]

cc: AO for R&D [each medical center]
[Administrative Officer name] CSPCC
[Project Manager name], CSPCC
Site Investigator

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 27A

For Capitated Studies
With Prototype Memo 26A

Date:

From: ACOS for R&D, [medical center name (000/00)]

Subj: Request for Cooperative Study Funding, CSP #[000]

To: Director, CSPCC [(000/00)]
[address]

1. Our local R&D Committee fully endorses the conduct of Cooperative Study #[000], "[title]," at this facility. Official minutes of the R&D Committee and Human Studies Subcommittee/IRB will be sent within one month of the review.
2. We understand that funding will not be released until we provide CSPCC (Center name) with IRB approval, R&D approval, stamped informed consent and HIPAA authorization.
3. We understand that CSP#[000] is a capitated study. [name] requests the following advanced capitation funds for start-up support of the study at this facility assuming a funding date of [00/00/00]. [name] is eligible to receive research funding as Site Investigator.

	Quarter (00)	
	FY__	Total
Advance Capitation	\$__	\$__

4. We understand that as soon as our site reaches a reimbursement level greater than the advanced funds due to study activity, we will be reimbursed based on the capitation rates below. These funds will be requested on a quarterly basis.

Capitated Funds	Patient Randomized	Follow-Up Visit
	\$ _____	\$ _____

[name]

cc: AO for R&D [each medical center]
[Administrative Officer name] CSPCC
[Project Manager name], CSPCC
Site Investigator

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 28

Upon receipt of participation list

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: CSP [#000], "[title]"

To: [Site Investigator's name, medical center name (000/00)]

1. [Chairperson] has informed me that you have agreed to serve as Site Investigator for your medical center in the cooperative study entitled ["title"], (CSP #000). I have attached a copy of the **Cooperative Studies Program Guidelines for the Planning & Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs** which contains the answers to many questions that are likely to arise during the course of the study. It would be helpful if you would review sections relevant to initiating and conducting a VA cooperative study. Note, that to serve as Site Investigator, it is necessary for you to be at least 5/8ths VA time or if you are less than 5/8ths VA time you must be granted a waiver by the VAHQ Eligibility Panel.
2. The Biostatistician on this study is (name) and the Project Manager is (name). (Name of Biostatistician) will ensure that all scientific aspects of the study are conducted appropriately. (His/Her) contact information is (phone number and extension) or (e-mail). (Project Manager name) will be your contact for budget issues, regulatory requirements, and all other administrative aspects of the study. (His/Her) contact information is (phone number and extension) or (e-mail).
3. I have requested your Research Office to schedule this proposal for the earliest possible review by the R&D Committee and the Human Studies Subcommittee/Institutional Review Board (IRB). I suggest that it might be useful for you to call the ACOS to reaffirm your interest, discuss any problems that might result from your participation, and enlist their support during this organizational phase and to ensure that this protocol is placed on the agenda for the next scheduled meeting. If conduct of the study requires participation by other services in your medical center, it is desirable that you touch base in these areas as well.
4. Also enclosed please find a Statement of Disclosure (Conflict of Interest) form, and a Site Investigator Agreement to Participate form. Please complete and return with a copy of your CV to (Project Manager name) as soon as possible.

2.

[Site Investigator]

5. It is also requested that you establish and maintain an Investigator Study File which will assist you in organizing all study related material (see attached Investigator Study File items for guidelines). Should you have any questions, please contact [Project Manager]. Also, SMART will provide an Essential Documents Binder to aid in organizing and maintaining your study file.

[name]

Attachments (Proposal)
(Guidelines)
(Prototype Memos 26 or 26A, 27 or 27A)
(Exhibit 16 - Investigator Study File Items
(Exhibit 17 - Statement of Disclosure)
(Exhibit 18 - Site Investigator Agreement)

cc: ACOS for R&D [each medical center]
AO for R&D [each medical center]
Study Charman (with copy of memo and list of SI's)
Director, CSPCRPCC (IF INVOLVED) (with copy of memo and list of SI's)
Study Biostatistician (with copy of memo and list of SI's)
[Administrative Officer name], CSPCC (with copy of memo and list of SI's)
[Project Manager name], CSPCC
CSPCC Central Study File

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: CSP [#000], "[title]"

To: [Site Investigator's name, medical center name (000/00)]

PROTOTYPE MEMO 28A

(For Capitated Study)
Upon receipt of participation list

1. [Chairperson] has informed me that you have agreed to serve as Site Investigator for your medical center in the cooperative study entitled "[title]", (CSP #[000]). I have attached a copy of the **Cooperative Studies Program Guidelines for the Planning & Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs** which contains the answers to many questions that are likely to arise during the course of the study. It would be helpful if you would review sections relevant to initiating and conducting a VA cooperative study. Note, that to serve as Site Investigator, it is necessary for you to be at least 5/8 time or if you are less than 5/8ths VA time you must be granted a waiver by the VAHQ Eligibility Panel.
2. The Biostatistician on this study is (name) and the Project Manager is (name). (Name of Biostatistician) will ensure that all scientific aspects of the study are conducted appropriately. (His/Her) contact information is (phone number and extension) or (e-mail). (Project Manager name) will be your contact for budget issues, regulatory requirements, and all other administrative aspects of the study. (His/Her) contact information is (phone number and extension) or (e-mail).
3. I have requested your Research Office to schedule this proposal for the earliest possible review by the R&D Committee and the Human Studies Subcommittee/Institutional Review Board (IRB). I suggest that it might be useful for you to call the ACOS to reaffirm your interest, discuss any problems that might result from your participation, and enlist their support during this organizational phase and to ensure that this protocol is placed on the agenda for the next scheduled meeting. If conduct of the study requires participation by other services in your medical center, it is desirable that you touch base in these areas as well.
4. Also enclosed please find a Statement of Disclosure (Conflict of Interest) form, and a Site Investigator Agreement to Participate form. Please complete and return with a copy of your CV to (project manager name) as soon as possible.
5. This is a capitated study. Sites will be reimbursed up to \$_____ per patient which will be allocated as follows: \$_____ at randomization and \$_____ for each follow-up visit. A site that randomizes and achieves its target enrollment of _____patients will be reimbursed a total of \$_____. Each site will be advanced funds to cover the start-up period and the first quarter of recruitment. As soon as your site has reached a reimbursement level greater than advanced funds due to study activity, you will be reimbursed based on the capitation rates above. Sites may enroll over the start amount of _____patients. Please remember that funding can only be requested after the Coordinating Center receives the site's IRB/R&D approval and approved informed consent and HIPAA authorization.

2.

[Site Investigator]

6. It is also requested that you establish and maintain an Investigator Study File which will assist you in organizing all study related material (see attached Investigator Study File Items for guidelines). Should you have any questions, please contact [Project Manager]. Also, SMART will provide an Essential Documents Binder to aid in organizing and maintaining your study file.

[name]

Attachments (Proposal)
(Guidelines)
(Prototype Memos 26 or 26A, 27 or 27A)
(Exhibit 16 - Investigator Study File Items)
(Exhibit 17 - Statement of Disclosure)
(Exhibit 18 - Site Investigator Agreement)

cc: ACOS for R&D [each medical center]
AO for R&D [each medical center]
Chairperson (with copy of memo and list of SI's)
Director, CSPCRPCC (IF INVOLVED) (with copy of memo and list of SI's)
Study Biostatistician (with copy of memo and list of SI's)
[Administrative Officer name], CSPCC (with copy of memo and list of SI's)
[Project Manager name], CSPCC

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 29

Upon determination of funding date

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Funding Chairperson's Office, CSP [#000]

To: Study Chairperson, [medical center name (000/00)]

1. Our current plan is to fund your office on [date]. Tentatively, we will fund the participating sites on [date].
2. Our goal is to have all personnel on duty early in [month] so that they can have a short period of orientation before attending the Organizational Meeting which we are tentatively scheduling for [late month]. We are anticipating the initiation of patient intake on [date].
3. Attached is a sample memo to request funds for your site. The dollar amounts should be based on the assumption that funding of the Chairperson's Office will begin on [date]. The grade levels of personnel should be filled at the grade level indicated in the study budget approved by CSSMRB, although dollar amounts may have to be adjusted later. Any exceptions should be justified.

[name]

Attachment: (Prototype Memo 30)

cc: ACOS for R&D
AO for R&D
Administrative Officer, CSPCC
Project Manager, CSPCC

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 30

With Memo 27

Date:

From: ACOS/R&D, [medical center name (000/00)]

Subj: Request for Cooperative Study Funding, CSP #[000]

To: Director, CSPCC[(000/00)]
[address]

1. Our local R&D Committee fully endorses the conduct of Cooperative Study #[000], "[title]," at this facility. Official minutes of the R&D Committee will be sent within six weeks.
2. [name] requests the following funds for support of the Study Chair's Office assuming a funding date of [00/00/00].

	1st Quarter FY__	2nd Quarter FY__	3rd Quarter FY__	4th Quarter FY__	Total
PERSONNEL:					
Job Title, Grade/Step, FTE	\$__	\$__	\$__	\$__	\$__
Job Title, Grade/Step, FTE	\$__	\$__	\$__	\$__	\$__
SUBTOTAL	\$__	\$__	\$__	\$__	\$__
EQUIPMENT	\$__	\$__	\$__	\$__	\$__
ALL OTHER COSTS	\$__	\$__	\$__	\$__	\$__
TOTAL	\$__	\$__	\$__	\$__	\$__

[name]

cc: AO for R&D [Study Chair's medical center]
[AO name] CSPCC

NOTE: This letter should be initiated by your Research Office.

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 31

3-4 weeks before meeting

Date:

From: Project Manager, [medical center name] CSPCC (#000/00)

Subj: Organizational Meeting, CSP [#000], "[title]"

To: [Participant's name, medical center name (000/00)]

1. You will soon receive some material for review prior to our Organizational Meeting for the cooperative study on "[title]" (#000), which will be held at [place] in [city] on [date]. A tentative agenda is attached.

[Insert information on hotel accommodations.]

2. For VA employees, travel authority and advance travel funds will be forwarded to your medical center's R&D office prior to your meeting from this Coordinating Center and VA Central Office. Adjustments (increase or withdrawal of balance) will be made subsequent to the trip and upon notification of actual costs. Please file your travel voucher promptly.

3. For non-VA employees, prior to the meeting you will receive a Letter of Agreement from the CSPCC which will request your services at the meeting and will provide for your fee and reimbursement of travel and per diem expenses.

[name]

Attachment (agenda)

cc: Study Chair (copy of memo and list of attendees)
ACOS for R&D [each medical center] (copy of memo and agenda)
AO for R&D [each medical center] (copy of memo and agenda)



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 32

Upon notification of selected
DMC members

[date]

000/00
CSP #000/00

[DMC Members]
[title]
[street address]
[city, state zip]

Dear Dr. _____:

Thank you for your willingness to accept our invitation to become a member of the Data Monitoring Committee for our study on ["title"], CSP #[000].

The Committee will consider all operational matters, monitor the ethical aspects of safety and efficacy, and evaluate the success and quality of the study's execution.

The Committee is scheduled to meet every twelve months and more frequently if needed. The Data Monitoring Committee meetings are usually held in [city, state] where your group will also meet with the Human Rights Committee from the Cooperative Studies Program Coordinating Center at [location of CSPCC]. Details and materials pertinent to the meeting will be supplied by the Coordinating Center. The first meeting will be held [date].

Enclosed please find a Statement of Disclosure (Conflict of Interest) form. Please complete and return to me as soon as possible.

We have enclosed a copy of the complete membership. The tenure of your appointment is expected to be for the duration of this study. If there is additional information you need, please let us know.

Sincerely,

[name]
Director, Cooperative Studies Program
Coordinating Center

Enclosures: (List of Data Monitoring Committee members)
(Exhibit 17 - Statement of Disclosure)



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 33
3-4 weeks before meeting

[date]

000/00
CSP #000/00

[Data Monitoring Committee Members]
[title]
[street address]
[city, state zip]

Dear _____:

The first meeting of the Data Monitoring Committee for [Chairperson's] cooperative study on "[title]" (#[000]) will be held at the [place] in [city] on [date]. Ordinarily, the first meeting of this Committee has three primary objectives.

First, I will review for you the duties and responsibilities of the Committee. Essentially, you will monitor the progress of the study throughout its course and decide at each meeting whether it should continue. However, I will have more to say about this at the meeting. Please refer to the previously sent copy of the **Cooperative Studies Program Guidelines for the Planning and Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs** which has a section concerning the operations of the Committee (see Chapter V, "Conducting a CSP Study, Section A, "CSP Study Management and Monitoring", Part 3, "Data Monitoring Committee").

Next, [Chairperson] will present an overview of the study protocol, and we will spend as much time as necessary discussing the specific details of the study. Although you are not being asked to provide a scientific review of the study (that has already been done) or to suggest changes in the protocol or forms, it is important that you have a clear understanding of the study. A copy of the protocol is enclosed.

The third agenda item is also critically important in terms of committee function. [name], who is the Study Biostatistician, will provide an in-depth review of the reporting procedures that have been proposed. You will find these in the Appendix BRDP of the protocol. These proposed reporting procedures are important because they are the primary way that you will be kept informed of the progress of the study throughout its course, and it will be mainly on the basis of these tables that you will decide at each meeting whether or not the study should continue. Therefore, I urge you to critically examine these tables before the meeting and actively engage [Study Biostatistician] in a discussion of this proposal.

2.

[Name]

A Letter of Agreement will be sent to you before the meeting which discusses the reimbursement of travel expenses plus a consultant fee of \$300. The agreement needs to be signed and returned.

I am looking forward to seeing you in [city].

Sincerely,

[name]
Director
Cooperative Studies Program
Coordinating Center

cc: Study Chair (copy of letter and list of attendees)

NOTE: If the DMC member is a VA person, please delete paragraph 5 and insert Paragraph 2 of Prototype Letter 35.

REQUIREMENTS FOR STUDY PERSONNEL

For CS # _____ Site Name _____ Site # _____

Study Personnel*	Role	Status (Indicate # of 8th's paid by VA)	Sanctions List Checked? **	Name, Date and Location of HSP Training	Name, Date and Location of GCP Training	Credentials Verified by ACOS for R&D yes/no

*Study personnel has been identified as Site Investigators, Study Coordinators, and other pre-specified personnel with significant involvement in study conduct. HSP and GCP Training **MUST** take place before patient entry begins and **ANNUALLY** thereafter. Certificates of training must accompany this form.

**If this individual is a site investigator, please check the following listings:
FDA Listings:
 Disbarment Listing: http://www.fda.gov/ora.compliance_ref/debar/default.htm
 Disqualified/Restricted Assurances: http://www.fda.gov/ora.compliance_ref/bimo/dis_res_assur.htm
 Disqualified/Totally Restricted List: http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listings:
<http://silk.nih.gov/public/cbz1bjc.@www.orilist.html>
 If on any of these listings, he/she **CANNOT PARTICIPATE** in this study.

ACOS for R&D Signature and Date: _____ Site Investigator Signature and Date _____

CSPCC Director Signature and Date: _____

Please mail this form to: [Project Manager], Cooperative Studies Program
 Coordinating Center, [Address], [City, State, Zip]

Investigator Study File Items

1. All approved versions of the Investigator's Brochure/product labeling (as appropriate to the trial)
2. All approved versions of the protocol and amendments/subprotocols, if any, and sample case report forms (CRFs)
3. All approved versions of any information given to study subjects
 - Informed consent forms
 - Any other written information
 - Advertisement for subject recruitment (if used)
4. All approved versions of the Operations Manual
5. Financial aspects of the trial
6. Insurance statement (if appropriate); compensation and indemnification issues
7. Signed agreement between involved parties, e.g.:
 - Investigators and CSP (e.g., Participating Investigator Agreement)
 - Participating Investigator statements of disclosure and/or confidentiality agreements (when appropriate)
8. Dated, documented approval of Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) and Research and Development (R&D) Committee of all versions of the following:
 - Protocol and any amendments/subprotocols
 - Informed consent forms
 - Any other written information to be provided to the subject(s)
 - Advertisement for subject recruitment (if used)
 - Subject compensation (if any)
 - Any other documents given approval/favorable opinion
 - Continuing review of the trial
9. IRB/IEC composition
10. Interim and annual reports to the IRB/IEC and R&D Committee
11. Curriculum vitae and/or other relevant documents evidencing qualifications of Participating Investigator and sub-investigator(s), including study coordinators.
12. All versions of Form FDA 1572 (for studies of regulated products), or a list of appropriately qualified persons to whom the Participating Investigator has delegated significant study-related duties (as appropriate to the trial)
13. Site Personnel Signature/Initial Log and Delegated Responsibilities Log

14. Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol (as appropriate to the protocol)
15. Medical/laboratory/technical procedures/tests (as appropriate to the protocol):
 - Certification or
 - Accreditation or
 - Established quality control and/or external quality assessment or
 - Other validation (where required)
16. Instructions for handling of investigational product(s) and trial-related materials, if not included in the Operations Manual
17. Shipping records for investigational products(s) and trial-related materials
18. Records of investigational product(s) accountability at the site
19. Documentation of investigational products(s) destruction (at end of trial, if specified by the protocol) or return to CSPCRPCC
20. Code break procedures for blinded trials
21. Documentation of site monitoring visits (as appropriate to the trial): Site Initiation Report and summary letters of routine/close-out site monitoring visits
22. Relevant communications with the CSP:
 - Documentation (letters, notes of meetings or phone calls) of decisions relating to inclusion /exclusion criteria, randomization rules, deviations from protocol, protocol violations, or code breaks
23. Signed and dated informed consent forms
24. Source documents
25. Signed, dated, and completed CRFs
26. Documentation of CRF corrections
27. Notification by originating Participating Investigator to the CSP, IRB/IEC and, as appropriate to the study, the regulatory authorities of serious adverse events/unanticipated adverse device effects and related reports, following specifications in the protocol
28. Notification by the CSP to Participating Investigators of unexpected serious adverse reactions/unanticipated adverse device effects (e.g., IND safety reports)
29. Subject screening log
30. Subject identification code list
31. Subject enrollment log
32. Record of retained body fluids/tissue samples (if any)
33. Final report to IRB/IEC
34. Documentation of site personnel's relevant training
35. Documentation of equipment information (e.g. date of receipt, calibration, maintenance logs)

STATEMENT OF DISCLOSURE

**Cooperative Study #[]
Study Title**

Except as noted below, I am not an employee (part or full-time, paid or unpaid) of any organization(s) either involved in the study(s) under review or whose products or services would be clearly and directly affected in a major way by the outcome of the study(s), nor am I an officer, member, owner, trustee, director, expert, advisor or consultant of such an organization. It is important to recognize that conflict of interest applies if these interests or relationships exist or appear to exist.

Except as noted below, I do not have any financial interest in any organization meeting the above criteria, nor does my spouse, minor child, nor an organization with which I am connected. (STATE "NONE" OR IDENTIFY ANY EXCEPTIONS)

I WILL NOTIFY THE director of the CSPCC promptly if (a) a change occurs in any of the above during the tenure of my responsibilities or (b) if I discover that an organization with which I have a relationship meets the criteria.

I AM AWARE of my responsibilities for the maintenance of the confidentiality of any non-public information that I receive or become aware of through this activity and for the avoidance of using any such information for my personal benefit or for the benefit of my associates or of an organization with which I am connected or with which I have a financial involvement.

PRINTED NAME: _____

SIGNATURE: _____

DATE: _____

VA COOPERATIVE STUDIES PROGRAM

SITE INVESTIGATOR AGREEMENT

I certify that I will follow all requirements for VA Cooperative Study #[], “[Study Title]”, including:

1. Adhering to the study’s protocol and following the study interventions as described in the protocol.
2. Adhering to applicable regulations and good clinical practices guidelines, including the maintenance and retention of the Investigator Study File.
3. Meeting local IRB and R&D Committee initial and ongoing approval requirements.
4. Reporting adverse experiences to the CSP and IRB as specified in the protocol and/or by local IRB requirements.
5. Hiring and supervising site personnel, and ensuring they are informed about their responsibilities in a CSP study.
6. Obtaining study specific space and equipment.
7. Attaining recruitment goals.
8. Assuring the proper administration of informed consent.
9. Assuring good quality data, including signing off on appropriate study forms.
10. Assuring complete patient follow-up with minimal losses.
11. Participating in teleconferences and study meetings.
12. Promptly responding to data queries from the Coordinating Center.
13. Certifying that all VA sensitive information is being used, stored and secured in accordance with the applicable VA and VHA policies and guidance.
14. Maintaining the confidentiality of study data and not publishing study data without prior approval of the study’s Executive Committee.

FACILITY NAME

SITE INVESTIGATOR (please print)

SITE INVESTIGATOR SIGNATURE

DATE

INFORMED CONSENT REVIEW

Several elements MUST be included in the consent document according to FDA and/or VA regulations. They are included in the consent checklist provided. Local or central IRB's may require additional requirements, however, the checklist (see Checklist 6) elements must remain in the consent. The minimal requirements for consent signatures as outlined by FDA and VA are: patient or patient representative, witness (two if subject can only sign by mark: VHA 1004.1 7C) and person obtaining consent. Site Investigator signature is no longer required, however, if it is on the consent signature list, it must be completed and should be done so within a reasonable timeframe (CSP recommends within 72 hours of patient signature).

Omissions or errors on informed consent documents should be corrected as soon as the error is noted. The copy of the informed consent provided to the CSPCC is reviewed upon arrival to ensure informed consent has been obtained and the form is fully executed. Informed consent can be considered obtained or should we say has been documented when the document contains the patient signature. Some informed consent findings may require immediate remedial intervention while others are less urgent. The following are examples of errors/omissions and suggested remedies that may be requested of the site by the project manager:

- Informed consent submitted without subject signature: Invalid
 - Contact the site to verify the current status of the informed consent
 - If site does not have a signed consent form immediately halt patient study participation
 - Instruct site to:
 - Document incident in a note to file
 - Inform the IRB in writing
 - Make plans to obtain valid informed consent

- Administrative errors and omissions:
 - Informed consent lacks signatures other than the subject or contains undated signatures
 - Instruct site to:
 - Correct the omission using the correct date (do not pre-date)
 - Generate a note to file documenting the omission and correction; attach the note to file to the informed consent and provide copies to the CSPCC
 - Other omissions/irregularities of lesser significance in headers, footers, etc
 - Remind sites, as necessary, to exercise care when completing and reviewing consent forms and to make such minor corrections to form whenever noted (resubmission to CSPCC generally not necessary)

- Specific authorizations within the informed consent document unanswered (e.g., a yes or no response to permit tissue banking):

NOTE -Omissions of this nature are assumed to be a denial unless a correction is obtained

To obtain correction, instruct site to:
 - Have subject add late response and initial and date the late entry/response
 - Generate a note to file documenting the omission and correction; attach the note to file to the informed consent and provide copies to the CSPCC

- Other unusual informed consent findings:
 - SMART is available to discuss remedies with the Project Manager and Quality Assurance Specialist at the CSPCC.

Selection of CSP Study Keywords

To standardize the classification of CSP studies and to facilitate their identification by topic(s), CSP studies will be categorized by keywords.

Keywords are organized according to the following categories:

1. Organ/System Type
2. Anatomic Region
3. DRA- An abbreviation for “designated research area”, DRAs are topics by which VA research appropriations are organized
4. Study Type - this category includes keywords describing the main study design or methods being used (e.g., questionnaires, epidemiologic, double-blind)
5. Intervention Type - this category refers to the main type(s) of intervention that is being examined in the study (e.g. behavioral, surgical)
6. Medication Class Type – this category refers to the main class(es) of medications being used in the study (e.g. laxatives, antibiotics)
7. Disease Type – this category is divided according to several subcategories
8. Special Terms – this category includes keywords that provide important descriptions of the study but may not fall under the other 7 categories (e.g. Gulf War, homocysteine)

* Specific keywords within each category are provided in the attached list.

Procedures

- For the CSP study, select at least 1-2 keywords from each of the 8 categories. If multiple keywords are appropriate within a particular category, try to limit selections to no more than 4 per category.
- Keywords listed under the Disease Type category have been sub-categorized by organ/system type (e.g., atrial fibrillation is listed under the Cardiovascular subcategory within the Disease Type category). Select only keywords within the relevant subcategory(ies). If multiple subcategories apply, select at least 1-2 keywords from each subcategory.
- In the case that a category is not applicable to a study (e.g. Medication Type in a non-drug study), no keywords need to be selected.
- Before entering a study’s keywords into the CSP study database, please confirm your selections with at least one member of the study leadership team (e.g., Study Biostatistician, Study Chair, CSP Coordinating Center)

Director). Medication terms may be confirmed with the Study Pharmacist if necessary.

- Study keywords are to be entered into the CSP study database (maintained by the Albuquerque Clinical Research Pharmacy Coordinating Center). Any questions about procedures can be directed to David Garnand at the CRPCC.
- If there are keyword(s) not listed that are critical for accurately describing the study, please notify your Administrative Officer/Assistant Director for Operations (AO). Your AO will then forward your request to add keywords to VA Central Office. This process also applies for modifications or deletions of any keyword(s) from the master list.
- For any unlisted keywords, CSP Coordinating Centers have the discretion to enter up to 3 words into the database without any prior approvals. If more than 3 keywords are unlisted, notify your AO as described above.

EXHIBIT 20A - CSP KEYWORDS

Hematology, Immunology & Oncology	Hepatic & Biliary	Disease Type	Musculoskeletal & Connective Tissue	Neurologic Disorders
acute leukemia	ascities	abscesses	ankylosing spondylitis	alzheimer's disease
allergic purpura	biliary calculi	acquired immunodeficiency syndrome	bursitis	amnesias
ALS	cholecystitis	AIDS	eosinophilic fasciitis	amyotrophic lateral sclerosis
anemia	choledocholithiasis	allergic rhinitis	fibromyalgia	anaphylaxis
chronic lymphocytic leukemia	cholestasis	bacteremia	gout	aphasia
chronic myelocytic leukemia	cirrhosis	cellulitis	infectious arthritis	attention deficit disorder
disseminated intravascular coagulation	encephalopathy	chickenpox	lupus erythematosus	brain abscess
graft vs host disease	fatty liver	cholera	neurogenic arthropathy	cns neoplasms
hemophilia	fibrosis	cytomegalovirus	osteoarthritis	coma
hepatitis	hepatic granulomas	diarrhea	osteomyelitis	concussion
hypersplenism	hepatitis	endocarditis	osteoporosis	contusion
lupus	hepatomegaly	flu	rheumatoid arthritis	delirium
lymphocytopenia	jaundice	gonorrhea		dementia
lymphoma	portal hypertension	herpes zoster		dyskinesia
macroglobulinemia		HIV		dyslexia
multiple myeloma		human immunodeficiency virus		dystonia
myelodysplastic syndrome		influenza		encephalitis
myelofibrosis		legionella		epilepsy
neutropenia		lyme disease		facial nerve disorder
plasma cell dyscrasias		malaria		headache
polycythemia vera		measles		hearing
rejection		meningitis		hematomas
scurvy		mumps		hemorrhage
thrombocythemia		otitis media		infarction
thrombocytopenia		pneumonia		insomnia
transplant		rubella		Lou Gherig's disease
		sarcoidosis		meningitis
		sepsis		mental retardation
		shingles		migraine
		sinusitis		multiple sclerosis
		sypthilis		myasthenia gravis
		tuberculosis		narcolepsy
				neuralgia
				pain
				parkinson's disease
				peripheral neuropathy
				PTSD
				sleep apnea
				spinal cord compression
				spinal cord injury
				stroke
				stupor
				TBI
				tics
				tourrette syndrome
				traumatic brain injury
				transient ischemic attacks
				tremor
				trigeminal neuralgia
				vertigo
				vision

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.**

<p>1. Agency/Subagency originating request</p>	<p>2. OMB control number b. <input type="checkbox"/> None a. _____ - _____</p>
<p>3. Type of information collection (<i>check one</i>)</p> <p>a. <input type="checkbox"/> New Collection b. <input type="checkbox"/> Revision of a currently approved collection c. <input type="checkbox"/> Extension of a currently approved collection d. <input type="checkbox"/> Reinstatement, without change, of a previously approved collection for which approval has expired e. <input type="checkbox"/> Reinstatement, with change, of a previously approved collection for which approval has expired f. <input type="checkbox"/> Existing collection in use without an OMB control number</p> <p><i>For b-f, note Item A2 of Supporting Statement instructions</i></p>	<p>4. Type of review requested (<i>check one</i>)</p> <p>a. <input type="checkbox"/> Regular b. <input type="checkbox"/> Emergency - Approval requested by: ___/___/___ c. <input type="checkbox"/> Delegated</p> <p>5. Small entities Will this information collection have a significant economic impact on a substantial number of small entities? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>6. Requested expiration date a. <input type="checkbox"/> Three years from the approval date b. <input type="checkbox"/> ___/___</p>
7. Title	
8. Agency form number(s) (<i>if applicable</i>)	
9. Keywords	
10. Abstract	
<p>11. Affected public (<i>Mark primary with "P" and all others with "X"</i>)</p> <p>a. <input type="checkbox"/> Individuals or households d. <input type="checkbox"/> Farms b. <input type="checkbox"/> Business or other for-profit e. <input type="checkbox"/> Federal Government c. <input type="checkbox"/> Not-for-profit institutions f. <input type="checkbox"/> State, Local, or Tribal Government</p>	<p>12. Obligation to respond (<i>Mark primary with "P" and all others that apply with "X"</i>)</p> <p>a. <input type="checkbox"/> Voluntary b. <input type="checkbox"/> Required to obtain or retain benefits c. <input type="checkbox"/> Mandatory</p>
<p>13. Annual reporting and recordkeeping hour burden</p> <p>a. Number of respondents _____ b. Total annual responses _____ 1. Percentage of these responses collected electronically _____ % c. Total annual hours requested _____ d. Current OMB inventory _____ e. Difference _____ f. Explanation of difference 1. Program change _____ 2. Adjustment _____</p>	<p>14. Annual reporting and recordkeeping cost burden (<i>in thousands of dollars</i>)</p> <p>a. Total annualized capital/startup costs _____ b. Total annual costs (O&M) _____ c. Total annualized cost requested _____ d. Current OMB inventory _____ e. Difference _____ f. Explanation of difference 1. Program change _____ 2. Adjustment _____</p>
<p>15. Purpose of information collection (<i>Mark primary with "P" and all others that apply with "X"</i>)</p> <p>a. <input type="checkbox"/> Application for benefits e. <input type="checkbox"/> Program planning or management b. <input type="checkbox"/> Program evaluation f. <input type="checkbox"/> Research c. <input type="checkbox"/> General purpose statistics g. <input type="checkbox"/> Regulatory or compliance d. <input type="checkbox"/> Audit</p>	<p>16. Frequency of recordkeeping or reporting (<i>check all that apply</i>)</p> <p>a. <input type="checkbox"/> Recordkeeping b. <input type="checkbox"/> Third party disclosure c. <input type="checkbox"/> Reporting: 1. <input type="checkbox"/> On occasion 2. <input type="checkbox"/> Weekly 3. <input type="checkbox"/> Monthly 4. <input type="checkbox"/> Quarterly 5. <input type="checkbox"/> Semi-annually 6. <input type="checkbox"/> Annually 7. <input type="checkbox"/> Biennially 8. <input type="checkbox"/> Other (describe) _____</p>
<p>17. Statistical methods Does this information collection employ statistical methods? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>18. Agency contact (<i>person who can best answer questions regarding the content of this submission</i>) Name: _____ Phone: _____</p>

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

- (a) It is necessary for the proper performance of agency functions;
- (b) It avoids unnecessary duplication;
- (c) It reduces burden on small entities;
- (d) It uses plain, coherent, and unambiguous language that is understandable to respondents;
- (e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;
- (f) It indicates the retention periods for recordkeeping requirements;
- (g) It informs respondents of the information called for under 5 CFR 1320.8 (b)(3) about:
 - (i) Why the information is being collected;
 - (ii) Use of information;
 - (iii) Burden estimate;
 - (iv) Nature of response (voluntary, required for a benefit, or mandatory);
 - (v) Nature and extent of confidentiality; and
 - (vi) Need to display currently valid OMB control number;
- (h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);
- (i) It uses effective and efficient statistical survey methodology (if applicable); and
- (j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee

Date

Instructions For Completing OMB Form 83-I

EXHIBIT 21

Please answer all questions and have the Senior Official or designee sign the form. These instructions should be used in conjunction with 5 CFR 1320, which provides information on coverage, definitions, and other matters of procedure and interpretation under the Paperwork Reduction Act of 1995.

1. Agency/Subagency originating request

Provide the name of the agency or subagency originating the request. For most cabinet-level agencies, a subagency designation is also necessary. For non-cabinet agencies, the subagency designation is generally unnecessary.

2. OMB control number

- If the information collection in this request has previously received or now has an OMB control or comment number, enter the number.
- Check "None" if the information collection in this request has not previously received an OMB control number. Enter the four digit agency code for your agency.

3. Type of information collection (check one)

- Check "New collection" when the collection has not previously been used or sponsored by the agency.
- Check "Revision" when the collection is currently approved by OMB, and the agency request includes a material change to the collection instrument, instructions, its frequency of collection, or the use to which the information is to be put.
- Check "Extension" when the collection is currently approved by OMB, and the agency wishes only to extend the approval past the current expiration date without making any material change in the collection instrument, instructions, frequency of collection, or the use to which the information is to be put.
- Check "Reinstatement without change" when the collection previously had OMB approval, but the approval has expired or was withdrawn before this submission was made, and there is no change to the collection.
- Check "Reinstatement with change" when the collection previously had OMB approval, but the approval has expired or was withdrawn before this submission was made, and there is change to the collection.
- Check "Existing collection in use without OMB control number" when the collection is currently in use but does not have a currently valid OMB control number.

4. Type of review requested (check one)

- Check "Regular" when the collection is submitted under 5 CFR 1320.10, 1320.11, or 1320.12 with a standard 60 day review schedule.
- Check "Emergency" when the agency is submitting the request under 5 CFR 1320.13 for emergency processing and provides the required supporting material. Provide the date by which the agency requests approval.
- Check "Delegated" when the agency is submitting the collection under the conditions OMB has granted the agency delegated authority.

5. Small entities

Indicate whether this information collection will have a significant impact on a substantial number of small entities. A small entity may be (1) a small business which is deemed to be one that is independently owned and operated and that is not dominant in its field of operation; (2) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; or (3) a small government jurisdiction which is a government of a city, county, town, township, school district, or special district with a population of less than 50,000.

6. Requested expiration date

- Check "Three years" if the agency requests a three year approval for the collection.
- Check "Other" if the agency requests approval for less than three years. Specify the month and year of the requested expiration date.

7. Title

Provide the official title of the information collection. If an official title does not exist, provide a description which will distinguish this collection from others.

8. Agency form number(s) (if applicable)

Provide any form number the agency has assigned to this collection of information. Separate each form number with a comma.

9. Keywords

Select and list at least two keywords (descriptors) from the "Federal Register Thesaurus of Indexing Terms" that describe the subject area(s) of the information collection. Other terms may be used but should be listed after those selected from the thesaurus. Separate keywords with commas. Keywords should not exceed two lines of text.

10. Abstract

Provide a statement, limited to five lines of text, covering the agency's need for the information, uses to which it will be put, and a brief description of the respondents.

11. Affected public

Mark all categories that apply, denoting the primary public with a "P" and all others that apply with "X."

12. Obligation to respond

Mark all categories that apply, denoting the primary obligation with a "P" and all others that apply with "X."

- Mark "Voluntary" when the response is entirely discretionary and has no direct effect on any benefit or privilege for the respondent.
- Mark "Required to obtain or retain benefits" when the response is elective, but is required to obtain or retain a benefit.
- Mark "Mandatory" when the respondent must reply or face civil or criminal sanctions.

13. Annual reporting and recordkeeping hour burden

- Enter the number of respondents and/or recordkeepers. If a respondent is also a recordkeeper, report the respondent only once.
- Enter the number of responses provided annually. For recordkeeping as compared to reporting activity, the number of responses equals the number of recordkeepers.
 - Enter the estimated percentage of responses that will be submitted/collected electronically using magnetic media (i.e., diskette), electronic mail, or electronic data interchange. Facsimile is **not** considered an electronic submission.
 - Enter the total annual recordkeeping and reporting hour burden.
 - Enter the burden hours currently approved by OMB for this collection of information. Enter zero (0) for any new submission or for any collection whose OMB approval has expired.
 - Enter the difference by subtracting line d from line c. Record a negative number (d larger than c) within parentheses.
 - Explain the difference. The difference in line e must be accounted for in lines f.1. and f.2.
 - "Program change" is the result of deliberate Federal government action. All new collections and any subsequent revision of existing collections (e.g., the addition or deletion of questions) are recorded as program changes.
 - "Adjustment" is a change that is not the result of a deliberate Federal government action. Changes resulting from new estimates or action not controllable by the Federal government are recorded as adjustments.

14. Annual reporting and recordkeeping cost burden (in thousands of dollars)

The costs identified in this item must exclude the cost of hour burden identified in Item 13.

- Enter the total dollar amount of annualized cost for all respondents of any associated capital or start-up costs.
- Enter recurring annual dollar amount of cost for all respondents associated with operating or maintaining systems or purchasing services.
- Enter total (14.a. + 14.b.) annual reporting and recordkeeping cost burden.
- Enter any cost burden currently approved by OMB for this collection of information. Enter zero (0) if this is the first submission after October 1, 1995.
- Enter the difference by subtracting line d from line c. Record a negative number (d larger than c) within parenthesis.
- Explain the difference. The difference in line e must be accounted for in lines f.1. and f.2.
 - "Program change" is the result of deliberate Federal government action. All new collections and any subsequent revisions or changes resulting in cost changes are recorded as program changes.

f.2. "Adjustment" is a change that is not the result of a deliberate Federal government action. Changes resulting from new estimations or actions not controllable by the Federal government are recorded as adjustments.

15. Purpose of information collection

Mark all categories that apply, denoting the primary purpose with a "P" and all others that apply with "X."

a. Mark "Application for benefits" when the purpose is to participate in, receive, or qualify for a grant, financial assistance, etc., from a Federal agency or program.

b. Mark "Program evaluation" when the purpose is a formal assessment, through objective measures and systematic analysis, of the manner and extent to which Federal programs achieve their objectives or produce other significant effects.

c. Mark "General purpose statistics" when the data is collected chiefly for use by the public or for general government use without primary reference to the policy or program operations of the agency collecting the data.

d. Mark "Audit" when the purpose is to verify the accuracy of accounts and records.

e. Mark "Program planning or management" when the purpose relates to progress reporting, financial reporting and grants management, procurement and quality control, or other administrative information that does not fit into any other category.

f. Mark "Research" when the purpose is to further the course of research, rather than for a specific program purpose.

g. Mark "Regulatory or compliance" when the purpose is to measure compliance with laws or regulations.

16. Frequency of recordkeeping or reporting

Check "Recordkeeping" if the collection of information explicitly includes a recordkeeping requirement.

Check "Third party disclosure" if a collection of information includes third-party disclosure requirements as defined by 1320.3(c).

Check "Reporting" for information collections that involve reporting and check the frequency of reporting that is requested or required of a respondent. If the reporting is on "an event" basis, check "On occasion."

17. Statistical methods

Check "Yes" if the information collection uses statistical methods such as sampling or imputation. Generally, check "No" for applications and audits (unless a random auditing scheme is used). Check "Yes" for statistical collections, most research collections, and program evaluations using scientific methods. For other types of data collection, the use of sampling, imputation, or other statistical estimation techniques should dictate the response for this item. Ensure that supporting documentation is provided in accordance with Section B of the Supporting Statement.

18. Agency contact

Provide the name and telephone number of the agency person best able to answer questions regarding the content of this submission.

19. Certification for Paperwork Reduction Act Submissions

The Senior Official or designee signing this statement certifies that the collection of information encompassed by the request complies with 5 CFR 1320.9. Provisions of this certification that the agency cannot comply with should be identified here and fully explained in item 18 of the attached Supporting Statement. NOTE: The Office that "develops" and "uses" the information to be collected is the office that "conducts or sponsors" the collection of information. (See 5 CFR 1320.3(d)).

5 CFR 1320.9 reads "As part of the agency submission to OMB of a proposed collection of information, the agency (through the head of the agency, the Senior Official, or their designee) shall certify (and provide a record supporting such certification) that the proposed collection of information--

"(a) is necessary for the proper performance of the functions of the agency, including that the information to be collected will have practical utility;

"(b) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;

"(c) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. § 601(6)), the use of such techniques as:

"(1) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;

"(2) the clarification, consolidation, or simplification of compliance and reporting requirements; or collections of information, or any part thereof;

"(3) an exemption from coverage of the collection of information, or any part thereof;

"(d) is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond;

"(e) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;

"(f) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;

"(g) informs potential respondents of the information called for under §1320.8(b)(3); [see below]

"(h) has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;

"(i) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and

"(j) to the maximum extent practicable, uses appropriate information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public."

NOTE: 5 CFR 1320.8(b)(3) requires that each collection of information:

"(3) informs and provides reasonable notice to the potential persons to whom the collection of information is addressed of:

"(i) the reasons the information is planned to be and/or has been collected;

"(ii) the way such information is planned to be and/or has been used to further the proper performance of the functions of the agency;

"(iii) an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden);

"(iv) whether responses to the collection of information are voluntary, require to obtain or retain a benefit (citing authority) or mandatory (citing authority);

"(v) the nature and extent of confidentiality to be provided, if any (citing authority); and

"(vi) the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(i)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 of the OMB Form 83-I is checked "Yes", Section B of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

Specific Instructions

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.
2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.
3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.
4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.
5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.
6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.
7. Explain any special circumstances that would cause an information collection to be conducted in a manner:
 - * requiring respondents to report information to the agency more often than quarterly;
 - * requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
 - * requiring respondents to submit more than an original and two copies of any document;
8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.
9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.
10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.
11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information
 - * requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;
 - * in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
 - * requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
 - * that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
 - * requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
12. Provide estimates of the hour burden of the collection of information. The statement should:
 - * Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.
 - * If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.
 - * Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.
13. Provide an estimate for the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).
 - * The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.
 - * If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use

EXHIBIT 21

existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

* Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

B. Collections of Information Employing Statistical Methods

The agency should be prepared to justify its decision not to use statistical methods in any case where such methods might reduce burden or improve accuracy of results. When Item 17 on the Form OMB 83-I is checked, "Yes," the following documentation should be included in the Supporting Statement to the extent that it applies to the methods proposed:

1. Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection methods to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

2. Describe the procedures for the collection of information including:

- * Statistical methodology for stratification and sample selection,
- * Estimation procedure,
- * Degree of accuracy needed for the purpose described in the justification,
- * Unusual problems requiring specialized sampling procedures, and
- * Any use of periodic (less frequent than annual) data collection cycles to reduce burden.

3. Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of test may be submitted for approval separately or in combination with the main collection of information.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

ACTIVE

I. Training Requirements

A. Training Requirements

1. Orientation, SOP, GCP/HSP, SMART and job specific training must be provided to site staff and certified before enrollment of patients can occur in the study. Also site staff should receive and be familiar with the CSP Guidelines.
2. VA Research and CSP policies requires that all study personnel (Chairs, SI's, Study Coordinators and other study personnel with significant involvement in the study conduct) be fully trained in the research protocol to which they are assigned, along with **annual** training in Good Clinical Practices, Human Subjects Protection, Cyber Security Awareness, VHA Privacy training and VA Research Data Security and Privacy. Please go to <http://www.research.va.gov/programs/pride/training/all-staff.cfm> for a complete listing of the required training for VA research staff.
3. CSP policies mandate Good Clinical Practices training in addition to those of VA Research. All Study Coordinators are required to take the 8-hour GCP course provided by SMART at study startup meetings. Investigator attendance at this course is optional unless the Investigator will be serving without a Study Coordinator. Coordinators joining an ongoing trial must obtain this training when it is next offered by SMART. This course satisfies the annual VA Research training requirements described above. Any coordinator unable to attend the meeting or joining the trial after the meeting must take the GCP course available on the ORD website (<http://www.research.va.gov/programs/pride/training/options.cfm>) and must attend the SMART training within 90 days of joining the trial.
4. **Tasks:**
 - a. **Project Manager's responsibility to track training of study personnel**
 - Ensure all study participants complete the required annual training.
 - Obtain, review and file documentation of required training.
 - b. **SMART**
 - Publish periodically for CSPCC a list of planned GCP course offerings.
 - Maintain a database of all attendees of GCP courses.

References:

- CSP Global SOP 1.2.1 – Training and Training Documentation
- CSP SMART SOP 1.3.0 Good Clinical Practice (GCP) Education and Training
- CSP Guidelines, Chapter IV, "Initiating a CSP Cooperative Study", Section G, "Hiring and Training of Study Personnel"
- Checklist 13 - Active Studies Checklist Items 1 – 2.

II. Meetings/Travel

A. Annual Meetings

1. The Study Group and Executive Committee are required to meet nine months after the start of recruitment and annually thereafter. The DMC and HRC will convene for a face-to-face meeting on an annual basis. If a study has special issues that require more frequent meetings by the DMC to ensure patient safety, the meetings will be scheduled after obtaining VACO approval.
2. **Set – Up Tasks:**
 - a. **Project Manager should begin planning the meeting a minimum of 6 months in advance of the target meeting time. Refer to Checklist 14 - Meeting Checklist for specific tasks.**

- b. Establish meeting date**
 - 80% participation is required to conduct the meeting.
- c. Determine meeting location by obtaining cost estimates from 3 locations (See Exhibit 23 – Meeting Estimates)**
 - Typically the lowest cost is selected unless compelling reasons exist and a higher cost site is approved in advance by VACO.
- d. Plan for the HRC to meet with DMC to conduct the annual HRC review.**
 - Having the meeting in proximity to the CSPCC is an important consideration to keep costs down.
- e. Reserve hotel sleeping accommodations and meeting rooms.**
 - Obtain purchase order and contract from hotel.
- f. Determine special goals of the meeting beyond usual study progress update**
 - Goals may include SMART Training, Site Coordinator Training, special laboratory training, etc.
- g. Notify participants of the date, location, time, etc. (See Memos 34 and 35).**
- h. Confirm attendance by meeting participants.**
- i. Request travel funds from VACO (Exhibit 3).**
- j. Send Travel Instructions, (Memo 35), LOA's (Letters 36 and 36A) and TWX (Exhibit 3) one month before the meeting. CSPCC Travel Clerk should provide a copy of the travel authorization to the Administrative Officer at respective VA sites.**

3. Pre - Meeting Preparation Tasks

- a. Hotel Arrangements**
 - Audiovisual needs confirmed
 - Finalize menu (if applicable)
 - SMART requirements
- b. Prepare other material to be made available at the time of the meeting.**
 - Name tags
 - List of expected attendees
 - Additional or revised agenda
 - Handouts, e.g., hard copy of PowerPoint presentations, etc.
- c. All meeting material should be distributed approximately 3 weeks prior to the meeting to allow the participants sufficient time to review the material and formulate questions and identify issues relative to the study.**
 - Meeting Agenda
 - Progress Report
 - Written synopsis of any proposed changes
 - Training material (if applicable)

References:

- CSP Global SOP 2.2.0 – Study/Travel Meetings, Attachment 2
- Exhibit 3 – Request for Travel Funds
- Exhibit 23 – Meeting Estimates
- Checklist 13 - Active Studies Checklist Items 3 – 15.
- Checklist 14 – Meeting Checklist

4. **Meeting Activity Tasks**
 - a. **Obtain signature of all attendees.**
 - b. **Ensure that minutes are recorded.**
 - c. **Establish that there is a quorum and, if applicable, appropriate representation.**
 - Executive Committee Meeting – quorum
 - DMC – statistician
 - HRC – quorum (to include physician and veteran)
 - *Note: if meeting held distant to the CSPCC, the HRC Chair can meet with the DMC and report back to the HRC.*
 - Special Consideration needed for DMC and HRC Meetings –
 - Blind must be maintained in presence of Chairs and others not privileged to unblinded data.

References:

- CSP Global SOP 2.2.0 – Study/Training Meetings, Attachment 3
- Checklist 13 - Active Studies Checklist Items 16-19

5. **Post–Meeting Tasks**
 - a. **Distribute Study Group Minutes to all Study Participants and VACO within 30 days of meeting.**
 - b. **Distribute Executive Committee Minutes to all members of the Executive Committee and VACO within 30 days of meeting.**
 - c. **Distribute DMC Minutes to all members of the DMC and VACO within 30 days of meeting.**
 - d. **Obtain DMC Executive Summary and summary of data safety from CSPCRPCC and distribute to SIs for use in reporting to their local IRBs. (See [Exhibit 24](#))**
 - e. **Distribute HRC Minutes to all members of the HRC.**
 - f. **Resolve any travel issues identified by study participants.**
 - g. **Calculate final cost of meeting for budget reporting purposes and future reference.**
 - h. **Maintain copies of all study minutes, meeting agendas, and correspondence in the Central Study File.**

Note: Minutes must be signed to be considered valid. The authorized signatory will usually be the Chairperson of the meeting, i.e. Study Chair would sign the Study Group and Executive Committee minutes, the DMC Chair would sign the DMC minutes, and the HRC Chair the minutes of the HRC Meeting.

References:

- CSP Global SOP 2.2.0 – Study/Training Meetings
- Standard Operating Procedures for Protection of Human Subjects in Research
- CSP Guidelines, Chapter V, “Conducting a CSP Study”, Section C, “Meeting/Travel Arrangements”
- Exhibit 23 – Meeting Estimates
- Exhibit 24 – Data Monitoring Committee Executive Summary
- Checklist 13 – Active Studies Checklist Items 20 – 27.

III. Study Budgets – Ongoing Monitoring

A. Budgetary Monitoring

1. The Project Manager will routinely monitor funding requests from the participating sites to ensure that they are within the financial constraints originally established. Significant variance from the original budget or “new” expenditures will require approval from VACO.
2. **Tasks:**
 - a. **The Project Manager will prepare the Annual Budget Request for submission to VACO.**
 - b. **Send correspondence to R&D Offices of participating sites by January 1 of each year requesting budget projections for next fiscal year (October thru September). (See Exhibit 25)**
 - Response from site requested no later than January 31.
 - c. **Compare each site’s budget request with the initial study budget**
 - If within reason, no action required.
 - If considerable additional funds or “new” purpose funding is requested by an individual site obtain justification and Chair’s approval.
 - d. **Project Manager should check for the following:**
 - If there is a “new” or significant increase in cost to the study, not site specific, e.g., increase in contracted services for laboratory testing, etc.
 - Type of funds required – Program 870 or 825
 - If applicable, in collaboration with Study Chair formulate justification for these additional costs.
 - e. **Compile study budget, including justification as appropriate.**
 - f. **Obtain initial review and approval from Administrative Officer and Study Biostatistician.**
 - g. **Obtain CSPCC Director’s Approval.**
 - h. **Forward the budget to Chair for final approval.**
 - i. **ADO/AO will compile with other study budgets and will forward official funding request to CSP Deputy Director for action/approval. (See Exhibit 26).**

References:

- Exhibit 25 – Request for Site Budget Projections
- Exhibit 26 – Study Budget Template
- Checklist 13 – Active Studies Checklist Items 28-35

B. Interim Requests for Additional Funding Support

1. Requests received during the course of the year that are in excess of the approved budget will require justification. Minor variances in personnel salaries may be necessary due to site personnel requiring additional personnel coverage due to extended sick leave or family leave situations – these situations can usually be easily justified. However, major increases in funding support will require strong justification and alternative solutions should be provided.
2. **Tasks:**
 - a. **In collaboration with Study Chair formulate justification for additional costs.**

- b. Obtain initial review and approval from Administrative Officer and Study Biostatistician.
- c. Obtain CSPCC Director's approval.
- d. Forward budget to Study Chair for final approval.
- e. Forward official funding request to CSP Deputy Director for action/approval. (See Memo 37). When approved, send Funding Request Form (Exhibit 22) to VACO

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section E, "Change in Funding Support"
- Exhibit 22 – Funding Request Form
- Checklist 13 - Active Studies Checklist Items 36-39.

IV. Updates

A. CSP Website <https://vaww.csp.research.med.va.gov/default.cfm>

1. The CSP website provides VACO, the CSPCCs, and Research Investigators with up-to-date information on the activities of the CSP program, the studies conducted by the CSP, and specific information pertinent to the operations of each of our clinical trials. The value of a website is dependent upon it containing current and accurate information.
2. Information contained on the website include:
 - a. Program-Wide Components
 - CSP Guidelines
 - Staff Operations Manual
 - Standard Operating Procedures
 - CSPCC Downloads (e.g., CSPCRPCC Drug Code Book, etc.)
 - b. Study Specific Components
 - Study Profile/Fact Sheet – brief synopsis of the study's design and objectives
 - Study Participants – names, affiliations, contact information, and function of the study
 - IRB Review Status for each participating site
 - Research Protocol (to be added at a future date) on Clinical Trials Support Center (CTSC)
 - Study Operations Manual including Case Report Forms (to be added at a future date) on CTSC
 - Study Publications
 - c. Center Specific Components
 - CSPCC Human Rights Committee Membership Roster
 - CSPCC Human Rights Committee Site Visits
3. Tasks:
 - a. **Routine review and updating is required quarterly.** However, CSP requires that when significant changes occur in a study, the web-site be updated in real time, i.e., as the information becomes available.
 - Project Manager -- is responsible for maintaining the "Study Specific Component" of the website.
 - Human Rights Coordinator – is responsible for maintaining the "Center Specific Components" of the website.
 - Web Master – the Web Master will be responsible for maintaining "Program Wide Components"

- b. It is **required** that the material maintained on the website will be the most recent “approved” version of the protocol and operations manual.

References:

- CSP Global SOP 2.1.0 – Developing, Approving and Amending Protocols
- Checklist 13 - Active Studies Checklist Item 40

V. Monitoring

A. Executive Committee Monitoring

1. The Executive Committee acts as the management group and decision-making body for the operational aspects of the study. The Committee meets nine months after the start of recruitment and annually thereafter and is typically held during the annual study group meeting. It decides on the following:

- Proposed changes in the study and on any subprotocols
- Use of study data
- Publication of study results
- Recommends actions or medical centers whose performance is unsatisfactory

2. **Tasks:**

- a. **Project Manager schedules Executive Committee Meeting**
- b. **Draft minutes prepared and distributed to Executive Committee members and VACO within 30 days of meeting.**
- c. **Copies of the minutes and all Executive Committee communications are kept in the Central Study File.**

Reference: Checklist 13 – Active Studies Checklist Items 41-43.

B. DMC Monitoring

1. The Data Monitoring Committee must conduct an in-depth assessment of safety and efficacy data at least annually. It is preferred that a face-to-face meeting be held for the annual reviews. Interim reviews and urgent need meetings of the DMC may be held via telephone conference.
2. The Data Monitoring Committee meetings will usually be held at the same intervals as and in conjunction with the Study Group/Executive Committee. The DMC meeting is usually held at or near the coordinating CSPCC so that the Data Monitoring Committee (or at least the DMC Chair) can meet with the Human Rights Committee to review issues pertinent to patient welfare.
3. At the initial DMC Meeting, the DMC establishes a monitoring plan to evaluate the safety and efficacy of the trial. The monitoring plan will remain in place during the course of the study. The DMC stipulates the type of analysis and sequential statistical procedures required to adequately monitor the study. At each subsequent meeting the DMC will review the material presented, request additional data if necessary, and evaluate the study's progress including enrollment, site performance, safety (adverse events and serious adverse events) and efficacy and review any new protocol amendments or sub-studies.
4. An Executive Summary of the DMC Meeting is prepared by the Project Manager or Biostatistician and signed by the DMC Chair. (See **Exhibit 24**). This Executive Summary is submitted to the participating IRBs along with a blinded summary of safety data through the Site Investigator and ACOS for R&D.

5. Minutes of each DMC review are recorded and submitted to the CSPCC Director for response by the Director and Study Biostatistician and subsequently forwarded to VACO. The minutes will state those actions that the Committee deems necessary or highly desirable. These are phrased as recommendations to Director, CSR&D who can either accept or reject the recommendations.
6. **Tasks:**
 - a. **Project Manager schedules the DMC Meeting.**
 - b. **Draft minutes forwarded to DMC Chair for comments.**
 - c. **Responses to the minutes are obtained from the Study Biostatistician, Study CRP, AE/SAE Specialist and CSPCC Director.**
 - d. **Once minutes are finalized, distribute copies to all appropriate individuals.**
 - e. **Copies of the minutes and all DMC communications are kept in the Central Study File.**
 - f. **The Executive Summary (Exhibit 24) is prepared.**

References:

- Human Rights Committee SOP
- CSP Global SOP 2.1.0 Developing, Approving and Amending Protocols
- CSP Global SOP 2.4.0 Study Initiation
- CSP Global SOP 2.9.0 Developing and Conducting Statistical Analyses
- CSP Global SOP 3.2.0 Central Monitoring
- CSP Global SOP 5.2.0 Data Monitoring Committee
- CSP Guidelines, Section V, "Conducting a CSP Study", Section A, "CSP Study Management and Monitoring", Part 4, "Human Rights Committee"
- Exhibit 24 – Executive Summary of DMC Meeting
- Checklist 13 – Active Studies Checklist Items 44-48

C. HRC Monitoring

1. The Human Rights Committee will perform an initial review of all research protocols conducted by their local CSPCC. HRC monitoring of all ongoing studies will be conducted annually unless more frequent monitoring is deemed necessary. The HRC will meet with the DMC or at a minimum the DMC Chair annually to be updated by the DMC relative to the progress of the study, safety concerns identified by the DMC, and to query the DMC relative to HRC concerns about the study.

The HRC will receive the same unblinded Progress Report that is prepared for the DMC. Note that there are some instances where the HRC will receive blinded Progress Reports. Interim Progress Reports will be reviewed by the Chair of the HRC and at his/her discretion a meeting of the full HRC may be called if needed.

The HRC will review and approve all changes to protocols and consent documents prior to implementation or use. Prompt reporting by the CSPCC Director to the HRC of any unanticipated problems involving risks to subjects, serious or continuing non-compliance with regulations is required.

Minutes of all HRC meetings will be recorded (See Annual Meetings in this Staff Handbook).

2. **Tasks:**
 - a. **HRC Coordinator or Quality Assurance Specialist will be responsible for scheduling all HRC meetings and sending Letter 38 to HRC members, documenting the meeting minutes and identifying sites in need of a HRC Site visit.**
 - b. **Project Manager is responsible for maintaining HRC Minutes in the Central Study File.**

Reference: Checklist 13 - Active Studies Checklist – Items 49-50.

D. SMART Monitoring

1. SMART conducts three types of visits to sites participating in CSP trials, i.e., monitoring visits, GCP site reviews and for-cause audits. The types and frequency of visits conducted for a trial are dependent on the nature of the trial as determined during planning. Each trial is budgeted to receive a program of routine site visits consisting of either monitoring visits or GCP site reviews. CSP trials that are intended to produce data for submission to FDA receive frequent and intense monitoring visits funded by the organization that anticipates submitting the data, e.g., other federal agencies or an industry partner. Trials not intended to produce data for an FDA submission receive GCP site reviews rather than monitoring visits. These reviews are typically conducted annually, but the budgeted frequency can be increased or decreased for trials presenting atypical levels of patient or regulatory risk. At a minimum, each site in a trial is visited at the start of the trial to set up GCP tools and practices.
2. A third type of visit, i.e., a for-cause audit, is budgeted for each trial on a limited basis to supplement the monitoring visits for GCP site reviews. For-cause audits are requested by study management as needed for any site in any trial when problems in study conduct are known or suspected. The request is made to the Director, CSPCRPCC.
3. **Tasks:**
 - a. **SMART schedules monitoring visits, GCP site reviews and for-cause audits as required.**

References:

- VHA Handbook 1200.5 – Requirements for the Protection of Human Subjects in Research
- CSP SMART SOP 6.1.0 – Pre-study Site Monitoring
- CSP SMART SOP 6.2.0 – Routine Site Monitoring
- CSP SMART SOP 6.3.0 – Closeout Site Monitoring
- CSP SMART SOP 6.4.0 – Coordination of Site Monitoring by External (Non-CSP) Monitors
- CSP SMART SOP 7.3.0 – Planning and Conducting Site Audits
- CSP SMART SOP 7.4.1 – GCP Site Reports and Follow-Up
- Checklist 13 - Active Studies Checklist Item 51

E. Periodic Reporting

1. As data are received at the CSPCC, they are key-entered, edited, and entered into the master file according to locally developed procedures for database management. (Note: Palo Alto does not key-enter; they use fax submission of data.) The Biostatistician establishes a routine for ongoing review of these data as they are received and for periodic reporting.
2. **Tasks:**
 - a. **Biostatistician creates a progress report**
 - A summary of patient screening and intake, baseline data, and other information about the progress of the study, which is not broken down by treatment group, is sent to the Study Group and Executive Committee three weeks before each annual meeting.

- An unblinded copy of the report with protocol specific analysis is generated for the DMC and HRC.

References:

- Standard Operating Procedures for Protection of Human Subjects in Research
- CSP Global SOP 3.6.1 – Reporting Adverse Events
- CSP Global SOP 6.1.0 – Pre-study Monitoring
- CSP Guidelines, Chapter V, “Conducting a CSP Study”, Section H, “Reporting of Adverse Events, Serious Adverse Events and Unanticipated Adverse Device Effects”
- Checklist 13 - Active Studies Checklist Item 52.

F. Adverse Events and Code Activity

1. Each protocol will define what adverse events will be collected for both routine and expedited reporting. Forms and instructions for recording these events will be provided in the Study Operations Manuals. If a study treatment is blinded (masked), code break activity is closely monitored since the potential for breaking the blind is of concern for both scientific and ethical reasons.
2. **Tasks:**
 - a. **The Study Clinical Research Pharmacist or AE Specialist at the CSPCRPCC is responsible for monitoring AEs and SAEs**
 - Take the appropriate procedures for notification of CSPCCs, VACO, Participating Sites, and the FDA, if appropriate.
 - b. **Study Clinical Research Pharmacist is responsible for code break activity.**
 - Compile an ongoing record of all code break activity occurring during a study.

References:

- CSP Guidelines, Chapter V, “Conducting a CSP Study”, Section H, “Reporting of Adverse Events, Serious Adverse Events and Unanticipated Adverse Device Effects”
- CSP Global SOP 3.6.1 – Reporting Adverse Events
- CSP Global SOP 5.2.0 – Data Monitoring Committee
- CSP Global SOP 6.1.0 – Pre-study Monitoring
- Checklist 13 - Active Studies Checklist Item 53.

G. Adverse Event Monitoring of CSPCRPCC/non-CSPCRPCC Studies

1. The CSPCRPCC Director or designee will inform the Director, CSR&D and Director, CSPCC, of SAEs and Unanticipated Adverse Device Effects (UADE) that in his/her judgment, the Director, CSR&D needs to be aware of. This includes studies that do not include drug or device components, e.g., surgical trials.
2. **Tasks:**
 - a. **Study Clinical Research Pharmacist or AE Specialist identifies serious adverse events or unanticipated adverse device effects that require reporting to CSPCC and CSR&D.**
 - b. **Events are reported in writing through the CSPCRPCC Director or designee after consulting with the study team and CSPCC. Events reported to regulatory authorities are reported at the same time to CSR&D.**

References:

- CSP Global SOP 3.6.1 – Reporting Adverse Events
- 21 CFR 312 – Investigational New Drug Application
- ICH Guidelines E2A – Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- Checklist 13 - Active Studies Checklist Item 54-55.

H. Patient Accrual

1. Patient accrual and losses will be monitored throughout the study. Adequate patient accrual is integral to the success of any research trial. Likewise, the dropout rate also impacts on whether or not the primary objective(s) of a study can be reached. The required patient sample size is defined in each study protocol. It will be the responsibility of the Study Programmer under the direction of the Study Biostatistician to routinely (*monthly*) prepare a report that includes number of patients screened, enrolled, terminated, lost-to-follow-up, or deceased.
2. On a quarterly basis, the CSP Deputy Director will request patient accrual and losses information to be included in a report to the Office of Management and Budget (OMB). Format for reporting this information will be provided by VACO.
3. **Tasks:**
 - a. **The Study Programmer under the direction of the Study Biostatistician will prepare a detailed table displaying patient accrual and losses.**
 - b. **The Project Manager will distribute the Table to the Study Chairs, CSPCC Director, participating sites, and DMC if appropriate.**
 - c. **DMC evaluation required if accrual is equal to or below 80%.**
 - If intake is in the range 65-80% of the expected sample, the Data Monitoring Committee should be notified. An in-depth evaluation of the accrual history by site should be performed and recommendation formulated. Possible recommendations include: study terminated or placed on probation, specific site(s) terminated or placed on probation.
 - Likewise, the DMC will take into consideration the drop out rate and what affect it will have on meeting the study objectives.
 - d. **OMB information (as directed by CSP Deputy Director) will be provided to VACO on quarterly basis.**

References:

- CSP Guidelines , Chapter V, "Conducting a CSP Study", Section A, "CSP Study Management and Monitoring", Part 3, "Data Monitoring Committee"
- Standard Operating Procedures for Protection of Human Subjects in Research
- Checklist 13 - Active Studies Checklist Items 56-57

I. Annual Review of Protocol by IRB/R&D

1. VA Regulations and CSP Policy mandate initial and annual review of all studies by the participating centers Human Studies Subcommittee/IRB and the local Research and Development Committee. The CSPCC will be responsible for ensuring initial and annual review by obtaining copies of the minutes of the local IRB review or a letter signed by the Chair of the IRB detailing the date of the review, the material reviewed, and the IRB decision on the study plus a copy of the approved informed consent. Like documentation will be required from the local R&D.
2. **Tasks:**
 - a. **Project Manager sends out reminder e-mail**
 - A reminder e-mail should be sent to the SI at least two months before the anniversary date of the initial review. A copy of this reminder e-mail should be sent to the site's ACOS for Research and Development.
 - b. **Project Manager sends out 30 day reminder e-mail**
 - Additional annual review reminder e-mail should be sent to the site as needed.

- c. **Project Manager requests approval from VACO to suspend site.**
- d. **Project Manager sends out suspension letters if approval is not received prior to expiration date.**
 - For those sites who fail to provide annual review documentation, **Memo 39** should be prepared and forwarded to VACO which serves to inform the Director, Clinical Science R&D Service of the problem and to also seek his/her concurrence. Project Managers should follow up immediately with VACO in order to receive concurrence in a timely manner. Once concurrence is obtained, forward **Letter 40** to the SI that suspends screening and randomizations. **Letter 41** is sent to the suspended site once annual review documentation has finally been provided to the CSPCC.

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section F, "Ethical Considerations", Part 3, "Yearly Medical Center Reviews"
- CSP Global SOP 5.1.0 – Assuring the Research and Development (R&D) Committee and Institutional Review Board/Independent Ethics Committee (IRB/IEC) Approval of Research
- VHA Handbook 1200.5 – Requirement for the Protection of Human Subjects in Research
- Checklist 13 - Active Studies Checklist Item 58.

J. Human Rights Site Visits

1. Human rights site visits to a medical center participating in a cooperative study are intended to observe, through discussion with the SI and study patients, the implementation of and the compliance with the informed consent procedure as stated in the protocol; also, the adherence to the underlying spirit and intent of protecting the rights and welfare of the patients.
2. A member of the HRC will also conduct a minimum of three site visits per year to participating medical centers to observe consenting procedures and evaluate the information imparted to the study participants. The HRC member will meet with the Site Investigator and study patients in order to accomplish their evaluation of the site.
3. **Tasks:**
 - a. **Human Rights Coordinator or Quality Assurance Specialist ensures that site visits are conducted annually.**
 - Factors to be considered in selecting a medical center for a site visit would include:
 1. ongoing phase (patient intake still in progress)
 2. higher patient intake rate
 3. availability of patients for interview
 4. a treatment intervention that involves a significant degree of risk for patients
 5. no prior visit for this study or any study
 6. existence of ethical problems related to the study as a whole, or specifically related to the investigator or the medical center
 7. all factors equal, locations with lower travel costs
 - b. **Project Manager coordinates site visit.**
 - Selects a date convenient to all, including patient scheduling.
 - c. **Project Manager prepares **Memo 42** for the CSPCC Director's signature requesting permission of the VAMC Director to perform the site visit.**
 - Coordinates making the travel arrangements for the HRC Member and the accompanying CSPCC staff member, usually, the Project Manager or Study Biostatistician.
 - Ensures that the Site Visit Report is completed in a timely manner and distributed.

Note: The HRC Coordinator or QAS will be responsible for reviewing the Site Visit Report to ensure that it does not contain any patients' personal identifying information other than the study ID numbers.

References:

- Standard Operating Procedures for Protection of Human Subjects in Research
- Checklist 13 - Active Studies Checklist Items 59-60.

K. Site Procedures for Closeout

1. The Study Biostatistician should discuss a study closeout plan with the Study Chair, Executive Committee and Study Team. Once this group approves the plan, it should be sent to the participating sites.
 - a. The plan should include items such as Procedures & Responsibilities; conducting patient closeout interviews; mailing of letter to study patients (if required); equipment disposal; record retention; publication plan; retaining IRB approvals if needed for any final materials (letters, etc.) that may be going to patients; and informing IRB of the ending date. VA sites should also notify their R&D offices.
 - b. For funding procedures, refer to CSP Staff Operations Manual, "Study Closeout", Section I, "Termination of Funding".
2. **Tasks**
 - a. **Closeout plan to be distributed to sites when appropriate.**

Reference:

- CSP Guidelines, Chapter VI, "Concluding a CSP Study", Section A, "Closing Down"
- CSP Global SOP 4.1.0 Archiving Study Documentation
- CSP Global SOP 4.2.0 Study Closeout
- CSP Staff Operations Manual, "Study Closeout"
- Checklist 13 - Active Studies Checklist Item 61

Checklist 13 - Active Studies Checklist

<u>DATE</u>	<u>TASK</u>
_____ 1	Training Requirements: Project Manager ensures all study personnel complete required training.
_____ 2	SMART publishes a listing of all GCP course offerings and maintains a database of all attendees of GCP courses.
_____ 3	Annual Meetings: Determine Annual Study Group, Executive Committee, DMC and HRC meeting dates. Project Manager should begin planning meetings approximately 6 months in advance of target meeting time. See Checklist 14 .
_____ 4	Establish meeting date.
_____ 5	Determine meeting location by obtaining cost estimates from 3 locations. See Exhibit 23 .
_____ 6	Arrange for HRC to meet with DMC to conduct annual HRC review.
_____ 7	Reserve hotel sleeping arrangements and meeting rooms; obtain purchase order and contract from hotel.
_____ 8	Determine special goals of meeting beyond usual study progress update.
_____ 9	Notify participants of date, time, location of meeting (Memo 34 and Memo 35)
_____ 10	Confirm attendance by meeting participants.
_____ 11	Request travel funds from VACO (Exhibit 3).
_____ 12	Send travel instructions, LOAs, TWXs one month before meeting (Memo 35, Letters 36 and 36A and Exhibit 3). CSPCC Travel Clerk should provide a copy of the travel authorization to the Administrative Officer at respective VA sites.
_____ 13	Confirm audiovisual requirements of speakers; finalize menu with hotel and determine any SMART requirements.
_____ 14	Prepare other material to be made available at time of meeting: name tags, list of expected attendees, additional or revised agenda, and handouts.
_____ 15	Approximately 3 weeks prior to meeting send meeting materials to participants: agenda; progress report, written synopsis of any proposed changes, and training material (if applicable).
_____ 16	Obtain signatures of all attendees.
_____ 17	Ensure that minutes are recorded.
_____ 18	Establish there is quorum and if applicable, appropriate representation.
_____ 19	Confirm that blind is maintained during meeting in presence of Chairs and others not privileged to unblinded data.

<u>DATE</u>	<u>TASK</u>
_____ 20	Distribute Study Group Minutes to all Study Participants and VACO within 30 days of meeting.
_____ 21	Distribute Executive Committee Minutes to all members of the Executive Committee and VACO within 30 days of meeting.
_____ 22	Obtain/distribute DMC Minutes to all members of the DMC and VACO within 30 days of meeting.
_____ 23	Obtain DMC Executive Summary and summary of data safety from CSPCRPCC and distribute to SIs for use in reporting to their local IRBs. (See Exhibit 24).
_____ 24	Distribute HRC Minutes to all members of the HRC.
_____ 25	Resolve any travel issues identified by study participants.
_____ 26	Calculate final cost of meeting for budget reporting purposes and future reference.
_____ 27	Maintain copies of all study minutes, meeting agendas, and correspondence in the Central Study File.
_____ 28	Budgetary Monitoring: Project Manager will prepare the Annual Budget Request for submission to VACO.
_____ 29	Send correspondence to R&D Offices of participating sites by January 1 st of each year requesting budget projections for next fiscal year. See Exhibit 25 .
_____ 30	Compare each site's budget request with the initial study budget.
_____ 31	Project Manager should check budget for any new or significant increases in cost.
_____ 32	Compiles study budget, including justifications, for review by Administrative Officer and Study Biostatistician.
_____ 33	Obtain CSPCC Director's approval.
_____ 34	Forward budget to Chair for final approval.
_____ 35	ADO/AO will compile with other study budgets and will forward official funding request to CSP Deputy Director for action/approval. See Exhibit 26 .
_____ 36	Interim Requests for Additional Funding Support: If additional funds are required for a study, formulate justification and obtain reviews and approvals from Administrative Officer, Study Biostatistician, CSPCC Director, and Study Chair.
_____ 37	Obtain CSPCC Director's approval.
_____ 38	Forward budget to Study Chair for final approval.
_____ 39	Forward official funding request (Memo 37 to VACO for action/approval. When approved, send Funding Request Form (Exhibit 22) to VACO
_____ 40	CSP Website: Update CSP website required on quarterly basis; however when significant changes occur, update in real time.

<u>DATE</u>	<u>TASK</u>
_____ 41	Executive Committee Monitoring: Project Manager schedules Executive Committee Meeting.
_____ 42	Draft minutes prepared and distributed to Executive Committee members and VACO within 30 days of meeting.
_____ 43	Copies of minutes and all Executive Committee communications are kept in the Central Study File.
_____ 44	DMC Monitoring: Project Manager schedules DMC meeting.
_____ 45	Draft minutes forwarded to DMC Chair for comments.
_____ 46	Responses to minutes are obtained from the Study Biostatistician, Study CRP, AE/SAE Specialist, and CSPCC Director.
_____ 47	Distribute DMC minutes after they are finalized; file copy of minutes and all DMC communications in Central Study file.
_____ 48	Executive Summary (Exhibit 24) is prepared.
_____ 49	HRC Monitoring: The HRC Coordinator or Quality Assurance Specialist is responsible for scheduling HRC meetings, notifying committee members (Letter 38), documenting minutes, and identifying sites in need of a HRC Site Visit.
_____ 50	Project Manager is responsible for maintaining HRC minutes in the Central Study File.
_____ 51	SMART Monitoring: SMART schedules monitoring visits, GCP site reviews and for-cause audits.
_____ 52	Periodic Reporting: Biostatistician prepares Progress Report for distribution to Study Group and Executive Committee; unblinded copy provided to DMC and HRC.
_____ 53	Adverse Events and Code Activity: Study Clinical Research Pharmacist or AE Specialist is responsible for monitoring AEs, SAEs and code break activity
_____ 54	Adverse Event Monitoring of CSPCRPCC/non-CRPCRPCC Studies: Study Clinical Research Pharmacist or AE Specialist identifies SAEs or UADEs that require reporting to CSPCC and CSR&D.
_____ 55	Events are reported in writing through the CSPCRPCC Director or designee after consulting with the study team and CSPCC. Events reported to regulatory authorities are reported at the same time to CSR&D
_____ 56	Patient Accrual: Study Programmer prepares patient accrual and losses tables for distribution to Study Chairs, CSPCC Director, participating sites and DMC if appropriate. DMC evaluation required if accrual is equal to or below 80%.
_____ 57	OMB information (as directed by CSP Deputy Director) will be provided to VACO on quarterly basis.

DATE

TASK

Annual Review of Protocol by IRB/R&D:

_____ 58

Reminder e-mail sent to sites at least 60 days before review due; 30 day reminder sent if required; suspension letters sent if necessary (**Memo 39, Letter 40 and Letter 41**).

Human Rights Site Visits:

_____ 59

Human Rights Coordinator or QAS ensures that site visits are conducted annually.

_____ 60

Project Manager coordinates site visit; prepares **Memo 42** to VAMC Director requesting permission to perform site visit.

Site Procedures for Closeout:

_____ 61

Closeout plan to be distributed to sites when appropriate.

Checklist 14 - Meeting Checklist

☐	DATE TO BE COMPLETED	TASK	PERSON RESPONSIBLE	TIMELINE
		Query Participants to determine Meeting Dates	Project Manager	7 Months
		Fill out Meeting Request Form	Project Manager	6 Months
		Request Proposals from Hotels	Travel Clerk	6 Months
		Prepare Meeting Worksheets (VA Employees)	Travel Clerk	6 Months
		Prepare Meeting Worksheets (Non-VA)	Travel Clerk	6 Months
		Send Estimates to Central Office	Travel Clerk	5 Months
		Obtain Signed Contract with Hotel	Travel Clerk	4 Months
		Determine Special Goals of Meeting	Project Manager	4 Months
		Notify Participants of Date, Location & Time	Project Manager	4 Months
		Send Meeting Worksheets to VACO	Travel Clerk	3 Months
		Prepare LOA's	Travel Clerk	2 Months
		Prepare TWX	Travel Clerk	2 Months
		Send Travel Instructions to VA Travelers	Project Manager	6 Weeks
		Send Travel Instructions to Non-VA Travelers	Project Manager	6 Weeks
		Prepare Material for Meeting	Project Manager	1 Month
		>Name Tags (Give list to Forms Designer)	Project Manager	1 Month
		>Prepare Sign-In Sheets (SOP 2.2.0, Attach. 3)	Project Manager	1 Month
		>Handouts or Power Point Presentations	Project Manager	1 Month
		Distribute Meeting Materials	Project Manager	3 Weeks
		>Meeting Agenda (SOP 2.2.0, Attachment 2)	Project Manager	3 Weeks
		>Progress Report	Project Manager	3 Weeks
		>Written Synopsis of any Proposed Changes	Project Manager	3 Weeks
		>Training Material (if applicable)	Project Manager	3 Weeks
		Confirm Attendance through Travel Clerk	Project Manager	1 Week
		Confirm AV Equip. through Travel Clerk	Project Manager	1 Week
		Confirm Menus through Travel Clerk	Project Manager	1 Week



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 34
2-4 weeks before every meeting

[date]

000/000
CSP #000/00

[Name of Consultant or DMC Members]
[address]

Dear _____:

The [type of meeting] for Cooperative Study “[title]” will be held at the [name of hotel] on [dates]. The hotel is located at [location of hotel]. [Provide information regarding shuttle service]. Reserve your room with the hotel by calling [phone number of reservations]. Your reservation must be made no later than [date]. To receive the government room rate of [amount], you must specify that you will be attending the **Department of Veterans Affairs, CSP #[000] Meeting**. All charges for your individual room are your responsibility. Please reserve your hotel room using your own personal credit card. The meeting will begin on [date and time] and is expected to adjourn on [date and time].

A Letter of Agreement which requests your services at the meeting is enclosed. This letter will provide for your fee and reimbursement of per diem, lodging and ground transportation expenses. **Please note there has been a change in the way you make air reservations.** Effective immediately, you should make your air reservations as follows: Call our travel agency, [name of government travel agency and phone number]. Tell them you are traveling for the Cooperative Studies Program at the Department of Veterans Affairs at [Center name]. They will assist you in making your tourist class air reservations and will issue an electronic air ticket. Please tell them that the [Center name] travel office will provide them with an obligation number for the cost of the ticket. **Since your ticket will be billed to the VA, you should not give out your personal credit card information when making your airline reservation.**

It is imperative that once you receive a copy of your itinerary from [name of government travel agency], that it be faxed to [name of travel clerk] at FAX # [travel clerk's FAX #].

Sincerely,

[name]
Project Manager
Cooperative Studies Program
Coordinating Center

Enclosures

NOTE: If the above letter is being sent to a Data Monitoring Committee Member, add the following paragraph:

Enclosed is a narrative report of the status of the study and some detailed tables of data which will form the basis of our discussion at the meeting.

Add under Enclosures: (Narrative Report & Printout)

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

PROTOTYPE MEMO 35

From: Project Manager, [medical center name] CSPCC (#000/00)

3-4 weeks before meeting

Subj: Travel Information for Meeting of CSP [#000]

To: [Name of VA Traveler], [Location]

1. The [type of meeting] for Cooperative Study #[000] “ [title]”, will be held at the [name of hotel] on [dates]. The hotel is located at [location of hotel]. [Provide information regarding shuttle service]. Reserve your room with the hotel by calling [phone number for reservations]. Your reservation must be made no later than [date]. To receive the government room rate of [amount], you must specify that you will be attending the **Department of Veterans Affairs, CSP #[000] Meeting**. All charges for your individual room are your responsibility. The meeting will begin on [date and time] and is expected to adjourn on [date and time].

2. Travel authority and advance travel funds will be forwarded to your medical center R&D office from the Cooperative Studies Program, VA Central Office. You should contact your Research Office or Travel Clerk to make your travel arrangements. Adjustments (increase or withdrawal of balance) will be made subsequent to the trip and upon notification of actual costs to [name of CSPCC travel coordinator], Travel Coordinator, CSPCC [medical center name], VAMC, [address]. Please file your travel voucher promptly.

[Project Manager’s name]

cc: ACOS for R&D [each medical center]
AO for R&D [each medical center]
Study Chair (copy of memo and list of attendees)
[AO name] CSPCC (copy of memo and list of attendees)
Study Biostatistician, CSPCC (copy of memo and list of attendees)



DEPARTMENT OF VETERAND AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 36
2-4 weeks before Meeting Review

[date]

000/00
CSP #000/00

[Name of Non-VA Traveler]
[Address]

Dear Dr. [Enter Name],

The [type of meeting] for Cooperative Studies #[000], [title], will be held at the [hotel name] on [date]. The hotel is located at [address]. [Shuttle service is available from the airport.] Reserve your room with the hotel by calling (phone number). Your reservation must be made **no later than [date]**. To receive the government room rate of [amount], you must specify that you will be attending the Department of Veterans Affairs CSP#[000]. All charges for your individual room are your responsibility. Please reserve your hotel room using your own personal credit card. The meeting will begin on [date] at [time] and is expected to adjourn at [date/time].

A Letter of Agreement which requests your services at the meeting is enclosed. This letter will provide for your fee and reimbursement of per diem, lodging and ground transportation expenses. **Please note there has been a change in the way you make air reservations.** Effective immediately, you should make your air reservations as follows: Call our travel agency, [name of travel agency at [phone #]]. Tell them you are traveling for the Cooperative Studies Program at the Department of Veterans Affairs at [CSP address]. They will assist you in making your **tourist class** air reservations and will issue an electronic air ticket. Please tell them that the [CSP Travel Office] office will provide them with an obligation number for the cost of the ticket. **Since your ticket will be billed to the VA, you should not give out your personal credit card information when making your airline reservation.**

It is **imperative** that once you receive a copy of your itinerary from Fed Traveler, that it be faxed to [Travel Clerk's Name] at FAX # ().

Sincerely,

[Study Biostatistician's Name]
Cooperative Studies Program
Coordinating Center

Enclosure (LOA)



DEPARTMENT OF VETERAN AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 36A
2-4 weeks before Meeting Review

[date]

000/00
CSP #000/00

[Name of Non-VA Traveler]
[Address]

Dear Dr. [Enter Name],

Under authority of Title 38, U.S.C. 213, Veterans Health Services and Research Administration, Department of Veterans Affairs, requests your services as a participant to attend the [NAME OF MEETING] for CSP #[000] "[title]" to be held at [hotel's name] in [city] on [date].

For these services we offer you the sum of \$___ (Per Diem: \$___; Lodging: \$___; Consultant Fee: \$___ and Ground Transportation: \$___). After these services are provided, it will not be necessary for you to make claim for reimbursement. Payment will be made by the U.S. Department of the Treasury.

If this arrangement is agreeable to you, please sign the original of this letter, insert your social security number in the space provided and return the original in the self-addressed envelope enclosed. A copy of this letter has been provided for your records.

The information requested on this form is solicited under authority of Title 38, United States Code, "Veterans Benefits", and will be used to reimburse you for services rendered. It will not be used for any other purpose. Disclosure is voluntary but failure to furnish this information will prevent our reimbursing you. Failure to furnish this information will have no adverse effect, however, on any other benefit to which you may be entitled.

Sincerely,

[Director's Name]
Director, Cooperative Studies Program
Coordinating Center

Attachment

AGREED: _____
[TRAVELER'S NAME]

SOCIAL SECURITY NUMBER: _____

TRAVEL EXPENSE ALLOWANCE

NAME: TRAVELER'S NAME
PLACE: MEETING LOCATION
DATE: _____

Expenses incurred are deductible under income tax regulations. However, Form W-2 that will be sent to you at the end of the year may indicate total compensation paid to you by the Department of Veterans Affairs. Therefore, we urge you to retain this notice for your record and to support your claim.

Per Diem (___ days @ \$___)	\$
Consultant Fee (if applicable)	\$
Lodging	\$
Ground Transportation	\$
TOTAL	\$

If you find in making your travel arrangements that we have made an error in computation, please insert the correct amount of your anticipated travel expense on the Letter of Agreement, sign it, and return it in the normal way. The error will be corrected for reimbursement.

[Name of Travel Coordinator]
Cooperative Studies Program
Coordinating Center

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 37

As needed

Date:

From: CSPCC Director, [medical center name] CSPCC (#000/00)

Subj: CSP [#000] Funding Request

To: Director, Clinical Science R&D Service, VACO

1. Attached is request from Dr. [name], Study Chair of CSP [#000], to increase funding for the Study Coordinator at the [name of VA] VAMC. The Study Coordinator is a [GS rating] employee working full-time on the study, but only being funded for half-time. Authorizing the additional funds will provide the level of funding the site would be eligible for if they had hired a nurse coordinator at half time as the protocol budget allowed.
2. The [name of VA] site is one of the top recruiting centers in this study and the workload warrants more than a half-time position. The Study Chair has recommended approval of this request based on the high productivity and excellent performance of this center.
3. I recommend approval of this request for an additional \$[amount] in Program 825 (or industry or 870) funds for the remainder of the study, through [Date].

[Name]

APPROVED/DISAPPROVED

[Name]
Director, Clinical Science R&D Service

cc: CSPCC AO [Name of CSPCC]
CSP Deputy Director, VACO (125A)
Staff Assistant – Finance, VACO
Study Chair (if applicable)
Others as appropriate



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 38
2 weeks before Annual
Review

[date]

000/00
CSP #000/00

[Human Rights Committee Members]
[title]
[address]
[city, state zip]

Dear _____:

This is to remind you that the Human Rights Committee will meet at the [place] in [city] at [time] [date] to review the cooperative study on "[title]" (#[000]). [name] from [city] is the Chairperson of this study and [name] is the Study Biostatistician.

This meeting is an annual review of an ongoing study. You will be meeting with the Data Monitoring Committee, which is the group that provides an independent oversight function for the entire study. In addition to the Study Chair and the Study Biostatistician, we expect the following to attend:

[name title institution]

Enclosed is a report prepared by [Study Biostatistician] for review by the Data Monitoring Committee and the Human Rights Committee.

Sincerely,

[name]
Director, Cooperative Studies Program
Coordinating Center

Enclosure (Biostatistician's Report)

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 39

Send to VACO when site's IRB
expired

Date:

From: Director, [name of CSPCC] (#000/00)

Subj: IRB Expiration

To: CSP Deputy Director, VACO (125A)

1. [Site Name] IRB approval for CSP #_____, “[Study Name],” expired on [Date]. Although the study was due for review, we have not received written confirmation that it was reviewed or approved. The Site Investigator and the ACOS for Research were notified in advance that written confirmation of IRB approval is needed to avoid suspension of the trial at their site.
2. In keeping with **Cooperative Studies Program Guidelines for the Planning and Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs**, I am requesting concurrence from the Director, Clinical Science R&D Service regarding suspension of CSP #_____ study activities at this site. The attached letter will be sent to the Site Investigator and to the ACOS for Research at [Site Name] once concurrence is obtained.
3. I would appreciate it if you would present this information to the Director, Clinical Science R&D Service, for review and concurrence.

[Name]
Director, [Name of CSPCC]

Attachment: **Letter #40**

concur / do not concur

(name)
Director, Clinical Science R&D Service

Date



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 40

Send when annual IRB
review is overdue

[Date]

000/00

CSP #000/00

[S.I. name]

[Address]

[City, State Zip]

Dear Dr. _____:

1. Your site has failed to provide written documentation of continuing IRB approval for CSP #_____, “[Study Name]” prior to the (month/day/year) expiration date of the previous IRB approval. Subsequently, patient screening and randomizations for CSP #____ are suspended at your site effective immediately. Please follow your local IRB’s guidelines pertaining to the safety precautions required for following patients already on board.
2. Official documentation signed by the Chair of your institution’s Human Subjects Subcommittee/IRB must be submitted to the [Name of Coordinating Center] to remove your site from suspension.
3. If you have any questions, please contact me at [phone number].

[Name]

Director, [Name of CSPCC]

cc: ACOS for R&D [Site Name]
Human Subjects Subcommittee Chairman [Site Name]
Study Chair
Study Nurse
Study Pharmacist
CSPCC AO [Name of CSPCC]
QA Specialist [Name of CSPCC]
Study Biostatistician
Study Project Manager



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 41

Send when suspension
has been lifted

[Date]

000/00

CSP #000/00

[S.I. name]

[Address]

[City, State Zip]

Dear Dr. _____:

1. Since your site has provided written documentation of continuing IRB approval for CSP #_____, “[Study Name]” the suspension of research activities related to CSP # _____ previously imposed by memo dated (m/d/y) has been lifted effective immediately.

2. If you have any questions, please contact me at [phone number].

[Name]

Director, [Name of CSPCC]

cc: CSP Deputy Director, VACO (125A)
ACOS for R&D [Site Name]
Human Subjects Subcommittee Chairperson [Site Name]
Study Chair
Study Nurse
Study Pharmacist
CSPCC AO [Name of CSPCC]
QA Specialist [Name of CSPCC]
Study Biostatistician
Study Project Manager

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 42

3-4 weeks before planned

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Human Rights Site Visit

To: ACOS for R&D (151) [S.I.'s medical center name (000)]

THRU: Medical Center Director (000)

1. I am writing to request permission to conduct a human rights site visit at your facility on [date]. It is a requirement of the Cooperative Studies Program that each fiscal year members of the [location] Cooperative Studies Human Rights Committee visit three VA medical centers that have ongoing cooperative studies that are assigned to the [location] Cooperative Studies Program Coordinating Center (CSPCC). This year the [place] VA Medical Center has been chosen for one of these visits because of its participation in the cooperative study "[title]" ([#000]).

2. [CSPCC Biostatistician or Project Manager] and CSPCC Human Rights Committee Member] will conduct the site visit at your Center. The purpose of this visit is to ensure that the human rights aspects of these studies are being observed. If possible, [HRC member] will observe at least one informed consent being given and will talk with study patients about their participation in the study. [CSPCC Biostatistician or Project Manager] and [HRC member] will also want to spend some time with the site investigator, [name].

3. Upon receipt of your permission we will proceed to work out a detailed agenda with the local investigator.

[name]

cc: CSP Deputy Director (VACO)
AO for R&D (151)
Chief of Staff
Study Chair
Site Investigator
Member, HRC

MEETING ESTIMATES

CSP #468

Meeting Dates: April 5, 2005

Meeting Type: DMC Meeting

ESTIMATE #1

Hotel Name and Location	
Name:	Hilton Suites
Address:	10 Drury Lane Oakbrook Terrace, IL 60181
Per Diem Information	
Lodging (Including taxes):	\$83.00/night + 12% tax = \$92.96/night
M&IE Rate:	\$43.00
Estimated Costs	
Total of Individual Travel Expenses (See Meeting Worksheet for breakdown)	\$ 5,231.00
Food & Beverages (Per Diem is adjusted for meals being provided)	\$ 291.20
Rental of Conference Rooms	\$ 250.00
AV Equipment	\$ 268.00
TOTAL ESTIMATED MEETING COSTS	\$ 6,040.20

ESTIMATE #2

Hotel Name and Location	
Name:	Hilton Chicago O'Hare Airport
Address:	O'Hare International Airport Chicago, IL 60666
Per Diem Information	
Lodging (Including taxes)	\$149.00/night + 14.9% tax = \$171.20/night
M&IE Rate	\$51.00
Estimated Costs	
Total of Individual Travel Expenses (See Meeting Worksheet for breakdown)	\$ 5,371.00
Food & Beverages (Per Diem is adjusted for meals being provided)	\$ 399.84
Rental of Conference Rooms	\$ 600.00
AV Equipment	\$ 360.00
ESTIMATED TOTAL MEETING COSTS	\$ 6,730.84

ESTIMATE #3

Hotel Name and Location	
Name	
Address	
Per Diem Information	
Lodging (Including taxes)	
M&IE Rate	
Estimated Costs	
Total of Individual Travel Expenses (See Meeting Worksheet for breakdown)	
Food & Beverages (Per Diem is adjusted for meals being provided)	
Rental of Conference Rooms	
AV Equipment	
ESTIMATED TOTAL MEETING COSTS	

DATA MONITORING COMMITTEE EXECUTIVE SUMMARY

Study #

Study Title

Date of Meeting

1. Phase of study:
2. Major issues at DMC:
 - a. Safety issues:
 - b. Recruitment issues:
 - (1) Number of patients accrued:
 - (2) Total sample size required:
 - (3) Percent of expected (actual sample size now/required sample size now)
 - c. Treatment effect issues:
 - d. Other issues:
3. DMC recommendations:

DMC Chairperson's Signature

NOTE: Summary to be prepared by Biostatistician for signature by the DMC Chairperson for distribution thru the Site Investigator and ACOS for R&D to IRBs at participating sites. Copy to also be provided to the Director, Clinical Science R&D Service.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date:

From: Assistant Director for Operations, _____ CSPCC ()

Subj: Submission of Request for Budgetary Support for VA Cooperative Studies for FY __

To: ACOS for R&D (151), VA Medical Center, (Center #), City, State

1. Input from your medical center is requested for the planning of budgetary support of cooperative studies coordinated by the Cooperative Studies Program for Fiscal Year __.
2. Please complete the attached budget request form(s), noting estimated personnel costs, and other operating costs associated with this study at your facility. This information can best be provided through the combined efforts of the Research Office and the Participating Investigator of this trial. The budget published in the approved protocol should serve as a guide. Please complete the attached form(s) for each study being conducted at your center during all or any part of FY __. If a Chairman's Office or laboratory is located at your center and your site is also a participant, separate forms should be completed.
3. Clinical care personnel, paid under Title 38, will have salary funds transmitted as part of the patient care budget, Program 870. This information must be submitted to the Cooperative Studies Program to ensure the ITA reflects clinical care personnel. It is requested that the name, current grade and step, and benefits for each clinical care employee be included in your submission.

NAME OF STUDY

CSP STUDY NO.

4. You should note that forms are being sent separately from five Cooperative Studies Program Coordinating Centers. As some cooperative studies at your center may be administered by different coordinating centers, forms may arrive at your center at varying times. If you have not received the form for a particular cooperative study by February 1, __, please contact the Coordinating Center charged with the responsibility for that study.
5. In providing the information requested, please be advised of the following:
 - a. Salary estimates should be based upon the projected pay schedule (January __), and include locality pay applicable to your location. **Costs associated with anticipated grade and/or step increases** for the period of January 1, __ through September 30, __ should also be included.
 - b. Columns are listed for the following: # of Paid Pay Periods, Annual Salary, Total Benefits, etc. This information is required to allow the Coordinating Centers to check computations prior to the budget review. These entries should be computed as follows:

2.

[ACOS for R&D (151)]

- (1) # Paid PP's: This column reflects the number of pay periods in the fiscal year that the individual is to be paid (i.e., 26 = full fiscal year, 13 = half fiscal year, etc.)
- (2) Annual Salary: Entries in this column reflect the annual pay rate for the employee, including locality pay, but exclusive of the estimated cost of the benefits package. Do **not** prorate salary to indicate employment for less than a full year or for part-time employment status in this entry.
- (3) Total Benefits: Please list the value of the employees anticipated benefit package. The percentage of benefits is computed based upon the annual salary. As in entry for annual salary, do **not** prorate based upon the type of length of appointment. Both actual dollar cost and percentage must be listed.
- (4) Actual Salary: This column identifies salary and benefits prorated to reflect the number of pay periods the employee is paid during the fiscal year; this column also reflects part-time employee status.
- (5) % of Time: This column indicates the employment status of the employee. If full-time, please indicate 100%; if half-time, indicate 50%, etc.

6. Employees, paid pursuant to the IPA, on contract, or fee for service agreement, should be listed with all of the above information included. Under the column, "Grade/Step", please indicate the employee is either "IPA", "Contract", or "FFS". The total amount paid to these employees will be included under "All Other Costs".

7. Please complete this form as accurately and completely as possible. VA Central Office will NOT accommodate requests for additional funds for items that could have been anticipated at the time of this budget request. It is expected that the funds requested on the attached form reflect actual needs for the study.

8. This information is needed as soon as possible, but not later than February 1, _____. Please return to the Assistant Chief for Operations, Cooperative Studies Program Coordinating Center (___), Veterans Affairs Medical Center, (City, State, ZIP). If you have any questions, please contact me at (phone #).

9. Thank you for your cooperation.

(Name)
Assistant Chief for Operations
Cooperative Studies
Program Coordinating Center

Attachment

cc: AO for Research & Development (151) (at site)

COOPERATIVE STUDIES PROGRAM, REQUEST FOR BUDGETARY SUPPORT, FY ____

VA STATION NAME «Station_Name»	STATION NO. «Station_No»
COOPERATIVE STUDY NAME «Study_Name»	STUDY NO. «Study_No»
INVESTIGATOR'S NAME «Investigators_Name»	
INVESTIGATOR'S STUDY TITLE «Investigators_Study_Title»	

1. STATUS (Check One)

Full-Time	Part-Time VA	Consultant	Attending	WOC
1. VA	2. (___/8 time)	3. (___/6 time)	4. (___/8 time)	5. (___/8 time)

2. PERSONNEL - PROJECTED FOR FY 20__

NAME OF EMPLOYEE (Indicate if new position or vacant)	Grade/Step*	#Paid Pay Periods	Annual Salary ¹	Total Benefits (%)	Actual Salary and Benefits	% of Time	Position Title
				(%)			
				(%)			
				(%)			
				(%)			
				(%)			
				(%)			

*Use two lines if projected step increase is involved: Indicate number of pay periods and costs at each level.

3. BUDGET

ITEM	ACTUAL FY __	ALLOCATION FY __	REQUESTED FOR FY __
Personnel costs including benefits - Program 870	\$ _____	\$ _____	\$ _____
Personnel costs including benefits - Program 825	\$ _____	\$ _____	\$ _____
Personnel costs including benefits - Non-Profit Corp.	\$ _____	\$ _____	\$ _____
IT costs (to include salary and all other IT expenses)	\$ _____	\$ _____	\$ _____
All other costs (including supplies and equipment) (Specify equipment in Remarks)	\$ _____	\$ _____	\$ _____
Total	\$ _____	\$ _____	\$ _____

REMARKS (Use overleaf if necessary)

¹Include locality pay.

SIGNATURE OF INVESTIGATOR		SIGNATURE OF ACOS FOR RESEARCH	
PHONE NO.	DATE	PHONE NO.	DATE

FY07 - CSP Center Core and Study Spreadsheet Instructions

Study Budget Template (Extracted from Exhibit 30A)

General

Use only these worksheets. An individual study budget sheet needs to be completed for each study, including pilot projects and career developments. Please submit a separate worksheet for each study, including NPC and Reimbursable studies. **DO NOT combine studies on a single worksheet.** Only include items in the study budgets that are in the approved study protocol or have been approved by Central Office after CSSMRB. The study budgets should include all study costs incurred at your Center (personnel & AOC). These costs will be listed under your Center. This year we have asked if you are a Center and ERIC please split the two onto individual worksheets. Indicate your Center or ERIC number on the CSP # line (for example, Palo Alto CSPCC is #145)

New Study Summary Sheet

Please insert the totals for each funding source for each study on this page. As you create your study sheets you can have that figures automatically inserted into the summary sheet.

Allocated FY 2006

You will **no longer have to fill in the previous years funding** on your spreadsheets. We have implemented this due to the limited amount of space left after adding the necessary IT appropriated funding. **I have inserted the necessary calculations on the spreadsheets for you to follow.**

Requested FY 2007 personnel costs

Salared studies - list all medical centers and indicate .825, 870, IT, and Travel. Ensure .870 funds are used for all study sites where there is a nurse working on a study. **Remember 870 funding is not an option to the field.**

Capitated studies that are receiving front-loaded payments - list each medical center and indicate the front-loaded amount in the .825 column. Capitation payments only - do not list the individual medical centers. Indicate one line item - "Estimated capitation payment" and include a total in the .825 column. Do not move line items in the worksheets.

The total should be based on estimated recruitment and the number of medical centers. Include salary costs for the chairs office(s) as a line item.

Requested FY 2007 All Other costs

Indicate costs beyond capitation rate and salaries if applicable for each site

Requested FY2007 Non-Profit

Include total payment requested for sites funded in whole or in part by the non-profit. If column filled, complete NP Details worksheet

Requested FY 2007 Travel Costs

For salared and capitated studies list out all sites and include a travel estimate using \$900/person/meeting. **On a separate line** you may request travel costs for conferences that study chair(s) if there will be any presentations of study data that a study staff member, such as a SI. These request will be approved based on the availability of funds. **Do not include this in with your regular site travel cost.**

Forecasting Worksheet

If there is a change in forecast, follow the instruction on the forecast worksheet. **Please be sure you have included the most up to date forecast.**

For each study, estimate costs until study end including the, CO approved, analysis period. Costs should be a lump sum for each entry, inclusive of salaries, equipment, supplies, etc.

CSP line items - including HERC, CSPCRPCC, and CSPCC

Personnel and AOC costs should match the information submitted on the Center Detail worksheet.

HERC and Albuquerque should provide the CSPCCs with their respective personnel and AOC totals to include.

All other costs should be submitted as one total. For explanation on the cost, please insert a comment in the cell.

If there is a lengthy explanation, please add a worksheet explaining the breakdown.

Include a total travel estimate for Center staff/DMC members based on the total expected meetings and number of attendees.

Submit a narrative explanation for any major changes to a study budget.

The submission for your Center should itemize all non-study costs in the Center - FTE & AOC report. Transfer the totals from the FTE & AOC report to the FY07 Center Core sheet.

On the FY07 Center Core sheet you should list each category on a separate line, such as DF, IT and Admin including the associated personnel & AOC for each category. Professional Development should be strategically planned and well thought out at each Center. On a separate line in the travel column for the Center,

include an estimate for Professional Development travel only. Estimate \$1000 per eligible employee and \$2000/person for

Core leadership(Director, Associate Director, ADO.) Professional Development registration fees should be a separate lin on the center AOC page.

Also include an estimate for the Human Rights site visits @ \$900 per person.

CSP #

Forecasting until Study End

	FY08		FY09		FY10	
	.825	.870	.825	.870	.825	.870
Chair office						
Sites - Capitated						
Sites - Salaried						
CSPCC						
HERC						
CRPCC						
Subtotal						
IT- Pay						
IT-Non-Pay						
Subtotal						
Travel						
Grand Total						

Please insert your most current version submitted to CO to start.
 If you deviate/change/modify any number in any out-years, please do a new table below highlighting the changes
 and an explanation must be provided.

STUDY CLOSEOUT

I. Termination of Funding

A. Written Notification

1. Each participating medical center, special laboratory, and chairperson's office should be notified of the funding expiration date so that they can begin to make arrangements for the relocation or if needed the termination of study personnel.
2. If medical center is on a capitation payment plan, notification of last payment should be sent to the participating center.
3. **Tasks:**
 - a. **Send Memo 43 to ACOS for R&D at each VA Medical Center four to six months prior to funding termination date.**
 - b. **Archival and storage of study data plan should be communicated to center in this Memo or as part of the study closeout plan.**
 - c. **The CSPCC and SMART should collaborate as to when the closeout monitoring visit is to be conducted at each site.**

Reference: Checklist 15 - Study Closeout Checklist Items 1-2

II. Unused Study Drugs Or Devices

A. Surplus

1. Upon the completion of a trial, surplus drugs or investigational devices must be handled and/or disposed of properly. The CSPCRPCC has the responsibility for related activities.
2. **Tasks**
 - a. **The CSPCRPCC will direct the return or disposition of all surplus drugs or investigational devices that were centrally distributed.**
 - b. **The CSPCRPCC will provide a final accounting of drugs or devices utilized during the study.**
 - c. **The CSPCRPCC will dispose of surplus drugs or devices in a manner determined by the CSPCRPCC.**

Reference: Checklist 15 - Study Closeout Checklist Item 3 – 5.

III. Study Equipment

A. Disposition of Study Equipment

1. Upon completion of a trial, equipment must be reviewed to determine if it can be utilized by other studies.

2. **Tasks:**
 - a. **CSPCC Administrative Officer or Project Manager will call the other coordinating centers to determine if equipment purchased specifically for the study can be usefully deployed to other studies.**
 - b. **If it is determined that the equipment can be utilized by other studies, arrangements will be made for its transfer through the appropriate Acquisition & Materiel Management Service. Otherwise, such equipment will be disposed of in accordance with the regulations of VA Handbook 7343 dated March 8, 1996. Further information on the Regional Research Equipment Program (RREP) can be found at the following website: http://www1.va.gov/oamm/oa/ars/policyreg/dirs_hbks/7343h.cfm. Contact the Administrative Officer for CSR&D for additional information.**

Reference: Checklist 15 - Study Closeout Checklist Items 6 - 7

IV. Acknowledgement of Participation

A. Certificates and Letters of Appreciation

1. At the end of the study Certificates and Letters of Appreciation should be prepared and sent to all Study Coordinators, Site Investigators, Study Chairs, and committee members.
2. **Tasks**
 - a. **Prepare the Certificates & Letters of Appreciation as defined in the table below for signature(s). Once signed, make copy for file and mail to each recipient.**

Type of Group	When	Certificate of Appreciation	Letter of Appreciation	Required Signature(s)
Site Coordinators and Nurses	After the date of last patient follow-up	Exhibit 27A	Memo 44	CSPCC Director, Study Biostatistician & Study Chair(s)
Site Investigators	After receipt of the final manuscript	Exhibit 27A	Memo 44	CSPCC Director, Study Biostatistician & Study Chair(s)
Study Chair(s)	After receipt of the final manuscript	Exhibit 27B	Memo 44	CSPCC Director & Director, CSR&D Service
DMC	After their last meeting	Exhibit 27C	Letter 45	CSPCC Director, Study Chair(s) & Director, CSR&D Service
Executive Committee	After receipt of final manuscript	Exhibit 27C	Memo 44	CSPCC Director, Study Chair(s) & Director, CSR&D Service
HRC	When a member completes a term of service	Exhibit 27D	Modified version of Letter 45	CSPCC Director & CSR&D Service
Others	Significant contribution to the success of the study	As appropriate	As appropriate	As appropriate

References:

- Exhibit 27A-27D – Certificates of Appreciation
- Checklist 15 - Study Closeout Checklist Item 8

V. Final Meetings

A. Manuscript Meeting

1. One manuscript meeting of the Executive Committee will be funded after the close of patient follow-up for the purpose of review of unblinded data summaries and final statistical analyses, and for assigning responsibility of manuscript preparation.
2. **Tasks:**
 - a. **The Project Manager should schedule an Executive Committee meeting as soon as the major analyses and results of the study are available for distribution and discussion.**
 - b. **Deadlines for completion of various sections and the complete major manuscript, as well as the more obvious secondary manuscripts should be identified.**
 - The major manuscript should be submitted to a journal for publication within 12-18 months of the close of patient follow-up.

Reference: Checklist 15 - Study Closeout Checklist Items 9 – 10.

B. Final Feedback Meeting

1. CSP may fund a “final feedback” or “wrap up” meeting of the Study Group, Executive Committee and DMC. At this meeting, the Chair and the Executive Committee present the major study results and their interpretations to the SI's and DMC. The general discussion of the results by the group may provide the manuscript writers with other useful interpretations, as well as give the SI's and DMC an opportunity to discuss the study's results and implications.
2. **Tasks**
 - a. **Final feedback/wrap up meeting should be held three to six months after the manuscript writing meeting to provide sufficient time to have a reasonably complete and final draft of the major manuscript available for discussion.**
 - b. **The judgment and recommendations of the CSPCC Director (after consultation with the Study Chair and Study Biostatistician) are very important in planning the most appropriate time for these meetings.**
 - c. **Consider conducting the final feedback meeting as a conference call if not possible to hold a meeting.**

Reference: Checklist 15 - Study Closeout Checklist Item 11

VI. Publications

A. Manuscripts

1. It is expected that there will be at least one major manuscript published from every completed cooperative study and when appropriate, from studies that are terminated early. It is also expected that these manuscripts will be submitted within 12 months after close of patient follow-up.
 - a. At the last Executive Committee meeting before the end of the patient follow-up, the Committee should submit a specific publication plan, including a timetable to the CSPCC Director so that progress of this activity can be monitored.
2. The Executive Committee is vested with the task of approving all papers to be published, but all manuscripts must be reviewed and approved by the CSPCC Director prior to submission for publication. Approval will be communicated in writing to the Director, Clinical Science R&D Service.
3. When any manuscript is accepted for publication, the Study Chair and the Study Biostatistician should write a summary of the results and send it to VACO along with a copy of the manuscript. Once the summary is approved by the Director, Clinical Science R&D Service, it should be forwarded to the Office of Research and Development's Communications Director. CSP/VACO will work with the appropriate offices to coordinate publicity efforts for major publications.
4. **Tasks:**
 - a. **Prior to submission, the CSP Center Director ensures that VA CSP is listed as the funding source and that authors have their VA affiliations indicated first.**
 - b. **Study Biostatistician and Study Chair prepare summary of the results and send through the CSPCC Director to the Director, Clinical Science R&D Service along with a copy of the manuscript to be submitted for review and concurrence. Summary should be brief, no longer than a page, indirect and informal language, describing the results of the study and its importance.**
 - c. **Study Biostatistician informs the Director, CSPCC, of the status of the submission, e.g., accepted, rejected, or submitted to another journal, or that publication is imminent.**
 - d. **The summary and a copy of the manuscript should be forwarded to the CSP Deputy Director so that publicity efforts can be coordinated.**
 - e. **Once manuscript is published, Study Biostatistician should duplicate the first page or the entire paper and provide this information to the center AO. The Perry Point CSPCC will request this material be provided to them in a particular format so it can be made available on the CSP website. Please contact VACO and Perry Point CSPCC for further guidance.**

References:

- Checklist 15 - Study Closeout Checklist Items 12 – 16
 - VHA Handbook 1200.19 – "Presentation of Research Results" issued June 19, 2001, clarifies policies and procedures related to the proper acknowledgements of VA research in scientific publications, presentations and media interviews.
- http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=361

B. Acknowledgements

1. Proper acknowledgement of VA research support in investigator publications and presentations is a requirement. The VA affiliation of an author must be listed first before any other affiliation such as a university.

2. **Tasks:**
 - a. **CSPCC Director or Assistant Director (Operations)/AO need to check the manuscript for compliance with the CSP Guidelines (refer to Chapter VI, “Concluding a CSP Study”, Section C, “Publications”).**
 - b. **Refer to Exhibit 28 for recommendations for acknowledgements.**
 - c. **An author’s VA affiliation needs to be listed first before their university affiliation if they have a joint appointment.**

Reference:
 - VHA Handbook 1200.19 “Presentation of Research Results” issued June 19, 2001, clarifies policies and procedures related to the proper acknowledgements of VA research in scientific publications, presentations and media interviews.
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=361
 - Exhibit 28 – Recommendations for Acknowledgements
 - Checklist 15 - Study Closeout Checklist Item 17

C. Reprints

1. If reprints are ordered, copies should be distributed to all involved with the study.
2. **Tasks:**
 - a. **Project Manager should obtain an electronic version of reprint when available.**
 - b. **Project Manager should see that copies of the reprints (usually six to eight weeks after publication) are distributed as follows:**
 - **15 copies to CSPCC Director**
 - **5 of these to CSP/VACO**
 - **Copy to each SI**
 - **Copy to each Executive Committee member**
 - **Copy to each DMC member**
 - **Copy to each Human Rights Committee member**
 - **Copy to the ACOS FOR R&D at each PMC**
 - **Copy to each CSPCC/CSPCRPCC/ERIC/CERC/HERC**
 - **Retain remaining copies at CSPCC**

Reference: Checklist 15 - Study Closeout Checklist Item 18

VII. Study Files

A. Storage at CSPCC and Sites

1. Research data forms are to be kept in accessible files for at least five years after the end of patient follow-up. These files can be retained for a longer period if required by applicable regulatory requirements or as agreed with an industry sponsor/partner, or if needed by the CSP.
2. **Tasks:**
 - a. **When a study is completely over and the results published, an appropriate staff member will review the files for completeness and move them to an inactive file. It is advisable to remove redundant or non-essential material from the correspondence file at this time.**

References:

- CSP Guidelines, Chapter VI, "Concluding a CSP Study", Section A., "Closing Down"
- Checklist 15 - Study Closeout Checklist Item 19

VIII. Public Data Set Release

A. Custodianship of Data

1. The CSP is the custodian of all data collected as part of a cooperative study. All site investigators must release their data to the participating CSPCC at the appropriate time. While most data should be submitted to the CSPCC shortly after it is collected, there may be special circumstances when a Study SI or a central laboratory investigator may legitimately keep the data for longer periods of time. In these circumstances, the Director of the CSPCC will determine when the appropriate time is to submit the data to the CSPCC.
2. All analyses related to the objectives of the study and publication plan as specified in the study protocol will be performed by the CSPCC. All raw data will reside at the CSPCC and will not be released until objectives and manuscript plan as stated in the protocol have been completed.
3. **Tasks:**
 - a. **The Study Biostatistician should communicate the CSP policy regarding custodianship of data to Study Chair & Study SI in the planning and organizational stages.**

References:

- CSP Guidelines, Chapter VI, "Concluding a CSP Study", Section D, "Custodianship of Data"
- Checklist 15 - Study Closeout Checklist Item 20

B. Release of Data

1. CSPCC will act as the repository of all study data from a completed cooperative study. Under certain conditions, data may be released to other investigators after all planned objectives and manuscripts are completed & upon approval of the Study Chair, Executive Committee (if it still exists), CSPCC Director and Director, CSR&D Service.
2. **Tasks:**
 - a. **Request for data must be received in writing with what data is needed and the intended use of data.**
 - b. **Appropriate approvals must be received prior to releasing data, i.e. Study Chair, Executive Committee, CSPCC Director, and Director, CSR&D.**

References:

- CSP Guidelines, Chapter VI, "Concluding a CSP Study", Section E., "Release of Study Data Sets"
- Checklist 15 - Study Closeout Checklist Item 21

Checklist 15 - Study Closeout Checklist

<u>DATE</u>	<u>TASK</u>
_____ 1	Termination of Funding: Send Memo 43 to ACOS for R&D at each Medical Center 4-6 months prior to termination date. This memo should include an archival and storage of study data plan or should be included as part of the Study Closeout Plan
_____ 2	CSPCC and SMART should collaborate regarding when closeout monitoring visit should be conducted at each site.
_____ 3	Unused Study Drugs or Devices: CSPCRPCC will direct return or disposition of all surplus drugs or investigational devices that were centrally distributed.
_____ 4	CSPCRPCC will provide final accounting of drugs or devices utilized during the study.
_____ 5	CSPCRPCC will dispose of surplus drugs or devices in a manner determined by the CSPCRPCC.
_____ 6	Study Equipment: CSPCC AO or Project Manager will call other centers to determine if equipment purchased specifically for a study can be usefully deployed to other studies.
_____ 7	If equipment can be utilized, proper arrangements will be made for transfer.
_____ 8	Acknowledgement of Participation: Refer to Table 1 for distribution of Memos 44 and 45 and corresponding certificates (Exhibits 27A thru 27D)
_____ 9	Manuscript Meetings: Project Manager should schedule an Executive Committee meeting once major analyses and results are available for distribution and discussion.
_____ 10	Identify deadlines for completion of major manuscript; identify secondary manuscripts.
_____ 11	Final Feedback Meeting: Final Feedback/wrap up meeting should be held 3-6 months after manuscript writing meeting. Timing as to when to have this meeting (or perhaps as a conference call) is important; therefore the CSPCC Director will determine (after consultation with Study Chair and Study Biostatistician).
_____ 12	Manuscripts: Prior to submission, the CSP Center Director ensures that VA CSP is listed as the funding source and that authors have their VA affiliations indicated first
_____ 13	Study Biostatistician and Study Chair prepare summary of results and along with copy of manuscript send this information thru the CSPCC Director to the Director, CSR&D Service.
_____ 14	Study Biostatistician informs the Director, CSPCC, of the status of the submission.
_____ 15	Summary of results and copy of manuscript should be forwarded to the CSP Deputy Director so that publicity efforts can be coordinated.
_____ 16	Details regarding this manuscript will be provided to the Perry Point CSPCC (upon request) for inclusion in a database which will be made available on the CSP website.

DATE

TASK

Acknowledgements:

_____ 17 CSPCC Director or AO need to check manuscript for compliance with CSP Guidelines. Refer to **Exhibit 28** for recommendations for acknowledgements. Author's VA affiliation should be listed before University affiliation if they have a joint appointment.

Reprints:

_____ 18 Project Manager should obtain an electronic version of reprint if available; reprints to be distributed (see CSP Staff Operations Manual Section VI., C., 2b for distribution list).

Storage of Study Files at CSPCC and Sites:

_____ 19 Files to be reviewed for completeness and moved to inactive file.

Custodianship of Data:

_____ 20 Study Biostatistician should communicate the CSP policy regarding custodianship of data to Study Chair and Study SI in the planning and organizational stage of study.

Release of Data:

_____ 21 Any request for release of data must be received in writing along with intended use of data. Approvals must be received from Study Chair, Executive Committee, CSPCC Director and Director, CSR&D.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 43
About 4-6 months before
end of funding

Date:
From: Director, [medical center name] CSPCC (#000/00)
Subj: End of Funding for CSP [#000], "[title]"
To: ACOS for R&D (151) [S.I.'s medical center name (000)]

1. This is to remind you that funding for CSP #[000] will end effective [date]. The Cooperative Studies Program will provide no additional funds for participating sites in this study beyond this date. It is, therefore, necessary that appropriate arrangements be made for the relocation or termination of personnel funded by this study.

**INSERT PARAGRAPH BELOW FOR PARTICIPATING SITES THAT ARE
DROPPED FROM STUDY OR IF STUDY IS TERMINATED EARLY.**

2. Please report all surplus funds to this Coordinating Center.

**INSERT PARAGRAPH BELOW FOR PARTICIPATING SITES THAT ARE
FUNDED ON A PER PATIENT COST.**

2. The last per patient cost payment will be made [date].

3. If you have any questions, please contact [name], Project Manager, at (insert phone number).

4. Thank you for your support of this cooperative study.

[name]

cc: Site Investigator
Study Chair(s)
CSP Deputy Director (copy of memo and list of terminated medical centers)
AO for R&D [medical center]
AO/ADO, CSPCC (copy of memo and list of terminated medical centers)

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 44

With certificate

Date:

From: Director, CSPCC

Subj: Certificate of Appreciation

To: Medical Center Director (000/00)

1. This is to express appreciation for the valuable service rendered by [name], [Executive Committee members/Study Chair/Site Investigators/Site Nurses/Site Coordinators] for CS# [000], from the [name] VA Medical Center to the VA Cooperative Studies Program.
2. It is requested that the attached copy of this certificate be placed in the recipient's personnel folder, and the attached original be presented to the person in recognition of the important contribution made to the Cooperative Studies Research effort of the Department of Veterans Affairs.

[name]

Attachments: (Certificate and Photocopy)



DEPARTMENT OF VETERANS AFFAIRS
[INSERT MEDICAL CENTER ADDRESS]

PROTOTYPE LETTER 45

After last DMC meeting

[date]

000/00
CSP #000/00

[Chairperson or Member of Data Monitoring Committee]
[title]
[street address]
[city, state zip]

Dear _____:

This letter and certificate are to express our appreciation to you for serving as (Chairperson or Member) of the Data Monitoring Committee for the Department of Veterans Affairs Cooperative Study #[000], ["title"].

Your careful monitoring of the study during its ongoing phase and valuable scientific input at the meetings contributed greatly toward the success of the study.

It was a pleasure to work with you. We will be sending you final results of the study as they become available.

Sincerely,

[Name]
Director, Clinical Science R&D Service

Enclosure

Department of Veterans Affairs

Certificate of Appreciation

Presented to

FOR MERITORIOUS SERVICE WITHIN THE VA COOPERATIVE STUDIES PROGRAM

This is given in recognition of your contribution to the Department of Veterans Affairs Cooperative Studies Program. We wish to express our sincere appreciation for your specific contributions as a

in the VA Cooperative Study on "_____."

Study Chairperson

Study Biostatistician

Director, [name of center] Cooperative Studies Program Coordinating Center



Presented on _____.

Department of Veterans Affairs

Certificate of Appreciation

Presented to

FOR MERITORIOUS SERVICE WITHIN THE VA COOPERATIVE STUDIES PROGRAM

This is given in recognition of your contribution to the Department of Veterans Affairs Cooperative Studies Program. We wish to express our sincere appreciation for your specific contributions as the Chairperson for the VA Cooperative Study on "_____."

Director, Clinical Science R&D Service

Director, [name of center] Cooperative Studies Program Coordinating Center



Presented on _____.

Department of Veterans Affairs

Certificate of Appreciation

Presented to

FOR MERITORIOUS SERVICE WITHIN THE VA COOPERATIVE STUDIES PROGRAM

This is given in recognition of your contribution to the Department of Veterans Affairs Cooperative Studies Program. We wish to express our sincere appreciation for your specific contributions as a _____ in the VA Cooperative Study on " _____."

Director, Clinical Science R&D Service

Study Chairperson

Director, [name of center] Cooperative Studies
Program Coordinating Center



Presented on _____.

Department of Veterans Affairs

Certificate of Appreciation

Presented to

FOR MERITORIOUS SERVICE WITHIN THE VA COOPERATIVE STUDIES PROGRAM

This is given in recognition of your contribution to the Department of Veterans Affairs Cooperative Studies Program. We wish to express our sincere appreciation for your specific contributions as a member of the Human Rights Committee of the [name of center] Cooperative Studies Program Coordinating Center.

Director, Clinical Science R&D Service

Director, [name of center] Cooperative Studies Program Coordinating Center



Presented on _____.

RECOMMENDATIONS FOR ACKNOWLEDGMENTS*

(Usually at end of paper before references)

- I. Office of the Chairperson/Co-Chairpersons:
(Name)(Co-Chairperson), (Name)(Co-Chairperson), (Name)(Study Coordinator, Assistant or Secretary), (Medical Center name)
- II. Participants - Medical Centers, Site Investigators and Support Personnel:
(Medical Center names in alphabetical order) (Name)
- III. Executive Committee:
(Name), (Co-Chairperson), (Medical Center name)
(Name), (Co-Chairperson), (Medical Center name)
(Name), (Study Biostatistician), (Medical Center name)
(Name), (Clinical Research Pharmacist), (VAMC, Albuquerque)
(Name), Consultant, regular, (Location)
(Name), Consultant, ad hoc, (Location)
- IV. Cooperative Studies Program Coordinating Center (CSPCC)
Director, CSPCC (Name)
Administrative Officer/ADO: (Name)
Study Biostatistician: (Name)
Statistician/Programmer: (Name)
Research Coordinator/Assistant: (Name)
Other (optional): (Name)
- V. Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC), Albuquerque, NM:
Director, CSPCRPCC: (Name)
Assistant Director for Administration: (Name)
Clinical Research Pharmacist: (Name)
Pharmaceutical Project Manager (Name)
AE/SAE Specialist (Name)
- VI. Special Laboratory:
(Name), (Location)
- VII. Data Monitoring Committee - Human Rights Committee:
Data Monitoring Committee: (Name), (Chairperson) (Biostatistician), (Location)
(List members and location)
Human Rights Committee: (Name), (Chairperson), VAMC, (Location)
(List members and location)
- VIII. Central Administration, Cooperative Studies Program (VACO):
(Name), Director, Clinical Science R&D Service
(Name), Deputy Director, CSP
(Name), Program Manager

*Be sure to include people who were with the study, made contributions, but did not remain with the study to the end.

SPECIAL CIRCUMSTANCES

I. Study Changes

A. Study Title

1. It is not uncommon during the planning stage or even after a study starts, for the Study Proponent/Chair to request that the study title be changed. Often this reflects changes in direction or emphasis that have taken place during planning. If the title is to be changed, it is desirable to do so before the CSSMRB review, i.e., before the preparation of the submission. It becomes less desirable later if the title of the study appears on study forms.
2. **Tasks (Prior to CSSMRB)**
 - a. **The Study Proponent/Chair must request the change in writing to the CSPCC Director.**
 - b. **The CSPCC Director and Study Biostatistician must concur and inform CSP/VACO and CSPCRPCC Director.**
3. **Tasks (After CSSMRB)**
 - a. **The Study Proponent/Chair must request the change in writing to the CSPCC Director.**
 - b. **The CSPCC Director and Study Biostatistician must concur and send memo to Director, CSR&D for approval.**

Reference: Checklist 16 - Special Circumstances Checklist Item 1

B. Study Budget

1. There are times during the course of an ongoing study when there may be a need to request additional funding for the study that would have an impact on the original CSSMRB budget (to include the CSP and PCC budget). Usually these changes are recommended by one of the monitoring groups such as the Executive Committee and/or DSMB. Some reasons may be to extend the patient intake period and/or follow-up period. Additional reasons for a budget increase would be to provide additional salary at a site to pay for the annual leave due to a nurse/coordinator who is retiring, or to pay for an increase in equipment operating/maintenance costs at the PCC.
2. These recommendations should be communicated to the CSP Deputy Director and Director, CSR&D Service. Any change to the CSSMRB budget must be approved by the CSPCC Director and Director, Clinical Science R&D Service.
3. **Tasks:**
 - a. **Request should be made from Study Chair to the CSPCC Director.**
 - Memo should provide justification for the change to the budget, i.e., sample size increase/decrease, need for additional equipment or personnel, extension of patient intake, etc.
 - b. **Project Manager should prepare cost estimate for the proposed change and provide the additional cost to the study to the CSPCC Director to include in his memo to the Director, CSR&D.**
 - c. **CSPCC Director sends memo to Director, CSR&D endorsing the study budget requests and requesting approval.**

Reference: Checklist 16 - Special Circumstances Checklist Item 2-3

II. Protocol Amendments/Substudies

A. Amendments/Changes

1. Subsequent to CSSMRB approval, no person or group including the Study Chair, Study Biostatistician, the Study Group, the Executive Committee, the DMC and the CSPCRPCC may unilaterally or collectively make study protocol amendments without the appropriate approvals.
2. **Tasks:**
 - a. **Project Manager or Pharmaceutical Project Manager should complete the “Executive Summary and Impact of Proposed Study Protocol Amendment/Subprotocol”. (Sample form on page 24 of CSP Global SOP 2.1.1)**

Reference:

- CSP Guidelines, Chapter V, “Conducting a CSP Study”, Section D, “Protocol Changes”
- CSP Global SOP 2.1.1 – Developing, Approving and Amending Protocols
- Checklist 16 - Special Circumstances Checklist Item 4

B. Substudies

1. Substudies are generally discouraged since they likely require additional resources and/or funds and place a burden on study personnel, the CSPCC, and the patients in the study. However, if a Study Chair or SI insists on proposing a substudy, procedures are described further in the CSP Guidelines. Substudies will only be considered when the entire study is on target with respect to expected accrual and budget.
2. **Tasks:**
 - a. **Project Manager should complete the “Executive Summary and Impact of Proposed Study Protocol Amendment/Substudy”. (Sample form on Page 24 of CSP Global SOP 2.1.1)**

References:

- CSP Guidelines, Chapter V, “Conducting a CSP Study”, Section K, “Subprotocols/Substudies”
- CSP Global SOP 2.1.1 – Developing, Approving and Amending Protocols
- Checklist 16 - Special Circumstances Checklist Item 5

C. Dual Enrollment

1. It is the CSP policy that a patient be enrolled in only one drug/device intervention, randomized clinical trial at any one time. It is permissible for patients to be in other non-interventional trials while participating in a CSP trial (e.g., surveys, long-term follow-up cohort studies, etc.).
2. Exemptions to the policy of patients participating in only one intervention trial will be allowed for individual patients on a case-by-case or a study-by-study basis.
3. Request submitted to VACO must have approval from both Study Chairs.
4. **Tasks:**
 - a. **If applicable, prepare and submit a request to Director, CSR&D Service for dual enrollment.**

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section G, "Data Collection, Editing and Patient Entry Policy"
- Checklist 16 - Special Circumstances Checklist – Item 6

III. Making Replacements

A. Medical Centers

1. If there is a need to replace a study site, the Study Chair proposes a replacement for the CSPCC's approval. The procedure for replacing a phased out medical center is identical to the original recruitment of participating centers.
2. **Tasks:**
 - a. **CSPCC Director sends memo to Director, CSR&D for approval of replacement site. Include appropriate information on Site Investigator (5/8th time, CV, training, etc).**
 - b. **Once approved, Project Manager prepares the necessary memos and sends them according to CSP Staff Operations Manual, Study Startup/Initiation section. Notify sites, CSPCRPCC , SMART and study team of change.**

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section P, "Putting a Medical Center on Probation" and Section Q, "Early Termination of a Medical Center"
- CSP Staff Operations Manual (See Study Startup/Initiation Section)
- Checklist 16 - Special Circumstances Checklist Item 7-8

B. Site Investigator

1. If there is a need to replace a Study SI, the new SI will have to be acceptable to the Study Chair and Executive Committee, and confirmed by the local IRB and R&D Committees. This information should be forwarded to the Director, Clinical Science R&D Service for concurrence.
2. New Study Co-Investigators need approval of the Study Chair and IRB/R&D. The CSPCRPCC needs to be notified if the study has drugs and/or devices involved.
3. **Tasks:**
 - a. **Study SI should send a memo recommending a replacement Study SI to the Study Chair with the new SI's curriculum vitae.**
 - b. **The Study Chair shall concur with request and forward to the CSPCC Director.**
 - c. **The Project Manager shall prepare to send Memo 46 to initiate R&D Committee approval.**
 - This memo informs the site ACOS for R&D that there is a new Site Investigator. The memo also requests that the name, degree, and social security number be sent to the Project Manager. Also confirming that the new Site Investigator is at least a 5/8th VA employee and that the required training has been met. It explains the transfer of funds procedure to the new investigator.
 - Check FDA Sanctions to ensure site personnel are eligible to participate in research.
 - Check DHSS, Public Health Services, Office of Research Integrity, Administrative Actions Listing

- If the prospective SI is less than 5/8ths then you must seek the appropriate waiver from the Clinical Science R&D Office. The request (**Memo 22**) should originate from the ACOS for R&D along with a recommendation from the Study Chair. When this is received, the CSPCC Director sends **Memo 22** to the Director, CSR&D for approval.

d. Memo 47 should be sent when Memo 46 is sent.

- This memo is from the Study Biostatistician introducing him/herself and explaining the Study Biostatistician's role in the study to the new Site Investigator.

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section O, "Replacement of a SI or Study Chairperson During the Course of a Study"
- http://www.fda.gov/ora/compliance_ref/debar/default.htm
- http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm
- http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
- <http://silk.nih.gov/public/cbz1bje.@www.orilist.html>
- Checklist 16 - Special Circumstances Checklist Item 9-10

C. Chair

1. If the Study Chair cannot continue to direct the study, he/she should inform the Director, CSPCC, in writing. In this letter he/she should nominate replacement(s) for the position. In cases of an "emergency", where there is little or no advance notice, the Director, Clinical Science R&D Service may temporarily appoint someone as Study Chair until the formal process is accomplished. However, if no suitable or available replacement Chair exists, the study may be terminated prematurely.
2. **Tasks:**
 - a. **The Study Chair should send a memo with his/her nominations for a replacement to the CSPCC Director as soon as possible.**
 - b. **The CSPCC Director sends a memo to Director, CSR&D Service for approval of replacement Study Chair.**
 - c. **After approval received from Director, CSR&D, the CSPCC Director should contact the nominees to see if they are willing to function as Chair of the study.**
 - d. **Once approved, Project Manager sends Memo 46 (appropriately modified) to initiate R&D Committee approval.**
 - e. **The Project Manger sends Memo 47 (appropriately modified) when Memo 46 is sent.**

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section O, "Replacement of a SI or Study Chairperson During the Course of a Study"
- Checklist 16 - Special Circumstances Checklist Items 11-13

D. DMC Member

1. If a DMC member must resign from the board for any reason, they should notify the Director, CSPCC in writing with possible replacement nominations.
2. **Tasks:**
 - a. **The CSPCC Director contacts the Chair of the DMC, unless it is the Chair who is resigning. In this case, the Director, CSR&D Service will discuss the replacement of the DMC member.**

- b. The CSPCC Director will contact the potential new DMC member to see if they are interested in serving on the committee.
- c. CSPCC Director may initiate **Memo 23** (appropriately modified).
- d. Once the nominated member is approved, the Project Manager sends **Letter 32 and 33** (appropriately modified) to the new member.

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section A., "CSP Management and Monitoring", Part 3, "Data Monitoring Committee"
- CSP Staff Operations Manual, Study Startup/Initiation section
- Checklist 16 - Special Circumstances Checklist Items 14-16

IV. Premature Phasing Out Of Participating Sites

A. Probation

1. If a participating center is not performing at the expected level, negotiations should take place between the Study Chair and SI. If these discussions fail to correct the problem, the Executive Committee can propose to place a participating site on probation. DMC should be notified of action taken.
2. **Tasks:**
 - a. **Study Chair sends recommendation on behalf of the Executive Committee to CSPCC Director.**
 - This memo should contain the site(s) going on probation, the probation period and the expectations during this probation period.
 - b. **CSPCC Director sends **Memo 48** to Study SI and copy to site's ACOS for R&D and if appropriate copy to CSPCRPCC Director. DMC should be notified of action taken.**
 - This memo should state the reason(s) why the center was put on probation and clearly specify the criteria the site must meet to be taken off probation within a specified time period.
3. After the probationary period has elapsed, the Study Chair should issue a follow-up letter to the Study SI evaluating the performance during the period. The letter should clearly state that the site is either taken off probation for good performance or the SI has failed to meet the probationary requirements. In case of failure, steps may be taken to decrease support or drop the site from the study. See **Memo 49** (appropriately modified).
4. **Tasks:**
 - a. **Study Chair sends memo to CSPCC Director.**
 - Memo should state rationale and the proposed action.
 - b. **CSPCC Director sends memo to Director, CSR&D**
 - Memo should state rationale and recommended proposed action.
 - Note: Concurrence from Director, CSR&D is not required.
5. In the event that the SI clearly acknowledges the lack of performance and even desires to be dropped from the study, the SI cannot act as an independent agent in the local decision. Instead, the SI should contact the local ACOS for R&D or write to the Study Chair with a copy to the local ACOS for R&D acknowledging the performance and the desire to be dropped.

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section P, "Putting a Medical Center on Probation" and Section Q, "Early Termination of a Medical Center"
- Checklist 16 - Special Circumstances Checklist Items 17-20

B. Phasing Out Medical Center

1. During the course of a study, it is sometimes necessary to drop one or more medical centers from the study. Early termination of a medical center is usually based on recommendation from the Executive Committee and most often reflects inadequate patient intake and is considered in the best interests of the study. After consultation with the Study Chair, the decision to terminate a center will be made by the CSPCC Director. The CSPCC Director will write comments and forward recommendation to the Director, CSR&D. Note that concurrence from the Director, CSR&D is not required. The DMC will be notified of the decision.
2. **Tasks:**
 - a. **A recommendation for phase out is sent to the CSPCC Director.**
 - b. **After consultation with the Study Chair, CSPCC Director writes comments and forwards the recommendation to the Director, CSR&D.**
 - c. **CSPCC Director will contact the ACOS for R&D of the participating medical center. The DMC will be notified of the decision.**
 - d. **After the ACOS for R&D has been contacted, the Project Manager will prepare Memo 50 to be sent to the SI through the Medical Center Director and the ACOS for R&D.**
 - This memo will include the date of termination and information that funding is not to exceed 45 days after termination date, including accumulated annual leave. These funds are provided for the relocation/placement of study personnel.
 - e. **Project Manager will ask the site's Administrative Officer for R&D to report all surplus study funds to the CSPCC.**
 - f. **If equipment has been purchased for the study and is needed at another medical center, instructions regarding the shipping of this equipment should be addressed in Memo 50. If the equipment is not needed by the CSP, it will be made available for other use at the site.**

References:

- CSP Chapter V, "Conducting a CSP Study", Section P, "Putting a Medical Center on Probation" and Section Q, "Early Termination of a Medical Center"
- Checklist 16 - Special Circumstances Checklist Items 21-25

C. Phasing Out a Laboratory

1. If there are reasons to phase out a laboratory (e.g., certification expiration, unsatisfactory performance, etc.) actions similar to those mentioned in Section B above (Phasing Out Medical Center) should be taken.

D. Medical Centers on Capitation

1. Some medical centers are supported by a capitation plan instead of recurring salary and all other funds. If the medical center has not received equipment, medical devices, or supplies to be used for the study, then there would be no reason to terminate early.
2. If the medical centers involved in a study have equipment, medical devices, or supplies that could be reallocated to a more promising center or a new center, then the center may be terminated early.
3. Executive Committee should set criteria for terminating a capitation center. Once the criteria are established, the process would be the same as a center that receives recurring funds.

V. Premature Termination of A Study

A. Recommendation for Termination

1. A cooperative study can be terminated before completion by recommendation to the Director, Clinical Science R&D on the basis of in-progress review by:
 - a. Data Monitoring Committee through the CSPCC Director and the Director, CSR&D.
 - b. CSPCC Director through the Director, CSR&D.
 - c. Or, the Director, CSR&D
2. The Human Rights Committee can also recommend the termination of a study.
3. If the recommendation for termination originates with the DMC, the recommendation in their report should be clear and unequivocal and should fully specify the reasons supporting this action. This report is handled in the same manner as any other DMC report.
4. **Tasks:**
 - a. **Study Biostatistician and the CSPCC Director prepare a cover memo recommending termination and distribute to the Study Chair, the DMC members, the Director, CSR&D and the CSPCRPCC Director.**
 - b. **CSPCC Director must inform CSP/VACO of this recommendation within 24 hours or sooner.**
5. If the recommendation is approved by the Director, CSR&D, the CSPCC Director will write all participating medical centers following the procedure described in CSP Guidelines, Chapter V, "Conducting a CSP Study", Section Q, "Early Termination of a Medical Center"
6. **Tasks:**
 - a. **Project Manager will make appropriate changes to Memo 50 and forward to participating sites.**

References:

- CSP Guidelines, Chapter V, "Conducting a CSP Study", Section Q, "Early Termination of a Medical Center"
- Checklist 16 - Special Circumstances Checklist Items 26 - 27

Checklist 16 - Special Circumstances Checklist

<u>DATE</u>	<u>TASK</u>
_____ 1	Changes to Study Title: Study Proponent/Chair must request change in writing to CSPCC Director. CSPCC Director and Study Biostatistician must concur and inform VACO and CSPCRPCC Director. If change is requested after CSSMRB, same procedure is followed except approval must be first obtained from Director, CSR&D.
_____ 2	Study Budget: Requests with full justification should be made from Study Chair to CSPCC Director.
_____ 3	Project Manager prepares cost estimates for proposed change and provides to CSPCC Director to include in his memo to Director, CSR&D.
_____ 4	Protocol Amendments: Project Manager should complete the "Executive Summary and Impact of Proposed Study Protocol Amendment/Subprotocol."
_____ 5	Substudies: Project Manager should complete the "Executive Summary and Impact of Proposed Study Protocol Amendment/Subprotocol."
_____ 6	Dual Enrollment: If applicable, prepare and submit a request to Director, CSR&D for dual enrollment.
_____ 7	Replacement of Medical Center: CSPCC Director sends memo to Director, CSR&D for approval of replacement site. Include appropriate information on Site Investigator.
_____ 8	Once approved, Project Manager prepares the necessary memos according to Startup section of this Staff Operations Manual. Notify sites, CSPCRPCC, SMART and study team of change.
	Replacement of Site Investigator: SI should send memo recommending replacement SI to Study Chair along with CV. If approved, Study Chair will forward to CSPCC Director. This information forwarded to Director, CSR&D for concurrence.
	Check FDA sanctions listings: http://www.fda.gov/ora/compliance_ref/debar/default.htm http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm
	Check DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listings: http://silk.nih.gov/public/cbz1bje.@www.orilist.html
_____ 9	Prepare Memo 22 if prospective SI is less than 5/8ths.
_____ 10	Project Manager prepares Memo 46 to initiate R&D Committee approval along with Memo 47 which introduces the Study Biostatistician to the new SI.
_____ 11	Replacement of Chair: Study Chair should send memo recommending replacement to CSPCC Director.

_____		CSPCC Director sends memo to Director, CSR&D for approval. After approval received, CSPCC Director to call nominee to see if willing to function as Chair.
_____	12	
_____	13	If agreed, Project Manager sends Memo 46 (appropriately modified) along with Memo 47 (appropriately modified) to initiate R&D Committee approval.
_____	14	Replacement of DMC Member: CSPCC Director contacts Study Chair regarding replacement of DMC member.
<u>DATE</u> <u>TASK</u>		
_____	15	CSPCC Director will contact the potential new DMC member regarding interest; CSPCC Director initiates Memo 23 (appropriately modified)
_____	16	Once member approved, Project Manager sends Letter 32 and 33 (appropriately modified) to the new member.
_____	17	Probation of Site: Study Chair sends recommendation on behalf of the Executive Committee to CSPCC Director.
_____	18	CSPCC Director sends Memo 48 to SI and copy to site's ACOS for R&D and if appropriate a copy to CSPCRPCC Director. DMC should be notified of action taken.
_____	19	After probationary period elapsed, Study Chair to send memo to CSPCC Director regarding proposed action. Send Memo 49 (appropriately modified)
_____	20	CSPCC Director sends memo to Director, CSR&D stating rationale and recommended proposed action. Note: Concurrence from Director, CSR&D is not required.
_____	21	Phasing Out Medical Center Recommendation for phase out sent to CSPCC Director. After consultation with Study Chair, CSPCC Director writes comments and forwards the recommendation to the Director, CSR&D.
_____	22	CSPCC Director will contact the ACOS for R&D of the participating medical center. The DMC will be notified of the decision.
_____	23	Project Manager will prepare Memo 50 which will be sent to the SI thru the Medical Center Director and the ACOS for R&D.
_____	24	Project Manager will ask the site's Administrative Officer for R&D to report all surplus study funds to the CSPCC.
_____	25	If equipment has been purchased for the study and is needed at another medical center, instructions regarding shipping will be included in Memo 50 . If equipment is not needed by the CSP, it will be made available for other use at the site.
_____	26	Premature Termination of a Study: Study Biostatistician and CSPCC Director prepare a cover memo recommending termination and distribute to the Study Chair, DMC members, Director, CSR&D and the CSPCRPCC Director. CSPCC Director must inform CSP/VACO of this recommendation within 24 hours or sooner.
_____	27	If approved by Director, CSR&D, the Project Manager will send Memo 50 (appropriately modified) and forward to participating sites.

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 46

As needed

Date:

From: Project Manager, [medical center name] CSPCC (#000/00)

Subj: Replacement of Site Investigator, CSP [#000], "[title]"

To: ACOS for R&D (151) [S.I.'s medical center name (000)]

1. I have been informed that there will be a change at your medical center in the site investigator for Cooperative Study #[000], "[title]." It is required by the **Cooperative Studies Program Guidelines for the Planning and Conduct of Cooperative Studies Office of Research and Development Department of Veterans Affairs** (see Chapter V, Section O) that we obtain a copy of the minutes of the R&D Committee Meeting when this is discussed and approved. We also must have the name, degree and last four digits of social security number of this individual. Note, that in order to serve as a Site Investigator, it is necessary for this individual to be at least 5/8th's time or be approved by the VACO Eligibility Panel (Reference: M-3, Part II, Chapter 3 - Medical Research Service, Eligibility Determination for Clinicians-Investigators).

2. This procedure has been established to facilitate record keeping and, more importantly, for VA funding purposes. When a new individual is approved, VACO withdraws funds from the former investigator and reassigns the funds to the new investigator. If the replacement SI has not received research funding before, please enter Investigator Data - Page 18 - information into the RDIS system.

3. VA Central Office has determined that the Site Investigator for all cooperative studies should receive training/course work in Human Subjects Protection (HSP) and Good Clinical Practices (GCP). Once a Site Investigator has been selected please provide me with the name of the training course, date taken, and location of training. If the Site Investigator has received no formal training, it is suggested that at a minimum, he/she take a course called "Overview of Good Clinical Practice and Human Subjects Protection" which covers the requirements for both GCP and HSP training. It's a two hour course and can be found at Collaborative IRB Training Initiatives (CITI): <http://www.citiprogram.org>. Additional options for Human subjects Protection and Good Clinical Practices can be found at: <http://www.research.va.gov/programs/pride/training/options.cfm>

Training requirements for research staff can be found at:
<http://www.research.va.gov/programs/pride/training/>

2.

[ACOS for R&D]

4. The attached spreadsheet (Requirements for Study Site Personnel) which requires information on the Site Investigator regarding training, appointment status, sanction status, and IRB approval should be completed and forwarded to me ASAP.

5. If you have questions, please call me at (insert phone number). Thank you for your cooperation.

[name]

Attachment: (Exhibit 15 – Requirement for Study Personnel)

cc: Study Chair
Current Study SI
CSP Deputy Director/VACO
CSPCRPCC Director
AO for R&D [medical center]

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 47

When memo 46 is sent

Date:

From: Study Biostatistician, [medical center name] CSPCC (#000/00)

Subj: Replacement Site Investigator in CSP [#000], "[title]"

To: [SI's name, medical center name (000/00)]

1. (Study Chairman) has informed me that you have agreed to serve as Site Investigator at your medical center in the cooperative study on "title of study" "CSP number". I have attached a copy of the **Guidelines for the Planning & Conduct of Cooperative Studies in the Department of Veterans Affairs**, which contains the answers to many questions that are likely to arise during the course of the study. It would be helpful if you would review sections relevant to initiating and conducting a VA Cooperative Study. Note, that to serve as Site Investigator, it is necessary for you to be at least 5/8 time or be approved by the VACO Eligibility Panel (Reference: M-3, Part II, Chapter 3 - Medical Research Service, Eligibility Determination for Clinicians-Investigators).
2. My responsibility is that of the Study Biostatistician from the (name of Center). The (name of Center) provides the funding, central administration, data processing and statistical analysis for the study. I supervise a study team, which helps me carry out these duties. The Coordinating Center Director is (name of Director), the Administrative Officer is (name of Administrative Officer), and (if appropriate) Project Manager (name of Project Manager). (Name of Project Manager) will provide administrative management for the study and will coordinate the start-up of the study at your site.
3. Your ACOS for R&D has been informed that the change in investigator for this study must be discussed and approved by the R&D Committee and that a copy of the minutes be sent to us. If you have any questions about funding or personnel issues, please contact [Project Manager] at the Coordinating Center. Our phone number is (number). I have enclosed a study protocol and operations manual.
4. The Cooperative Studies Program has a Clinical Research Pharmacy Coordinating Center (CRPCC) located at the VA Medical Center, Albuquerque, NM, which manages the drug/device-related aspects of the study. (Name) is the study Clinical Research Pharmacist and (name) is the CRPCC Project Manager. They will be sending you various FDA and VA forms, as appropriate, which you will need to complete before any drugs or drug-related items are sent to your facility. They will also be sending you a copy of Vol. II of the Operations Manual. Please call them if you have any drug/device-related questions at (505) 248-3203.

2.

[SI name]

5. VA Central Office has determined that the Site Investigator for all cooperative studies should receive training/course work in Human Subjects Protection (HSP) and Good Clinical Practices (GCP). Once a Site Investigator has been selected please provide me with the name of the training course, date taken, and location of training. If the Site Investigator has received no formal training, it is suggested that at a minimum, he/she take a course called "Overview of Good Clinical Practice and Human Subjects Protection" which covers the requirements for both GCP and HSP training. It's a two hour course and can be found at Collaborative IRB Training Initiatives (CITI): <http://www.citiprogram.org>. Additional options for Human subjects Protection and Good Clinical Practices can be found at: <http://www.research.va.gov/programs/pride/training/options.cfm>

Training requirements for research staff can be found at:
<http://www.research.va.gov/programs/pride/training/>

Provide HSP and GCP training information (i.e., name of training class, date taken and location of training) to your ACOS so it may be forwarded to (Project Manager).

6. Also enclosed is a Statement of Disclosure (Conflict of Interest) form and a Site Investigator Agreement to Participate form. Please complete and return to me as soon as possible.

7. An Investigator Study File should have been established at the initiation of the study at your center. Also SMART provided an Essential Document Binder to aid in organizing and maintaining your study files. Please familiarize yourself with these documents. Attached is a guideline of the Investigator Study File items.

[Name]

Attachments: Protocol & Operations Manual
CSP Guidelines
Exhibit 16 - Investigator Study File Guidelines
Exhibit 17 - Statement of Disclosure
Exhibit 18 - Site Investigator Agreement

cc: ACOS for R&D
AO for R&D
Study Chair
CSPCRPCC Director

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 48
As needed

Date:

From: Study Chairman, CSP#

Subj: Probation of CSP Site (#000), "[title]"

To: Site Investigator [S.I.'s medical center name (000)]

THRU: Director, [name of CSPCC] (#000/00)

1. We are writing to inform you that the [name of site], will be placed on a three month probationary status from [dates]. The Trial Executive Committee has noted that your site has [insert #] randomizations, but has not randomized any patients in the past [insert #] months. Each site must continue to enroll patients on a timely basis if the study is to meet its patient accrual goal of [insert #] by [insert date of patient accrual].
2. The probationary period ends on [date]. During this period, recruitment as well as screening activity will be closely monitored. In order for your site to be taken off probation, it must enroll at least [insert #] eligible patients during this period. It is our hope that you can meet and, perhaps exceed this goal.
3. If, however, by the end of the probationary period you are unable to recruit the minimum number of patients, the Trial Executive Committee will consider recommending termination of your site as a participating center in this Trial.
4. We appreciate your attention to this most important issue.

[name]

cc: Biostatistician
Project Manager (CSPCC)
Assistant Director for Operations (CSPCC)
ACOS for R&D [medical center]
AO/R&D [medical center]

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

PROTOTYPE MEMO 49

As needed

Date:

From: Study Chairman, CSP#

Subj: Removal from Probation of CSP Site (#000), "[title]"

To: Site Investigator [S.I.'s medical center name (000)]

THRU: Director, [name of CSPCC] (#000/00)

1. The Trial Executive Committee of CSP# is pleased to note that you have met your [name requirements] for remaining on the study.
2. Accordingly, we are writing to inform you that [Site Name] is removed from probation effective [date]. We look forward to working with you toward the successful completion of the study.

[name]

cc: Biostatistician
Project Manager (CSPCC)
Assistant Director for Operations (CSPCC)
ACOS for R&D [medical center]
AO/R&D [medical center]

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

PROTOTYPE MEMO 50

As needed

Date:

From: Director, [medical center name] CSPCC (#000/00)

Subj: Early Termination of CSP Site (#000), "[title]"

To: Site Investigator [S.I.'s medical center name (000)]

THRU: ACOS for R&D [S.I.'s medical center name (000)]
Medical Center Director [S.I.'s medical center name (000)]

1. Sometimes during the course of a study, it becomes necessary to drop a [medical center or laboratory] prematurely from the study. Such an action has been recommended by the [Executive Committee or Data Monitoring Committee].
2. Therefore, your site will be terminated from the study effective [date]. Funding not to exceed 45 days will be provided for the relocation/placement of study personnel. Any surplus study funds must be reported to this Cooperative Studies Program.
3. In unusual circumstances, a request for extension can be submitted. Funding for up to an additional 45 days from termination date (no more than 90 days total) may be provided if the need is documented and justified. In either case, accumulated annual leave must be included within the limits of salary support.

[name]

cc: Study Chair(s)
CSP Deputy Director (VACO)
AO for R&D [medical center]
ADO, CSPCC
Project Manager, CSPCC
CSPPCC

COORDINATING CENTER RESPONSIBILITIES

I. Annual Report

A. Preparation of Annual Report

1. Each coordinating center provides a detailed status report to the Director, Clinical Science R&D Service /VACO (two copies), and courtesy copy to the other coordinating centers. This report is due on July 1st. The suggested format and detailed instructions are available in **Exhibit 29**.

II. Coordinating Center Annual Budget Request

A. Preparation of Coordinating Center Annual Budget Request

1. The Coordinating Center Annual Budget Request should be prepared in the format shown in **Exhibits 30 and 30A** and date due is determined by CSP/VACO but is usually on March 1st. The budget will be sent electronically to the CSP Deputy Director and the Staff Assistant for Finance.

III. Central Printing

A. Submitting Requests for Printing

1. Requests for printing of study-related forms can be sent to the Perry Point Cooperative Studies Program Coordinating Center. See **Exhibit 31** and **Exhibit 31A** for additional information.

IV. Travel and Meeting Information

A. Submission of Quarterly Travel and Meeting Information

1. Travel Clerks should prepare and submit to VA Headquarters a quarterly report of all projected travel. This will include names of travelers, type of travel, contact person, date of travel and location of meeting. See **Exhibit 32** for details.

V. VA Non-Profit Funds

A. Procedures for Spending VA Non-Profit Funds

1. Each Coordinating Center should develop a good working relationship with their affiliated VA Non-Profit .

2. Tasks:

- a. Any request for spending that is outside the normal day-to-day funding of a study must first be approved by the CSP Deputy Director.
- b. Centers are to provide the CSP Finance Officer with monthly or quarterly reports of spending from the VA Non-Profit accounts. See **Exhibit 33** for a description of the report and due dates.

VI. Budget Status Reports

A. Submission of Quarterly Budget Status Reports

1. Each Coordinating Center should prepare a Quarterly Budget Status Report to VA Headquarters. This includes updates on study expenditures compared to original projected budget and also a report on status of capitation payments needed.

2. Tasks:

- a. Administrative Officer for Operations prepares a Quarterly Budget Status Report for submission to VA Headquarters. See **Exhibit 33** for details.
- b. Administrative Officer for Operations prepares a Capitation Report for submission to VA Headquarters. See **Exhibit 33** for details.

VII. OMB Performance Reports

A. Submission of Monthly OMB Performance Report

1. Each Coordinating Center should prepare a Monthly Performance Report which provides data on site performance and overall CSP trial patient accrual by study.

2. Tasks:

- a. Administrative Officer for Operations prepares a Monthly OMB Performance Report to VA Headquarters. See **Exhibit 33** for details.

VIII. Research and Development Information System (RDIS) (ePromise)

A. Submission of RDIS Report

1. The Center's activities, budget information, FTE, etc., are included as part of the local R&D report, and is subject to deadlines and content imposed by the RDIS. The local Research Office provides a set of reporting forms and information on requirements, and can answer questions.

OUTLINE FOR ANNUAL REPORT

Format for Annual Report is as follows:

Update of Studies

CSPCC Status Report

Center Highlights

Cooperative Studies

 Studies by Areas of Research

Human Rights Committee

Personnel

 Staff Assignments by Study (include study phase as well as CSP #)

CSSMRB Schedule

Publications

 Publications by Study (include study phase in first column)

 Publications by Journal

 Center Publications (organize by author and within that list by articles and/or presentations)

Staff Listing

NOTE: The CSPCC Status Report section should be separated from the Annual report by a separate cover sheet and should include a title page and table of contents. These pages should be numbered consecutively throughout the report.

ANNUAL REPORT

DEFINITIONS AND FORMAT

The Annual Report is prepared in two volumes. Volume I contains information on all cooperative studies assigned to the CSPCC that are still in an active phase. See sample formats for all sections of the Annual Report (located in latter portion of this Appendix). Volume II contains similar information on inactive studies dating back to the beginning of our current numbering system.

A cooperative study enters Volume I of the Annual at the next issue after it is assigned for planning and will remain in the report until no further activity is contemplated, at which time the pages concerning that study are moved to Volume II.

Report is due on July 1st. If there has been no change in Volume II, it need not be submitted.

I. VOLUME I

A. Table of Contents

The first page of the report states the current phase of all studies included in the report and also serves as a Table of Contents.

The study phases are defined as follows:

- o **Planning (CSSMRB-estimated date):** From the time the study is assigned to the CSPCC for planning until planning is terminated by the proponent (or by CSP) or until CSSMRB action.
- o **Planning Terminated by Proponent:** There will be instances in which this should state by CSP. After this entry is made, the pages are transferred to Volume II.
- o **Disapproved by CSSMRB (date):** Move to Volume II.
- o **Approved by CSSMRB-Awaiting Funding:** A study is reported in this phase until a decision has been made to release it for funding or until it is dropped from the waiting list.
- o **Dropped from Waiting List:** Move to Volume II.
- o **Ongoing-Organizational:** From time CSPCC is notified that the study has been released for funding until official date of first patient intake.
- o **Ongoing-Patient Accrual:** From date of first patient intake until date of last patient intake.
- o **Ongoing-Patient Follow-Up:** Until date of last patient follow-up.
- o **Terminated:** When a study is stopped before completion by recommendation of Chairperson, Executive or DMB, CSSMRB or CSPCC Director and with concurrence of Director, Clinical Science R&D Service. If analysis and publication are not feasible, move to Volume II. Otherwise add - **Primary Analysis and Manuscript Writing** or other entries as appropriate and retain in Volume I until activity ceases

EXHIBIT 29 (con't)

- o **Primary Analysis and Manuscript Writing:** From date of last patient follow-up until a major manuscript has been submitted for publication.
- o **Manuscript Submitted/Accepted:** Until paper appears in print.
- o **Continuing Activity:** This category assumes that the major paper has been submitted even if it has not yet appeared in print and should be used if analysis and reporting of secondary papers continues or if there is extended follow-up or continuing activity of any kind beyond the original study.
- o **Completed:** This implies that at least the major manuscript has been published and there is no continuing activity. However, there may be instances in which **Completed-Not Published** is a more appropriate entry. In either event, move to Volume II.

The last entry on the Table of Contents page is the CSPCC Status Report.

B. First Study Page

This first page of the study report can be included in the first Annual Report after the study is assigned to the Center for planning.

- o **The CSP Study Number** is assigned by CSP/VACO. The full title from the Principal Proponent's letter of intent should be entered on the first page but abbreviated titles can be used on all succeeding pages. If there is subsequently a change in the official title, it should be changed on the report.
- o **Current Study Phase:** As defined in A.
- o **Principal Proponent:** Enter name and degree. Below state VAMC number and name and telephone number. If study is approved by CSSMRB, change title to Study Chairperson.
- o **Study Biostatistician:** Enter name and degree.
- o **Clinical Research Pharmacist:** Enter name and degree. Omit this line if no CSPCRPCC involvement.
- o **Health Economist (if applicable):** Enter name and degree

The first page will also contain the following:

- o **Background**
- o **Objectives**
- o **Design**
- o **Sample Size**
- o **Patient Population**
- o **Medications**
- o **Primary Outcome Measures**
- o **Impact Statement**

EXHIBIT 29 (con't)

C. Second Study Page

This second page will also be included in the first Annual Report after the study is assigned to the Center. Some information can be included immediately and other information added as the study progresses.

- o **The CSP Study Number and title.**
- o **Study Funding Source(s):** Enter primary (and secondary, tertiary) funding source and dollar amounts in order of percentage of funds supplied, e.g., VA CSP funds, NIH-NCI, CIBA.
- o **No. of Participating VAMC's - Authorized:** This information is available after CSSMRB review. Enter the number of VAMC's approved by CSSMRB (do not count Chairperson's Office or central laboratories). This number may change if approved number is subsequently revised by CSSMRB or CSP.
- o **No. of Participating VAMC's - Funded:** Available at the time centers are funded. Enter the number of VAMC's currently receiving funds. This number will increase if all centers are not funded initially or decrease if VAMC's are either dropped or complete patient follow-up.
- o **No. of Non-VA Participating Sites - Authorized:** Self-explanatory. Omit this line if no such participation.
- o **No. of Non-VA Participating Sites - Funded:** Self-explanatory.
- o **No. of VA Support Functions - Authorized:** Enter number of authorized functions in support of the study that are performed at VAMC's, e.g., Chairperson's Office and/or separately funded central laboratories (list who they are) located at a VAMC, and any clinical monitoring.
- o **No. of VA Support Functions - Funded:** Currently receiving funds.
- o **No. of Non-VA Support Functions - Authorized:** Examples are outside contracts to provide data processing analysis, cost-effectiveness studies or laboratory tests performed at a non-VA hospital (list who they are).
- o **No. of Non-VA Support Functions - Funded:** Currently receiving funds.
- o **Duration of Patient Intake:** Enter the length of time in months that CSSMRB approved for patient intake into the study. When extensions of intake are granted, show the revised duration and add a footnote showing the original dates.
- o **Duration of Patient Follow-Up:** Enter the length of time in months that CSSMRB approved for patient follow-up in the study. When extensions of patient follow-up are approved, show the revised duration and add a footnote showing the original dates.
- o **Request for Planning:** Enter the date when the request for planning the study was submitted. Date can be obtained from Principal Proponent's letter of intent.

EXHIBIT 29 (con't)

- o **Active Planning Approved:** Date approved for the study planning to begin. From letter to Principal Proponent signed by Director, Clinical Science R&D Service or date of telephone notification by Director, Clinical Science R&D Service.
- o **First Planning Meeting:** Enter starting date after the meeting has been held.
- o **Second Planning Meeting:** Same.
- o **Third or More:** If planning exceeds two meetings.
- o **1st CSSMRB Evaluation:** Enter date and CSSMRB recommendation with Scientific Merit Priority (SMP) Score. The various outcomes are: Approved unconditionally; Approved with recommendations for change; Disapproved.
- o **Funding of Chairperson's Office:** Date that personnel are authorized to be on duty (normally three months prior to initial patient intake). Note: VACO or other funding source may send funds to the VAMC before this date. There may even be some expenditure of funds for equipment or supplies before this date.
- o **Funding First VAMC:** Date personnel are authorized to be on duty (normally two months after funding of Chairperson's Office). Note: VACO or other funding source may send funds to the VAMC before this date.
- o **Start Patient Intake:** Self-explanatory but note that the goal is to start patient intake no more than three months after funding of Chairperson, one month after funding of sites. If initiation of intake is delayed, intake time is lost.
- o **Last Patient Intake:** Add the number of months approved by CSSMRB for intake plus three months after funding of Chairperson.
- o **Last Patient Follow-Up:** Add the number of months approved by CSSMRB for follow-up to the date of last patient intake. If a request for extension of patient intake or follow-up is approved, these two dates should be revised but the original dates should be retained in a footnote at the bottom of the page.
- o **First Ongoing CSSMRB Review:** Enter expected date (three years from date of first patient intake) and adjust after actual meeting. Note that if a special CSSMRB meeting takes place (e.g., for extension of intake), the regular three-year review would be scheduled for three years from that date. No CSSMRB review in last year of follow-up.
- o **Second Ongoing CSSMRB Review:** Three years after first or special CSSMRB review.
- o **Major Manuscript Submitted:** Date from letter to editor when major manuscript is first submitted for publication.
- o **No. and % of Women Participating**
- o **No. and % of Minorities Participating:** Give total number and percent of minorities participating, then list total number and percent participating in the following categories:

EXHIBIT 29 (con't)

American Indian or Alaskan Native, Asian or Pacific Islander, Black, not of Hispanic origin, and Hispanic.

D. Third Study Page: VA Sites and Participant Directory.

This page is used to maintain information on the participants at each VA site involved in a cooperative study.

- o **Participants Name & Degree:** Begin this list with the Study Chairman and Co-Chairman (if appropriate), followed by each site investigator by numerical order of the VAMCs, ending with any VA central laboratories.
- o **Site Number & Name & Participants Telephone No.:** For the Study Chairperson and each participant, enter the site number and name of the VAMC
- o **Date of Entry:** Enter the date when the SI first started participating in the study. In the case of a SI at a site first entering the study, the date of entry will be the date when his site was authorized funds by CSP/VACO. For a SI who is added to a study at a site already active in a study, the date of entry will be the date of a letter informing CSP/VACO or the CSPCC of his addition (usually R&D minutes).
- o **Date Discontinued:** Enter the date when the SI left participation in the study. For a SI who is participating in the study to its conclusion, this date should correspond to the last date of patient follow-up for the study. If a site is terminated before the completion of the study, the date of exit is the date funding of the site is ended. For a SI who resigns before a study has concluded, the date entered should be the date that the SI withdrew from participation.
- o **Example:** In the illustrative format (see page 4 in the Sample Format of Annual Report - located in this Appendix), the first hospital entered 4/14/83 and is still active. The second hospital entered 5/27/83 and was terminated on 2/25/85; the SI is listed as past SI. The third hospital entered 4/14/83 and is still active but the first SI resigned on 8/24/84 and is indicated as Past SI. His replacement was appointed the same day and is indicated as Current SI.
- o **Status Condition:**
 - Current Site Investigator:** One, and only one, Participating Investigator for each site must be identified as the current SI.
 - Past Site Investigator:** This designation should be used when a current SI (or Associate Investigator) resigns from active participation in a study.

E. Fourth Study Page

- o **Data Monitoring Committee Members:** Enter information shown on sample format.
- o **Executive Committee Members:** Enter information shown on sample format.

EXHIBIT 29 (con't)

- o **Study Meeting History:** Enter meeting dates beginning with Organizational Meeting. Routine means regularly scheduled meetings of Study Group, Executive and Data Monitoring Committee, and Human Rights Committee. If there is a special meeting, enter the date and identify the meeting on the left, e.g., a special Technician Meeting, End Point Committee Meeting, Human Rights Committee Site Visit. Below the dotted line, enter estimated date of next scheduled meetings.
- o **Narrative Reports:** The biostatistician should provide a brief summary of the current status of the study including important events or problems since last Annual Report. This narrative, appropriately edited, should be retained to provide a chronological history. Date is the date of the Annual.
- o **Publication History:** The cumulative publication history of the study should be presented under three main headings using the following reference style:
 - A. **Submitted for Publication:**
Author(s), title, submitted to (or accepted by) (journal).
 - B. **Publications:**
Author(s), title, journal, year, volume, pages.
 - C. **Presentations:**
Author(s), (presenters), title, meeting, place, date.

References should be in chronological order with new entries being added as the study progresses.

F. Patient Intake Graph

There should be one or more patient intake graphs for every study. In studies with two or more strata, there may need to be a graph for each strata. In these instances, there may or may not be a need for a total. Currently there is variability among centers in how the graphs are drawn but as a minimum, each graph should show the projected intake line (E) and the actual or observed performance (O).

G. Coordinating Center Status Report

The final pages of the Annual Report are devoted to a center report using the format discussed previously.

EXHIBIT 29 (con't)

II. VOLUME II

When a study reported in Volume I becomes inactive for any of the reasons described in I.A., final entries should be made and all of the study pages should be moved to Volume II for the next Annual. The Table of Contents page should list studies in numeric order giving number and title.

III. SEQUENTIAL ACTION BY CRITICAL EVENTS

A. Study Assigned to Coordinating Center for Planning. After a study has been assigned to the Center for planning, the following entries should be made on the next issue of the report:

1. Enter the CSP number and title of the study.
2. Indicate phase as **Planning**.
3. Enter personnel assigned to study.
 - a. Principal Proponent - include telephone number
 - b. Study Biostatistician
 - c. Clinical Research Pharmacist (if appropriate)
4. Abstract to include following components: background, objective, design, sample size, patient population, medications, primary outcome, impact. Update after Second Planning Meeting, if appropriate.
5. Dates of request of planning and active planning approved.
6. Planning meeting dates as they occur.
7. Prospective date of CSSMRB evaluation.
8. Study narrative.

Note: If Principal Proponent or CSP decide to terminate planning, describe the circumstances in the narrative, change the study phase and move to Volume II.

B. CSSMRB Evaluation

1. Disapproved by CSSMRB.
 - a. Change study phase.
 - b. Enter date of CSSMRB and outcome on page 2.
 - c. Possible reasons for disapproval in study narrative.
 - d. Move to Volume II.

EXHIBIT 29 (con't)

2. Approved by CSSMRB
 - a. Change study phase.
 - b. Change Principal Proponent to Study Chairperson.
 - c. Enter Study Funding Source(s).
 - d. Enter number of authorized participating and support stations.
 - e. Enter duration of intake and follow-up.
 - f. Enter date of CSSMRB.
 - g. Footnote any conditions on approval or include in study narrative.
 - h. Enter VA sites as identified.
 - i. Study narrative.

C. Funding Decisions by CSP

1. Dropped from waiting list.
 - a. Change study phase.
 - b. Move to Volume II.
2. Released for study funding.
 - a. Change study phase.
 - b. Enter date of release.
 - c. As known, enter dates of funding of Chairperson's Office, funding of VAMCs, first and last patient intake, last patient follow-up, and first ongoing CSSMRB review.
 - d. Enter SI names, participating sites, entry dates and site status.
 - e. Enter dates of organizational meetings.
 - f. Enter information on Data Monitoring Committee members.
 - g. Enter information on Executive Committee members.

D. Initiation of Study

For each successive Annual Report:

1. Enter correct study phase.
2. Enter meeting dates since last Annual.
3. Provide brief study narrative.
4. Update Patient Intake Graph.
5. Maintain Participant Directory, e.g., as SI's resign and new SI's are approved, change their status and enter respective dates of participation; same for dropping and replacing a site.

EXHIBIT 29 (con't)

E. After Date of Last Patient Follow-Up

1. Change study phase.
2. Change number of sites funded as stations terminate on page 2.
3. As participating stations terminate, show the date of termination and change the participating site status.
4. Study narrative.
5. Final Patient Intake Graph.

F. Manuscript Submitted/Accepted

1. Enter date submitted.
2. Change study phase. If there is continuing activity of any sort, report as such and retain in Volume I. Otherwise retain as Submitted/Accepted until paper appears in print, make final entries and then move to Volume II.

IV. SAMPLE FORMAT OF ANNUAL REPORT

As shown on following pages.

SAMPLE FORMAT OF ANNUAL REPORT

TABLE OF CONTENTS

Page

Planning

CSP #000	Title
CSP #100	Title

Approved By CSSMRB - Awaiting Funding

CSP #000	Title
----------	-------	-------

Ongoing - Organizational

Ongoing - Patient Accrual

Ongoing - Patient Follow-Up

Primary Analysis and Manuscript Writing

Manuscript Submitted/Accepted

Continuing Activity

Status Report of _____ CSPCC

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE
Current Study Phase:

Study Chairperson: (Name and Degree)
(Site #, Name, FTS #)
Study Biostatistician: (Name and Degree)
Clinical Research Pharmacist: (Name and Degree) (when appropriate)
Health Economist: (Name and Degree) (when appropriate)

Background:

Objectives:

Design:

Sample Size:

Patient Population:

Medications:

Primary Outcome Measure:

Impact:

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE

Study Funding Source(s): (primary)(secondary)(tertiary)

No. of VA Participating Sites	Authorized (#)	Funded (#)
No. of Non-VA Participating Sites (IF ANY)	(#)	(#)
No. of VA Support Functions	(#)	(#)
No. of Non-VA Support Functions (IF ANY)	(#)	(#)
Duration of Patient Intake	(#) Months *	
Duration of Patient Follow-Up	(#) Months	

RECORD OF SIGNIFICANT DATES

Request for Planning:	00/00/00	
Active Planning Approved:	00/00/00	
First Planning Meeting:	00/00/00	
Second Planning Meeting:	00/00/00	
CSSMRB Evaluation:	00/00/00	(Outcome) (Priority Score:)
Released for Funding Status:	00/00/00	
Funding of Chairperson's Office:	00/00/00	
Funding First VAMC:	00/00/00	
Start Patient Intake:	00/00/00	
Last Patient Intake:	00/00/00*	
Last Patient Follow-Up:	00/00/00*	
First Ongoing CSSMRB Review:	00/00/00	
Major Manuscript Submitted:	00/00/00	

	<u>#</u>	<u>%</u>
No. and % of Women Participating:		
No. And % of Minorities Participating:	(total)	(total)
American Indian or Alaskan Native	A	@
Asian or Pacific Islander	A	@
Black, not of Hispanic origin	A	@
Hispanic	A	@

*Original Duration of Patient Intake (#) Months, extended administratively by (CSSMRB, CSP).

Original Dates:	
Last Patient Intake:	00/00/00
Last Patient Follow-Up:	00/00/00

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE

VA SITE & PARTICIPANT DIRECTORY

<u>PARTICIPANTS</u>	<u>VA SITE NO. & NAME</u>	<u>DATE OF ENTRY</u>	<u>DATE DIS- CONTINUED</u>	<u>STATUS CONDITION</u>
Study Chairperson (Name, Degree)	(#)(name,state) (phone #)	03/01/83		Active Current SC
Participant (Name, Degree)	(#)(name,state) (phone #)	04/14/83		Active Current SI
Participant (Name, Degree)	(#)(name,state) (phone #)	05/27/83	02/25/85	Terminated Past SI
Participant (Name, Degree)	(#)(name,state) (phone #)	04/14/83	08/24/84	Active Past SI
(Name, Degree)	(#)(name,state) (phone #)	08/24/84		Current SI
Central Lab - Chemistry (Name, Degree)	(#)(name,state) (phone #)	04/14/83		Active Current SI

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE

DATA MONITORING COMMITTEE

CHAIRPERSON (discipline represented) (Name, Degree) (Title) (Address) (Telephone Number)	MEMBER (discipline represented) (Name, Degree) (Title) (Address) (Telephone Number)
MEMBER (discipline represented) (Name, Degree) (Title) (Address) (Telephone Number)	MEMBER (discipline represented) (Name, Degree) (Title) (Address) (Telephone Number)

EXECUTIVE COMMITTEE

CHAIRPERSON (Name, Degree) (Address) (Telephone Number)	BIostatistician (Name, Degree) (Address) (Telephone Number)
CLINICAL RESEARCH PHARMACIST (Name, Degree) (Address) (Telephone Number)	CHIEF, CENTRAL LAB (Name, Degree) (Address) (Telephone Number)
SITE INVESTIGATOR (Name, Degree) (Address) (Telephone Number)	SITE INVESTIGATOR (Name, Degree) (Address) (Telephone Number)

STUDY MEETING HISTORY

	<u>STUDY GROUP</u>	<u>EXECUTIVE COMMITTEE</u>	<u>DATA MONITORING COMMITTEE</u>	<u>HUMAN RIGHTS COMMITTEE</u>	<u>SPECIAL</u>
Organizational	00/00/00	00/00/00	00/00/00		
Routine	00/00/00	00/00/00			
Routine			00/00/00	00/00/00	
Technician Meeting					00/00/00
HRC Site Visit					00/00/00

Scheduled	00/00/00	00/00/00	00/00/00	00/00/00	

NARRATIVE REPORTS

Date 1st Annual After Study Assigned
Date 2nd Annual
Date etc.

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE

PUBLICATION HISTORY

Submitted

Author(s), Title, Submitted to (or Accepted by), Journal

Published

Author(s), Title, Journal, Year, Volume, Pages

Presentations

Author(s) (Presenters), Title, Meeting, Place, Date

EXHIBIT 29 (con't)

CSP STUDY 000 - TITLE

PATIENT INTAKE GRAPH

EXHIBIT 29 (con't)

STATUS REPORT

(_____) CSP COORDINATING CENTER

1. Center Highlights.
2. Cooperative Studies:
 Studies by Area of Research
3. Human Rights Committee.
4. Personnel
 Staff Assignments by Study
5. CSSMRB Schedule
6. Publications:
 Publications by Study
 Publications by Journal
 Publications by Staff
7. Staff Listing.

EXHIBIT 29 (con't)

SAMPLE FORMAT OF STATUS REPORT SHOWN ON FOLLOWING PAGES

STATUS REPORT

(Date)

EXHIBIT 29 (con't)

STATUS REPORT

Cooperative Studies Program Coordinating Center
[city, state]

TABLE OF CONTENTS

	Page
CENTER HIGHLIGHTS	
COOPERATIVE STUDIES	
Studies by Area of Research	
HUMAN RIGHTS COMMITTEE	
PERSONNEL	
Staff Assignments by Study	
CSSMRB SCHEDULE	
PUBLICATIONS	
Publications by Study	
Publications by Journal	
Publications by Staff.....	
STAFF LISTING.....	

EXHIBIT 29 (con't)

CENTER HIGHLIGHTS

[Report on Center highlights from previous six months. Suggested topics are number of studies in planning, patient accrual, follow-up, primary analyses, manuscript writing phase, and ongoing activity, personnel changes, space issues, major equipment purchases, etc.]

EXHIBIT 29 (con't)

COOPERATIVE STUDIES BY AREA OF RESEARCH

[Area of Research, i.e., **CARDIAC**]

Study #	Title
---------	-------

EXHIBIT 29 (con't)

STAFF ASSIGNMENT BY STUDY

<u>PHASE AND STUDY</u>	<u>BIOSTATISTICIAN</u>	<u>PROJECT MANAGER</u>	<u>PROGRAMMER</u>	<u>COMPUTER ASSISTANT</u>
------------------------	------------------------	------------------------	-------------------	---------------------------

PLANNING

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

APPROVED/AWAITING FUNDING

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

ONGOING-ORGANIZATIONAL

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

ONGOING-PATIENT ACCRUAL

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

ONGOING-PATIENT FOLLOW-UP

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

ANALYSIS/MANUSCRIPT WRITING

Study #	[name]	[name]	[name]	[name]
---------	--------	--------	--------	--------

MANUSCRIPT SUBMITTED/ACCEPTED

Study #	[name]	[name]	[name]	[name]
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CONTINUED ANALYTIC ACTIVITY

Study #	[name]	[name]	[name]	[name]
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EXHIBIT 29 (con't)

CSSMRB SCHEDULE

APRIL (YEAR)

[CSP #__ - Type of Review, i.e., New Proposal, Ongoing Review]

OCTOBER (YEAR)

[CSP #__ - Type of Review, i.e., New Proposal, Ongoing Review]

EXHIBIT 29 (con't)

PUBLICATIONS BY JOURNAL

JOURNAL	Number of Articles
	(Total No.)

EXHIBIT 29 (con't)

PUBLICATIONS BY STAFF
(other than study publications)

Published

(List by staff alphabetically)

Presentations

(List by staff alphabetically)

EXHIBIT 29 (con't)

PERSONNEL LIST

Cooperative Studies Program Coordinating Center (151__)
Veterans Administration Medical Center
(city, state, zip)

_____	, Director	Phone #
_____	, Assistant Director	FAX #
_____	, Assistant Director for Administration	Phone #
		Phone #

ADMINISTRATIVE SUPPORT SECTION
[list name, title, phone #]

BIostatISTICS SECTION
[list name, title, phone #]

DATABASE MANAGEMENT SECTION
[list name, title, phone #]

STATISTICAL PROGRAMMING SECTION
[list name, title, phone #]

INFORMATION TECHNOLOGY SECTION
[list name, title, phone #]

PERSONNEL LIST FOR TERM EMPLOYEES

[list name, title, phone #]

Center Budget Submission Template

FY 07 CSP Center -- FTE & AOC Details

General

Only use the attached spreadsheets. Budgets submitted in other formats will not be accepted.

Worksheets are linked together, so updates may be made across all sheets.

Many cells already contain formats so you may not have to calculate salary cost for each study.

List ALL employees. For each employee, list GS level (if applicable), funds, title, yearly salary, fringe, total cost and FTE.

Separate worksheets are included for different types of funding. The "ALL Core" worksheet is a summary of all funding sources.

Worksheets are provided for VA, Reimbursable and Non-Profit Funds.

Non-Profit money refers to all money that will be coming into your Centers associated Non-Profit during FY07 and any residual funds currently at the Non-Profit.

Accompanying Narratives should focus on changes between FY06 and FY07. If there are no changes with a given study, you may

indicate "No change." Important things to explain would be an increase or decrease in FTE, high AOC costs, or switch in study category

No cost of living adjustments (COLA) should be included.

Studies

Studies should be broken down according to the following categories: Planning, Active, Analyses. Definitions are as follows:

Planning: LOI approved through notification of funding

Active: Study start-up through 6 months after last patient follow-up

Analysis: up to one year after Active phase ends

The category for each study should be determined by where the study will be in FY07. For example, if the last patient follow-up for a study was February 2006, that given study would be in the Analysis column for FY07.

Planning studies should remain in the planning column. If studies are funded during the course of FY07, a budget supplement may be requested.

FTE distributions should reflect **ACTUAL FTE** working on the study, i.e., must be able to withstand audit. Undistributed FTE must be accounted for in the Excess Capacity column. If you have a position that an employee has left and not filled please mark and vacant with the title. If you are requesting for a new position please mark with TBH and position title. (remember we are working with a flat line budget)

AOC

AOC costs for the Center (Core and in support of studies) are included in the AOC worksheets. Listed on the spreadsheet are common types of AOC costs, add or delete items as dictated by your Center or studies. All items must have a title -- "Miscellaneous" can not be used.

This year we have a separate AOC spreadsheet for IT, Reimbursable and non-profit.

Travel funds for planning studies - if your Center has a study in planning, please estimate the travel dollars necessary for FY07. This is an estimate only for purposes of budget planning.

The Summary cells contain formulas to add up the total funds requested. The cells should not need to be modified.

Non-Profit Report

The non-profit report should report ALL money currently at the local non-profits, an expected year end balance, an estimate of an new money expected and all expenses.

(Name) CSPCC - FY07 Personnel Costs - ALL Funding Sources

Personnel Cost Basis		GS Level	Funds	Title	Yearly Salary	Fringe	FTE	TOTAL
Name							Cost	FTE
AA	11/2	VA	QAS		52,864	15,859	68,723	1.0
BB	13/2	VA	RA	Bio	102,382	-	102,382	1.0
CC	9/1	VA	ADO		77,775	23,333	101,108	1.0
DD	11/4	VA	RHSS		42,282	12,685	54,967	1.0
EE	9/5	VA	RHSS		56,276	16,883	73,159	1.0
FF	13/4	VA	IPM	PM	47,920	14,376	62,296	1.0
GG	12/5-IT	VA	Bio		80,206	24,062	104,268	1.0
HH	11/6	VA	IPM	IT	72,386	21,716	94,102	1.0
II	7/2	NP	RA	PM	59,688	17,906	77,594	0.8
JJ	11/2	VA	EQUIC		51,159	15,348	66,507	0.75
KK	14/6	VA	IPM	IT	100,525	30,158	130,683	1.0
LL	9/1	VA	RHSS		42,282	12,685	54,967	1.0
MM	13/10	VA	Bio		94,790	28,437	123,227	1.0
NN	9/1	VA	PC		42,282	12,685	54,967	1.0
OO	7/2	NP	Asst		35,718	10,715	46,433	1.0
PP	7/2	NP	RA		35,718	10,715	46,433	1.0
RR	12/4	VA	Prog.		72,800	-	72,800	1.0
SS	15/10	VA	Director		131,756	39,527	171,283	1.0
TT	14/10	VA	DNA		85,000	25,500	110,500	0.2
UU	7/1	VA	AD		112,014	33,604	145,618	1.0
VV	11/2	VA	RHSS		34,566	10,370	44,936	1.0
WW	7/5	VA	PC		39,175	11,753	50,928	1.0
XX	11/1	VA	EQUIC		51,159	15,348	66,507	0.5
YY	13/10	VA	DP		94,790	28,437	123,227	1.0
AAA	11/3	VA	PM		54,570	16,371	70,941	1.0
BBB	7/1	VA	RHSS		34,566	10,370	44,936	1.0
CCC	12/3	VA	IPM	Prog	65,403	19,621	85,024	1.0
DDD	9/1	VA	RHSS		42,282	12,685	54,967	1.0
EEE	9/2	VA	Asst		43,691	13,107	56,798	1.0
FFF	12/5	VA	Prog		69,491	20,847	90,338	1.0
GGG	9/2	VA	RHSS		43,691	13,107	56,798	1.0
HHH	12/3-IT	VA	IPM	IT	68,128	20,438	88,566	1.0
III	8/10	VA	Asst		49,766	14,930	64,696	1.0
JJJ	12/3	VA	Prog		65,403	19,621	85,024	1.0
KKK	9/1	VA	RHSS		42,282	12,685	54,967	1.0
LLL	12/5	VA	Prog		69,491	20,847	90,338	1.0
MMM	7/6	VA	DP		40,327	12,098	52,425	1.0
NNN	7/4	VA	DP		38,023	11,407	49,430	1.0
OOO	12/4	VA	Prog		67,447	20,234	87,681	1.0
PPP	14/10	VA	Epi		112,014	33,604	145,618	1.0
QQQ	7/4	VA	DP		38,023	11,407	49,430	1.0
TBH	7/1	NP	RA		34,566	10,370	44,936	1.0
TBH								43.75

(Name) CSPCC - FY07 Personnel Costs - ALL Funding Sources

Name	Active		102	103	104	105	106	107	108	109	110	Analysis		IT	ADMIN	Excess Capacity	SUM
	101	100										111	112				
AA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
BB	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1.00
CC	0.15	0	0	0.25	0	0	0	0	0	0	0	0	0	0	0.6	0	1.00
DD	0	0.1	0	0	0.8	0	0	0	0	0	0	0.1	0	0	0	0	1.00
EE	0.1	0.1	0.1	0.2	0.1	0.2	0.1	0	0	0.1	0	0	0	0	0	0	1.00
FF	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1.00
GG	0	0.5	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	1.00
HH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
II	0	0	0	0	0.8	0	0	0	0	0	0	0	0	0	0	0	0.80
JJ	0	0.2	0.4	0	0	0	0	0	0	0	0	0.2	0	0	0.2	0	1.00
KK	0	0	0	0.75	0	0	0	0	0	0	0	0	0	0	0	0	0.75
LL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
MM	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1.00
NN	0	0	0	0	0	0.5	0	0.5	0	0	0	0	0	0	0	0	1.00
OO	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1.00
PP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
QQ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
RR	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1.00
SS	0	0.1	0.1	0.1	0.4	0.1	0.1	0.1	0	0.1	0	0	0	0	0	0	1.00
TT	0	0	0	0	0.1	0.1	0	0	0.1	0	0	0.1	0	0	0.6	0	1.00
UU	0	0	0	0	0.2	0	0	0	0	0	0	0	0	0	0	0	0.20
VV	0.2	0	0.2	0	0	0	0	0	0	0	0	0	0	0	0.6	0	1.00
WW	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1.00
XX	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0.50
YY	0	0	0	0	0.75	0	0	0	0	0.25	0	0	0	0	0	0	1.00
ZZ	0	0	0	0	0	0.5	0	0	0.25	0.25	0	0	0	0	0	0	1.00
AAA	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0.50
BBB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
CCC	0	0.4	0.5	0	0	0	0	0	0	0	0	0.1	0	0	0	0	1.00
DDD	0.1	0	0.6	0	0	0	0	0	0	0.3	0	0	0	0	0	0	1.00
EEE	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
FFF	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1.00
GGG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
HHH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
III	0	0.2	0.1	0.1	0.1	0.2	0.2	0.2	0	0.1	0	0	0	0	0	0	1.00
JJJ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
KKK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
LLL	0	0	0	0	0	0.5	0	0	0	0	0	0.5	0	0	0	0	1.00
MMM	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
NNN	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1.00
OOO	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
PPP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
QQQ	0.25	0	0	0	0	0	0	0.75	0	0	0	0	0	0	0	0	1.00
TBH	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1.00
TBH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.00
TBH	0	0	0	0	0	0	0.5	0.25	0.25	0	0	0	0	0	0	0	1.00
Grand Total	0.8	3.6	3	2.5	5.25	4.5	3.9	0.6	1.6	2	3	4	3	6	0	43.75	

(Name) CSPCC - FY07 Personnel Costs - ALL Funding Sources

Cost distribution (ALL)	Planning	Active	102	103	104	105	106	107	108	109	110	Analysis	112	IT	ADMIN	Excess Capacity	SUM
	100	101										111					
Name																	
AA		0	0	0	0	0	0	0	0	0	0	0	0	0	68,723	0	68,723
BB		0	0	0	0	0	0	0	0	0	102,382	0	0	0	0	0	102,382
CC		15,166	0	25,277	0	0	0	0	0	0	0	0	0	0	60,665	0	101,108
DD		0	5,497	0	43,973	0	0	0	0	0	0	5,497	0	0	54,967	0	54,967
EE		7,316	7,316	14,632	7,316	14,632	7,316	7,316	7,316	7,316	0	0	0	0	0	0	73,159
FF		0	52,134	0	62,296	0	0	0	0	0	0	0	0	0	0	0	62,296
GG		0	52,134	0	0	0	52,134	0	0	0	0	0	0	0	0	0	104,268
HH		0	0	0	0	0	0	0	0	0	0	0	0	94,102	0	0	94,102
II		0	0	0	62,076	0	0	0	0	0	0	0	0	0	0	0	62,076
JJ		0	9,287	18,573	0	0	0	0	0	0	0	9,287	0	0	9,287	0	46,433
KK		0	0	49,880	0	0	0	0	0	0	0	0	0	0	0	0	49,880
LL		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MM		0	0	0	54,967	0	54,967	0	0	0	0	0	0	130,683	0	0	130,683
NN		0	0	0	61,614	0	61,614	0	0	61,614	0	0	0	0	0	0	54,967
OO		0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	0	123,227
PP		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54,967
QQ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	46,433
RR		0	0	0	0	0	0	0	0	0	72,800	0	0	0	0	0	46,433
SS		0	8,768	8,768	35,072	8,768	8,768	8,768	8,768	8,768	0	0	0	0	0	0	87,981
TT		0	0	17,128	17,128	0	0	0	17,128	0	0	17,128	0	0	102,770	0	171,283
UU		0	0	0	22,100	0	0	0	0	0	0	0	0	0	0	0	22,100
VV		29,124	0	29,124	0	0	0	0	0	0	0	0	0	0	0	0	145,618
WW		0	0	0	0	0	0	44,936	0	0	0	0	0	0	87,371	0	145,618
XX		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44,936
YY		0	0	0	0	34,825	0	0	0	0	0	0	0	0	0	0	34,825
ZZ		0	0	0	0	34,825	0	0	0	0	0	0	0	0	0	0	46,433
AAA		0	0	0	0	0	0	0	0	11,608	0	0	0	0	0	0	46,433
BBB		0	0	0	0	25,464	0	0	12,732	12,732	0	0	0	0	0	0	50,928
CCC		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	33,253
DDD		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EEE		4,494	0	28,376	35,471	0	0	0	0	0	0	0	0	0	0	0	123,227
FFF		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GGG		0	85,024	0	0	0	0	0	0	13,481	0	0	0	0	0	0	70,941
HHH		0	0	0	0	0	54,967	0	0	0	0	0	0	0	0	0	44,936
III		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	85,024
JJJ		0	11,360	5,680	5,680	5,680	11,360	11,360	0	5,680	0	0	0	0	0	0	54,967
KKK		0	0	0	0	0	0	0	0	0	0	90,338	0	0	56,798	0	56,798
LLL		0	0	0	0	0	42,512	0	0	0	0	0	0	0	0	0	90,338
MMM		0	54,967	0	0	0	0	0	0	0	0	0	0	88,566	0	0	88,566
NNN		0	0	90,338	0	0	0	0	0	0	0	0	0	0	0	0	64,696
OOO		0	0	0	0	0	0	0	0	0	0	42,512	0	0	0	0	85,024
PPP		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	90,338
QQQ		21,920	0	0	0	0	0	0	0	0	0	0	52,425	0	0	0	52,425
TBH		0	0	0	145,618	0	0	65,761	0	0	0	0	49,430	0	0	0	49,430
TBH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87,681
TBH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	145,618
TBH		0	0	0	0	0	22,468	11,234	11,234	0	0	0	49,430	0	0	0	49,430
Grand Total		78,020	262,728	222,231	188,980	436,084	296,750	256,475	41,094	121,198	175,182	218,289	274,512	313,351	496,742	0	3,381,636

(Name) CSPCC - FY07 Personnel Costs (VA)

Personnel Cost Basis		GS Level	Funds	Title	Yearly Salary	Fringe	FTE	VA
AA	11/2	VA	QAS		52,864	15,859	68,723	
BB		VA-R	Bio		102,382	-	102,382	
CC	13/2	VA	ADO		77,775	23,333	101,108	
DD	9/1	VA	RHSS		42,282	12,685	54,967	
EE	11/4	VA	RHSS		56,276	16,883	73,159	
FF	9/5	VA-IPA	PM		47,920	14,376	62,296	
GG	13/4	VA	Bio		80,206	24,062	104,268	
HH	12/5-IT	VA-IPA	IT		72,386	21,716	94,102	
II	11/6	VA	PM		59,688	17,906	77,594	
JJ	7/2	NP	RA		35,718	10,715	46,433	
KK	11/2	VA	EQUIC		51,159	15,348	66,507	
LL	14/6	VA-IPA	IT		100,525	30,158	130,683	
MM	9/1	VA	RHSS		42,282	12,685	54,967	
NN	13/10	VA	Bio		94,790	28,437	123,227	
OO	9/1	VA	PC		42,282	12,685	54,967	
PP	7/2	NP	Prog. Asst		35,718	10,715	46,433	
QQ	7/2	NP	RA		35,718	10,715	46,433	
RR		VA-R	Prog.		72,800	-	72,800	
SS	12/4	VA	Prog.		67,447	20,234	87,681	
TT	15/10	VA	Director		131,756	39,527	171,283	
UU		VA-IPA	DNA		85,000	25,500	110,500	
VV	14/10	VA	AD		112,014	33,604	145,618	
WW	7/1	VA	RHSS		34,566	10,370	44,936	
XX	11/2	VA-IPA	EQUIC		52,864	15,859	68,723	
YY	7/2	VA	RA		35,718	10,715	46,433	
ZZ	7/5	VA	PC		39,175	11,753	50,928	
AAA	11/1	VA	EQUIC		51,159	15,348	66,507	
BBB	13/10	VA	DP		94,790	28,437	123,227	
CCC	11/3	VA	PM		54,570	16,371	70,941	
DDD	7/1	VA	RHSS		34,566	10,370	44,936	
EEE	12/3	VA-IPA	Prog		65,403	19,621	85,024	
FFF	9/1	VA	RHSS		42,282	12,685	54,967	
GGG	9/2	VA	Prog. Asst		43,691	13,107	56,798	
HHH	12/5	VA	Prog		69,491	20,847	90,338	
III	9/2	VA	RHSS		43,691	13,107	56,798	
JJJ	12/3-IT	VA-IPA	IT		68,128	20,438	88,566	
KKK	8/10	VA	Prog Asst		49,766	14,930	64,696	
LLL	12/3	VA	Prog		65,403	19,621	85,024	
MMM	9/1	VA	RHSS		42,282	12,685	54,967	
NNNN	12/5	VA	Prog		69,491	20,847	90,338	
OOO	7/6	VA	DP		40,327	12,098	52,425	
PPP	7/4	VA	DP		38,023	11,407	49,430	
QQQ	12/4	VA	Prog		67,447	20,234	87,681	
TBH	14/10	VA	Epi		112,014	33,604	145,618	
TBH	7/4	VA	DP		38,023	11,407	49,430	
TBH	7/1	NP	RA		34,566	10,370	44,936	
							3,569,797	

(Name) CSPCC - FY07 Personnel Costs (VA)

Name	100	101	102	103	104	105	106	107	108	109	110	111	112	IT	ADMIN	Capacity	SUM
AA															1	0	1
BB																0	0
CC	0.15				0.25										0.6	0	1
DD		0.1	0.1	0.1	0.2	0.8						0.1				0	1
EE	0.1	0.1	0.1	0.2	0.1	0.2	0.1	0.1		0.1						0	1
FF		0.5				1										0	1
GG								0.5								0	1
HH													1			0	1
II						0.8										0	0.8
JJ																0	0
KK					0											0	0
LL													1			0	1
MM							1									0	1
NN						0.5	0.5									0	1
OO								1								0	1
PP																0	0
QQ																0	0
RR																0	0
SS			0.1	0.1	0.1	0.4	0.1	0.1	0.1	0.1						0	1
TT					0.1	0.1						0.1			0.6	0	1
UU						0.2										0	0.2
VV		0.2		0.2											0.6	0	1
WW								1								0	1
XX					0											0	0
YY						0.75				0.25						0	1
ZZ							0.5		0.25	0.25						0	1
AAA							0									0	0
BBB													1			0	1
CCC			0.4	0.5								0.1				0	1
DDD	0.1		0.6							0.3						0	1
EEE			1													0	1
FFF							1									0	1
GGG															1	0	1
HHH																0	1
III			0.2	0.1	0.1	0.1	0.2	0.2		0.1		1				0	1
JJJ																0	1
KKK													1			0	1
LLL															1	0	1
MMM			1				0.5					0.5				0	1
NNNN																0	1
OOO													1			0	1
PPP													1			0	1
QQQ	0.25							0.75								0	1
TBH						1										0	1.00
TBH													1			0	1
TBH																0	0
Grand Total	0.8	3.4	2.6	0.75	5.25	4	3.65	1.6	0.35	1.6	0	1.8	4	3	4.8	0	36

(Name) CSPCC - FY07 Personnel Costs (VA)

Name	Cost Distribution (VA only)										Active	SUM					
	100	101	102	103	104	105	106	107	108	109			110	Analysis	IT	ADMIN	Excess Capacity
AA		0	0	0	0	0	0	0	0	0	0	0	0	68,723	0	68,723	0
BB		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CC		15,166	0	0	25,277	0	0	0	0	0	0	0	0	60,665	0	101,108	0
DD		0	5,497	0	43,973	0	0	0	0	0	0	5,497	0	0	0	54,967	0
EE		7,316	7,316	14,632	7,316	14,632	7,316	7,316	0	0	0	0	0	0	0	73,159	0
FF		0	0	0	62,296	0	0	0	0	0	0	0	0	0	0	62,296	0
GG		0	52,134	0	0	0	0	52,134	0	0	0	0	0	0	0	104,268	0
HH		0	0	0	0	0	0	0	0	0	0	0	94,102	0	0	94,102	0
II		0	0	0	0	62,076	0	0	0	0	0	0	0	0	0	62,076	0
JJ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KK		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LL		0	0	0	0	0	0	0	0	0	0	0	130,683	0	0	130,683	0
MM		0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	54,967	0
NN		0	0	0	0	61,614	0	61,614	0	0	0	0	0	0	0	123,227	0
OO		0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	54,967	0
PP		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QQ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RR		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SS		0	8,768	8,768	8,768	8,768	8,768	8,768	8,768	0	0	17,128	0	102,770	0	87,681	0
TT		0	0	0	0	17,128	17,128	0	0	0	0	0	0	0	0	171,283	0
UU		0	0	0	0	22,100	0	22,100	0	0	0	0	0	0	0	22,100	0
VV		29,124	0	29,124	0	0	0	0	0	0	0	0	0	87,371	0	145,618	0
WW		0	0	0	0	0	0	44,936	0	0	0	0	0	0	0	44,936	0
XX		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YY		0	0	0	0	34,825	0	34,825	0	0	11,608	0	0	0	0	46,433	0
ZZ		0	0	0	0	0	0	25,464	0	12,732	12,732	0	0	0	0	50,928	0
AAA		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BBB		0	0	0	0	0	0	0	0	0	0	123,227	0	0	0	123,227	0
CCC		0	28,376	35,471	0	0	0	0	0	0	0	7,094	0	0	0	70,941	0
DDD		4,494	0	26,961	0	0	0	0	0	13,481	0	0	0	0	0	44,936	0
EEE		0	85,024	0	0	0	0	0	0	0	0	0	0	0	0	85,024	0
FFF		0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	54,967	0
GGG		0	0	0	0	0	0	0	0	0	0	0	0	56,798	0	56,798	0
HHH		0	0	0	0	0	0	0	0	0	0	90,338	0	0	0	90,338	0
III		0	11,360	5,680	5,680	5,680	11,360	11,360	0	5,680	0	0	0	0	0	56,798	0
JJJ		0	0	0	0	0	0	0	0	0	0	0	88,566	0	0	88,566	0
KKK		0	0	0	0	0	0	0	0	0	0	0	0	64,696	0	64,696	0
LLL		0	0	0	0	0	42,512	0	0	0	0	42,512	0	0	0	85,024	0
MMM		0	54,967	0	0	0	0	0	0	0	0	0	0	0	0	54,967	0
NNNN		0	0	90,338	0	0	0	0	0	0	0	0	0	0	0	90,338	0
OOO		0	0	0	0	0	0	0	0	0	0	52,425	0	0	0	52,425	0
PPP		0	0	0	0	0	0	0	0	0	49,430	0	0	0	0	49,430	0
QQQ		21,920	0	0	0	0	0	65,761	0	0	0	0	0	0	0	87,681	0
TBH		0	0	0	0	145,618	0	0	0	0	0	0	0	0	0	145,618	0
TBH		0	0	0	0	0	0	0	0	0	49,430	0	0	0	0	49,430	0
TBH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grand Total		78,020	253,441	203,658	71,485	436,084	274,282	245,241	29,860	121,198	162,569	274,512	313,351	441,022	0	2,904,723	0

(Name) CSPCC - FY07 IT (VA only)

Personnel Cost Basis		FTE		Cost		VA	
Name	GS Level	Funds	Title	Yearly Salary	Fringe	FTE Cost	VA
AA	11/2	VA	QAS	52,864	15,859	68,723	
BB		VA-R	Bio	102,382	-	102,382	
CC	13/2	VA	ADO	77,775	23,333	101,108	
DD	9/1	VA	RHSS	42,282	12,685	54,967	
EE	11/4	VA	RHSS	56,276	16,883	73,159	
FF	9/5	VA-IPA	PM	47,920	14,376	62,296	
GG	13/4	VA	Bio	80,206	24,062	104,268	
HH	12/5-IT	VA-IPA	IT	72,386	21,716	94,102	
II	11/6	VA	PM	59,688	17,906	77,594	
JJ	7/2	NP	RA	35,718	10,715	46,433	
KK	11/2	VA	EQUIC	51,159	15,348	66,507	
LL	14/6	VA-IPA	IT	100,525	30,158	130,683	
MM	9/1	VA	RHSS	42,282	12,685	54,967	
NN	13/10	VA	Bio	94,790	28,437	123,227	
OO	9/1	VA	PC	42,282	12,685	54,967	
PP	7/2	NP	Prog. Asst	35,718	10,715	46,433	
QQ	7/2	NP	RA	35,718	10,715	46,433	
RR		VA-R	Prog.	72,800	-	72,800	
SS	12/4	VA	Prog.	67,447	20,234	87,681	
TT	15/10	VA	Director	131,756	39,527	171,283	
UU		VA-IPA	DNA	85,000	25,500	110,500	
VV	14/10	VA	AD	112,014	33,604	145,618	
WW	7/1	VA	RHSS	34,566	10,370	44,936	
XX	11/2	VA-IPA	EQUIC	52,864	15,859	68,723	
YY	7/2	VA	RA	35,718	10,715	46,433	
ZZ	7/5	VA	PC	39,175	11,753	50,928	
AAA	11/1	VA	EQUIC	51,159	15,348	66,507	
BBB	13/10	VA	DP	94,790	28,437	123,227	
CCC	11/3	VA	PM	54,570	16,371	70,941	
DDD	7/1	VA	RHSS	34,566	10,370	44,936	
EEE	12/3	VA-IPA	Prog	65,403	19,621	85,024	
FFF	9/2	VA	RHSS	42,282	12,685	54,967	
GGG	9/2	VA	Prog. Asst	43,691	13,107	56,798	
HHH	12/5	VA	Prog	69,491	20,847	90,338	
III	9/2	VA	RHSS	43,691	13,107	56,798	
JJJ	12/3-IT	VA-IPA	IT	68,128	20,438	88,566	
KKK	8/10	VA	Prog Asst	49,766	14,930	64,696	
LLL	12/3	VA	Prog	65,403	19,621	85,024	
MMM	9/1	VA	RHSS	42,282	12,685	54,967	
NNNN	12/5	VA	Prog	69,491	20,847	90,338	
OOO	7/6	VA	DP	40,327	12,098	52,425	
PPP	7/4	VA	DP	38,023	11,407	49,430	
QQQ	12/4	VA	Prog	67,447	20,234	87,681	
TBH	14/10	VA	Epi	112,014	33,604	145,618	
TBH	7/4	VA	DP	38,023	11,407	49,430	
TBH	7/1	NP	RA	34,566	10,370	44,936	
						3,569,797	

(Name) CSPCC - FY07 IT (VA only)

FTE Distribution (VA-IT-om)		Planning	Active	100	101	102	103	104	105	106	107	108	109	110	Analysis		112	IT	ADMIN	Excess Capacity	SUM	
Name																						
AA																				1	0	1
BB																					0	0
CC		0.15		0.25					0.8										0.6		0	1
DD		0.1	0.1	0.1	0.2	0.1	0.1	0.2	0.1	0.2	0.1	0.1	0.1			0.1					0	1
EE		0.1	0.1	0.1	0.2	0.1	0.1	0.2	0.1	0.2	0.1	0.1	0.1								0	1
FF		0.5			1						0.5										0	1
GG																					0	1
HH									0.8								1				0	1
II																					0	0.8
JJ																					0	0
KK				0																	0	0
LL																	1				0	1
MM										1											0	1
NN										0.5			0.5								0	1
OO											1										0	1
PP																					0	0
QQ																					0	0
RR																					0	0
SS						0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1								0	1
TT								0.1	0.1	0.1	0.1	0.1	0.1			0.1			0.6		0	1
UU									0.2												0	0.2
VV		0.2					0.2												0.6		0	1
WW											1										0	1
XX								0													0	0
YY									0.75				0.25	0.25							0	1
ZZ										0.5		0.25	0.25								0	1
AAA																					0	0
BBB																	1				0	1
CCC						0.4	0.5									0.1					0	1
DDD		0.1				0.6							0.3								0	1
EEE					1																0	1
FFF										1											0	1
GGG																			1		0	1
HHH																					0	1
III						0.2	0.1	0.1	0.1	0.2	0.2	0.1	0.1			1					0	1
JJJ																		1			0	1
KKK																			1		0	1
LLL																					0	1
MMM										0.5						0.5					0	1
NNN																					0	1
OOO																					0	1
PPP																					0	1
QQQ		0.25									0.75										0	1
TBH									1												0	1.00
TBH																					0	1
TBH																					0	0
Grand Total		0.8	3.4	2.6	0.75	5.25	4	3.65	0.35	1.6	0	1.8	4	3	4.8	0	36					

(Name) CSPCC - FY07 IT (VA only)

Name	Cost Distribution (VA only)										Active	Analysis										ADMIN	Excess Capacity	SUM				
	100	101	102	103	104	105	106	107	108	109		110	111	112	IT													
AA		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	68,723	0	68,723
BB		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CC		15,166	0	0	0	25,277	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	60,665	0	101,108
DD		0	5,497	0	0	0	43,973	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5,497	0	0	0	0	54,967	0
EE		7,316	7,316	7,316	7,316	14,632	7,316	14,632	7,316	7,316	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	73,159	0
FF		0	0	0	0	0	62,296	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	62,296	0
GG		0	52,134	0	0	0	0	0	0	0	52,134	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	104,268	0
HH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	94,102	0	0	94,102	0
II		0	0	0	0	0	62,076	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	62,076	0
JJ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KK		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LL		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MM		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	130,683	0	0	130,683
NN		0	0	0	0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54,967	0
OO		0	0	0	0	0	0	0	0	0	61,614	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	123,227	0
PP		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54,967	0
QQ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RR		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SS		0	8,768	8,768	8,768	8,768	35,072	8,768	8,768	8,768	8,768	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87,681	0
TT		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	171,283	0
UU		0	0	0	0	0	0	0	0	0	22,100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22,100	0
VV		29,124	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22,100	0
WW		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	145,618	0
XX		0	0	0	0	0	0	0	0	0	44,936	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44,936	0
YY		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZ		0	0	0	0	0	0	0	0	0	34,825	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	46,433	0
AAA		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	50,928	0
BBB		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCC		0	28,376	35,471	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	123,227	0
DDD		4,494	0	26,961	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	70,941	0
EEE		0	85,024	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44,936	0
FFF		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	85,024	0
GGG		0	0	0	0	0	0	0	0	0	54,967	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54,967	0
HHH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	56,798	0
III		0	11,360	5,680	5,680	5,680	5,680	11,360	11,360	11,360	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	56,798	0
JJJ		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	90,338	0
KKK		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	88,566	0
LLL		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	64,696	0
MMM		0	54,967	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	85,024	0
NNNN		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	54,967	0
OOO		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	90,338	0
PPP		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	52,425	0
QQQ		21,920	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	49,430	0
TBH		0	0	0	0	0	0	0	0	0	145,618	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87,681	0
TBH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	145,618	0
TBH		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	49,430	0
Grand Total		78,020	253,441	203,658	71,485	436,084	274,282	245,241	29,860	121,198	0	162,569	274,512	313,351	441,022	0	2,904,723	0	0	0	0	0	0	0	0	0	0	0

(Name) CSPCC - FY07 Personnel Costs - Reimb.

Personnel Cost Basis			Funds	Title	Yearly Salary	Fringe	FTE	REIMB TOTAL
Name	GS Level	Funds	Title	Yearly Salary	Fringe	FTE	REIMB TOTAL	
AA	11/2	VA	QAS	52,864	15,859	68,723		
BB		VA-R	Bio	102,382	-	102,382		
CC	13/2	VA	ADO	77,775	23,333	101,108		
DD	9/1	VA	RHSS	42,282	12,685	54,967		
EE	11/4	VA	RHSS	56,276	16,883	73,159		
FF	9/5	VA-IPA	PM	47,920	14,376	62,296		
GG	13/4	VA	Bio	80,206	24,062	104,268		
HH	12/5-IT	VA-IPA	IT	72,386	21,716	94,102		
II	11/6	VA	PM	59,688	17,906	77,594		
JJ	7/2	NP	RA	35,718	10,715	46,433		
KK	11/2	NP	EQUIC	51,159	15,348	66,507		
LL	14/6	VA-IPA	IT	100,525	30,158	130,683		
MM	9/1	VA	RHSS	42,282	12,685	54,967		
NN	13/10	VA	Bio	94,790	28,437	123,227		
OO	9/1	VA	PC	42,282	12,685	54,967		
PP	7/2	NP	Prog. Asst	35,718	10,715	46,433		
QQ	7/2	NP	RA	35,718	10,715	46,433		
RR		VA-R	Prog.	72,800	-	72,800		
SS	12/4	VA	Prog.	67,447	20,234	87,681		
TT	15/10	VA	Director	131,756	39,527	171,283		
UU		VA-IPA	DNA	85,000	25,500	110,500		
VV	14/10	VA	AD	112,014	33,604	145,618		
WW	7/1	VA	RHSS	34,566	10,370	44,936		
XX	11/2	VA-IPA	EQUIC	52,864	15,859	68,723		
YY	7/2	VA	RA	35,718	10,715	46,433		
ZZ	7/5	VA	PC	39,175	11,753	50,928		
AAA	11/1	VA	EQUIC	51,159	15,348	66,507		
BBB	13/10	VA	DP	94,790	28,437	123,227		
CCC	11/3	VA	PM	54,570	16,371	70,941		
DDD	7/1	VA	RHSS	34,566	10,370	44,936		
EEE	12/3	VA-IPA	Prog	65,403	19,621	85,024		
FFF	9/1	VA	RHSS	42,282	12,685	54,967		
GGG	9/2	VA	Prog. Asst	43,691	13,107	56,798		
HHH	12/5	VA	Prog	69,491	20,847	90,338		
III	9/2	VA	RHSS	43,691	13,107	56,798		
JJJ	12/3-IT	VA-IPA	IT	68,128	20,438	88,566		
KKK	8/10	VA	Prog Asst	49,766	14,930	64,696		
LLL	12/3	VA	Prog	65,403	19,621	85,024		
MMM	9/1	VA	RHSS	42,282	12,685	54,967		
NNN	12/5	VA	Prog	69,491	20,847	90,338		
OOO	7/6	VA	DP	40,327	12,098	52,425		
PPP	7/4	VA	DP	38,023	11,407	49,430		
QQQ	12/4	VA	Prog	67,447	20,234	87,681		
TBH	14/10	VA	Epi	112,014	33,604	145,618		
TBH	7/4	VA	DP	38,023	11,407	49,430		
TBH	7/1	NP	RA	34,566	10,370	44,936		

(Name) CSPCC - FY07 Personnel Costs - Reimb.

FTE Distribution (REIMB)	Planning		Active		100	101	102	103	104	105	106	107	108	109	110	Analysis		112	IT	ADMIN	Excess Capacity	SUM	
	100	101	102	103												111	111						
Name																							
AA																							0
BB																							1
CC																							0
DD																							0
EE																							0
FF																							0
GG																							0
HH																							0
II																							0
JJ																							0
KK																							0
LL																							0
MM																							0
NN																							0
OO																							0
PP																							0
QQ																							0
RR																							0
SS																							1
TT																							0
UU																							0
VV																							0
WW																							0
XX																							0
YY																							0
ZZ																							0
AAA																							0
BBB																							0
CCC																							0
DDD																							0
EEE																							0
FFF																							0
GGG																							0
HHH																							0
III																							0
JJJ																							0
KKK																							0
LLL																							0
MMM																							0
NNN																							0
OOO																							0
PPP																							0
QQQ																							0
TBH																							0.00
TBH																							0
TBH																							0
Grand Total																							2

(Name) CSPCC - FY07 Personnel Costs - Reimb.

Name	Cost Distribution (REIMB)		Planning		Active		102	103	104	105	106	107	108	109	110	Analysis 111	112	IT	ADMIN	Excess Capacity	SUM	
	100	101	100	101	100	101																
AA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
BB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	102,382	0	0	0	0	0	0	102,382
CC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FF	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
II	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JJ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OO	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QQ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	72,800	0	0	0	0	0	0	72,800
SS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TT	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
UU	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
WW	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
XX	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
YY	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ZZ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AAA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BBB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DDD	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EEE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FFF	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GGG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HHH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
JJJ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KKK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
LLL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MMM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NNN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OOO	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PPP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QQQ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TBH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TBH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TBH	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grand Total	0	0	0	0	0	0	0	0	0	0	0	0	0	0	175,182	0	0	0	0	0	0	175,182

(Name) CSPCC - FY07 Personnel Costs - Non-Profit

Personnel Cost Basis		GS Level		Funds	Title	Yearly Salary	Fringe	FTE	Non-Profit TOTAL
Name								Cost	
AA	11/2	VA	QAS			52,864	15,859	68,723	
BB		VA-R	Bio			102,382	-	102,382	
CC	13/2	VA	ADO			77,775	23,333	101,108	
DD	9/1	VA	RHSS			42,282	12,685	54,967	
EE	11/4	VA	RHSS			56,276	16,883	73,159	
FF	9/5	VA-IPA	PM			47,920	14,376	62,296	
GG	13/4	VA	Bio			80,206	24,062	104,268	
HH	12/5-IT	VA-IPA	IT			72,386	21,716	94,102	
II	11/6	VA	PM			59,688	17,906	77,594	
JJ	7/2	NP	RA			35,718	10,715	46,433	
KK	11/2	VA	EQUIC			51,159	15,348	66,507	
LL	14/6	VA-IPA	IT			100,525	30,158	130,683	
MM	9/1	VA	RHSS			42,282	12,685	54,967	
NN	13/10	VA	Bio			94,790	28,437	123,227	
OO	9/1	VA	PC			42,282	12,685	54,967	
PP	7/2	NP	Prog. Ass			35,718	10,715	46,433	
QQ	7/2	NP	RA			35,718	10,715	46,433	
RR		VA-R	Prog.			72,800	-	72,800	
SS	12/4	VA	Prog.			67,447	20,234	87,681	
TT	15/10	VA	Director			131,756	39,527	171,283	
UU		VA-IPA	DNA			85,000	25,500	110,500	
VV	14/10	VA	AD			112,014	33,604	145,618	
WW	7/1	VA	RHSS			34,566	10,370	44,936	
XX	11/2	VA-IPA	EQUIC			52,864	15,859	68,723	
YY	7/2	VA	RA			35,718	10,715	46,433	
ZZ	7/5	VA	PC			39,175	11,753	50,928	
AAA	11/1	VA	EQUIC			51,159	15,348	66,507	
BBB	13/10	VA	DP			94,790	28,437	123,227	
CCC	11/3	VA	PM			54,570	16,371	70,941	
DDD	7/1	VA	RHSS			34,566	10,370	44,936	
EEE	12/3	VA-IPA	Prog			65,403	19,621	85,024	
FFF	9/1	VA	RHSS			42,282	12,685	54,967	
GGG	9/2	VA	Prog. Ass			43,691	13,107	56,798	
HHH	12/5	VA	Prog			69,491	20,847	90,338	
III	9/2	VA	RHSS			43,691	13,107	56,798	
JJJ	12/3-IT	VA-IPA	IT			68,128	20,438	88,566	
KKK	8/10	VA	Prog Ass			49,766	14,930	64,696	
LLL	12/3	VA	Prog			65,403	19,621	85,024	
MMM	9/1	VA	RHSS			42,282	12,685	54,967	
NNNN	12/5	VA	Prog			69,491	20,847	90,338	
OOO	7/6	VA	DP			40,327	12,098	52,425	
PPP	7/4	VA	DP			38,023	11,407	49,430	
QQQ	12/4	VA	Prog			67,447	20,234	87,681	
TBH	14/10	VA	Epi			112,014	33,604	145,618	
TBH	7/4	VA	DP			38,023	11,407	49,430	
TBH	7/1	NP	RA			34,566	10,370	44,936	

(Name) CSPCC - FY07 Personnel Costs - Non-Profit

Name	Work distribution (Non-Profit)										Analysis	IT	ADMIN	Excess Capacity	SUM	
	100	101	102	103	104	105	106	107	108	109						110
AA																0
BB																0
CC																0
DD																0
EE																0
FF																0
GG																0
HH																0
II																0
JJ			0.2	0.4								0.2		0.2		1
KK																0
LL																0
MM																0
NN																0
OO																0
PP																0
QQ												1		1		1
RR																0
SS																0
TT																0
UU																0
VV																0
WW																0
XX																0
YY																0
ZZ																0
AAA																0
BBB																0
CCC																0
DDD																0
EEE																0
FFF																0
GGG																0
HHH																0
III																0
JJJ																0
KKK																0
LLL																0
MMM																0
NNN																0
OOO																0
PPP																0
QQQ																0
TBH																0.00
TBH																0
TBH																1
Grand Total			0	0.2	0.4	0	0	0.5	0.25	0.25	0.25	0.25	0	1.2	0	4

(Name) CSPCC - FY07 Personnel Costs - Non-Profit

Name	Planning		Active		103	104	105	106	107	108	109	110	Analysis		IT	ADMIN	Excess Capacity	SUM
	100	101	102	101									111	112				
AA			0		0			0					0		0		0	
BB			0		0			0					0		0		0	
CC			0		0			0					0		0		0	
DD			0		0			0					0		0		0	
EE			0		0			0					0		0		0	
FF			0		0			0					0		0		0	
GG			0		0			0					0		0		0	
HH			0		0			0					0		0		0	
II			0		0			0					0		0		0	
JJ			9,287		18,573			0					9,287		9,287		0	46,433
KK			0		0			0					0		0		0	
LL			0		0			0					0		0		0	
MM			0		0			0					0		0		0	
NN			0		0			0					0		0		0	
OO			0		0			0					0		0		0	
PP			0		0			0					0		0		0	
QQ			0		0			0					46,433		46,433		0	46,433
RR			0		0			0					0		0		0	46,433
SS			0		0			0					0		0		0	
TT			0		0			0					0		0		0	
UU			0		0			0					0		0		0	
VV			0		0			0					0		0		0	
WW			0		0			0					0		0		0	
XX			0		0			0					0		0		0	
YY			0		0			0					0		0		0	
ZZ			0		0			0					0		0		0	
AAA			0		0			0					0		0		0	
BBB			0		0			0					0		0		0	
CCC			0		0			0					0		0		0	
DDD			0		0			0					0		0		0	
EEE			0		0			0					0		0		0	
FFF			0		0			0					0		0		0	
GGG			0		0			0					0		0		0	
HHH			0		0			0					0		0		0	
III			0		0			0					0		0		0	
JJJ			0		0			0					0		0		0	
KKK			0		0			0					0		0		0	
LLL			0		0			0					0		0		0	
MMM			0		0			0					0		0		0	
NNNN			0		0			0					0		0		0	
OOO			0		0			0					0		0		0	
PPP			0		0			0					0		0		0	
QQQ			0		0			0					0		0		0	
TBH			0		0			0					0		0		0	
TBH			0		0			22,468	11,234	11,234	0	0	0	0	0	0	0	44,936
Grand Total			0		9,287	18,573		22,468	11,234	11,234	0	0	55,720		55,720		0	184,236

(Name) CSPCC - FY07 Personnel Costs -Other VA

Personnel Cost Basis		GS Level		Funds	Title	Yearly Salary	Fringe	FTE	Non-Profit
Name								Cost	TOTAL
									FTE
AA	11/2	VA	QAS	52,864		15,859		68,723	
BB		VA-R	Bio	102,382				102,382	
CC	13/2	VA	ADO	77,775		23,333		101,108	
DD	9/1	VA	RHSS	42,282		12,685		54,967	
EE	11/4	VA	RHSS	56,276		16,883		73,159	
FF	9/5	VA-IPA	PM	47,920		14,376		62,296	
GG	13/4	VA	Bio	80,206		24,062		104,268	
HH	12/5-IT	VA-IPA	IT	72,386		21,716		94,102	
II	11/6	VA	PM	59,688		17,906		77,594	
JJ	7/2	NP	RA	35,718		10,715		46,433	
KK	11/2	VA	EQUIC	51,159		15,348		66,507	
LL	14/6	VA-IPA	IT	100,525		30,158		130,683	
MM	9/1	VA	RHSS	42,282		12,685		54,967	
NN	13/10	VA	Bio	94,790		28,437		123,227	
OO	9/1	VA	PC	42,282		12,685		54,967	
PP	7/2	NP	Prog. Ass	35,718		10,715		46,433	
QQ	7/2	NP	RA	35,718		10,715		46,433	
RR		VA-R	Prog.	72,800				72,800	
SS	12/4	VA	Prog.	67,447		20,234		87,681	
TT	15/10	VA	Director	131,756		39,527		171,283	
UU		VA-IPA	DNA	85,000		25,500		110,500	
VV	14/10	VA	AD	112,014		33,604		145,618	
WW	7/1	VA	RHSS	34,566		10,370		44,936	
XX	7/2	VA-IPA	EQUIC	52,864		15,859		68,723	
YY	7/2	VA	RA	35,718		10,715		46,433	
ZZ	7/5	VA	PC	39,175		11,753		50,928	
AAA	11/1	VA	EQUIC	51,159		15,348		66,507	
BBB	13/10	VA	DP	94,790		28,437		123,227	
CCC	11/3	VA	PM	54,570		16,371		70,941	
DDD	7/1	VA	RHSS	34,566		10,370		44,936	
EEE	12/3	VA-IPA	Prog	65,403		19,621		85,024	
FFF	9/2	VA	RHSS	42,282		12,685		54,967	
GGG	9/2	VA	Prog. Ass	43,691		13,107		56,798	
HHH	12/5	VA	Prog	69,491		20,847		90,338	
III	9/2	VA	RHSS	43,691		13,107		56,798	
JJJ	12/3-IT	VA-IPA	IT	68,128		20,438		88,566	
KKK	8/10	VA	Prog Ass	49,766		14,930		64,696	
LLL	12/3	VA	Prog	65,403		19,621		85,024	
MMM	9/1	VA	RHSS	42,282		12,685		54,967	
NNN	12/5	VA	Prog	69,491		20,847		90,338	
OOO	7/6	VA	DP	40,327		12,098		52,425	
PPP	7/4	VA	DP	38,023		11,407		49,430	
QQQ	12/4	VA	Prog	67,447		20,234		87,681	
TBH	14/10	VA	Epi	112,014		33,604		145,618	
TBH	7/4	VA	DP	38,023		11,407		49,430	
TBH	7/1	NP	RA	34,566		10,370		44,936	

(Name) CSPCC - FY07 Personnel Costs -Other VA

Work distribution (Other VA)	Planning	Active	100	101	102	103	104	105	106	107	108	109	110	Analysis	112	IT	ADMIN	Excess Capacity	SUM
Name																			
AA																			0
BB																			0
CC																			0
DD																			0
EE																			0
FF																			0
GG																			0
HH																			0
II																			0
JJ					0.2	0.4								0.2			0.2		1
KK																			0
LL																			0
MM																			0
NN																			0
OO																			0
PP																			0
QQ														1			1		1
RR																			0
SS																			0
TT																			0
UU																			0
VV																			0
WW																			0
XX																			0
YY																			0
ZZ																			0
AAA																			0
BBB																			0
CCC																			0
DDD																			0
EEE																			0
FFF																			0
GGG																			0
HHH																			0
III																			0
JJJ																			0
KKK																			0
LLL																			0
MMM																			0
NNN																			0
OOO																			0
PPP																			0
QQQ																			0
TBH																			0
TBH									0.5	0.25	0.25								0
TBH									0.5	0.25	0.25								1
Grand Total					0	0.2	0.4	0	0.5	0.25	0.25	0	0	1.2	0	0	1.2	0	4

(Name) CSPCC - FY07 VA AOC costs

AOC VA

	Planning		Active										Analysis		
	100	101	102	103	104	105	106	107	108	109	110	111	112	IT	ADMIN
Meeting Expenses(hotel, etc.)		5000	15000	15000	15000	15000	15000	15000	15000	15000	15000	0	0	0	0
LOAs		5000	7500	5000	5000	5000	5000	5000	5000	5000	5000	0	0	0	0
Equipment		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fed-Ex		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Phone Calls		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Printing/Copying		0	0	0	0	0	0	0	0	0	0	0	0	0	0
HRC		1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	0	0	0	0
Misc Office Supplies, etc.		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Patient Reimbursements		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Support Contracts		0	0	0	0	0	0	0	0	0	0	0	0	40000	0
General Supplies		0	0	0	0	0	0	0	0	0	0	0	0	0	25000
Books, Journals		0	0	0	0	0	0	0	0	0	0	0	0	0	5000
Registration Fees		0	0	0	0	0	0	0	0	0	0	0	0	0	15000
Professional Development Registration Fees		0	0	0	0	0	0	0	0	0	0	0	0	0	15000
Office Furniture/Repairs		0	0	0	0	0	0	0	0	0	0	0	0	0	45000
AOC Totals		11000	23500	21000	0	0	40000	105000							
Grand Total VA - AOC		347500													

Travel - Planning Meetings Only - Estimate \$900/person. Give one lump sum

CSP # 100 \$7,200

(Name) CSPCC - FY07 IT AOC (VA Only) costs

AOC IT (va only)

	Planning		Active										Analysis				
	100		101	102	103	104	105	106	107	108	109	110	111	112	IT	ADMIN	
IT Training Registrations			5000	15000	15000	15000	15000	15000	15000	15000	15000	15000	15000	0	0	0	0
Telecommunications			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Software Licensing			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hardware			0	0	0	0	0	0	0	0	0	0	0	0	0	60000	0
Services/ contracts			0	0	0	0	0	0	0	0	0	0	0	0	0	10000	0
Misc Computer Supplies, etc.			0	0	0	0	0	0	0	0	0	0	0	0	0	0	9000
AOC Totals			5000	15000	0	0	70000	9000									
Grand Total IT (va only) - AOC			219000														

(Name) CSPCC - FY07 Reimbursable AOC costs

AOC Reimbursables	Active										Analysis				
	Planning 100	101	102	103	104	105	106	107	108	109	110	111	112	IT	ADMIN
Meeting Expenses	5000	15000	15000	15000	15000	15000	15000	15000	15000	15000	15000	0	0	0	0
LOAs	5000	7500	5000	5000	5000	5000	5000	5000	5000	5000	5000	0	0	0	0
Equipment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fed-Ex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Phone Calls	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Printing/Copying	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HRC	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	0	0	0	0
Misc Supplies, etc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Patient Reimbursements	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Software Licensing	0	0	0	0	0	0	0	0	0	0	0	0	0	60000	0
Support Contracts	0	0	0	0	0	0	0	0	0	0	0	0	0	40000	0
Contracts	0	0	0	0	0	0	0	0	0	0	0	0	0	50000	0
Hardware	0	0	0	0	0	0	0	0	0	0	0	0	0	10000	0
General Supplies	0	0	0	0	0	0	0	0	0	0	0	0	0	0	25000
Books, Journals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5000
Services/ contracts	0	0	0	0	0	0	0	0	0	0	0	0	0	0	9000
Registration Fees	0	0	0	0	0	0	0	0	0	0	0	0	0	0	15000
Office Furniture/Repairs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	45000
AOC Totals	11000	23500	21000	21000	21000	21000	21000	21000	21000	21000	21000	0	0	160000	99000
Grand Total Reim AOC	0														

(Name) CSPCC - FY07 Non-Profit AOC costs

AOC NPC

	Active										Analysis				
	100	101	102	103	104	105	106	107	108	109	110	111	112	IT	ADMIN
Meeting Expenses		5000	15000	15000	15000	15000	15000	15000	15000	15000	15000	0	0	0	0
LOAs		5000	7500	5000	5000	5000	5000	5000	5000	5000	5000	0	0	0	0
Equipment		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fed-Ex		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Phone Calls		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Printing/Copying		0	0	0	0	0	0	0	0	0	0	0	0	0	0
HRC		1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	0	0	0	0
Misc Supplies, etc.		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Patient Reimbursements		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Software Licensing		0	0	0	0	0	0	0	0	0	0	0	0	60000	0
Support Contracts		0	0	0	0	0	0	0	0	0	0	0	0	40000	0
Contracts		0	0	0	0	0	0	0	0	0	0	0	0	50000	0
Hardware		0	0	0	0	0	0	0	0	0	0	0	0	10000	0
General Supplies		0	0	0	0	0	0	0	0	0	0	0	0	0	25000
Books, Journals		0	0	0	0	0	0	0	0	0	0	0	0	0	5000
Services/ contracts		0	0	0	0	0	0	0	0	0	0	0	0	0	9000
Registration Fees		0	0	0	0	0	0	0	0	0	0	0	0	0	15000
Office Furniture/Repairs		0	0	0	0	0	0	0	0	0	0	0	0	0	45000
AOC Totals		11000	23500	21000	0	0	160000	99000							
Grand Total Non_Profit AOC		21000													

(Name) CSPCC FY07 Non-Profit Expected Activity

Study	200	201	202	203	204	205	TOTAL
Expected Yr End Balance	700	400000					
Expected Income (show each billing milestone)							
10/1/2004	2000	50000					
3/31/2005	7000	150000					
8/1/2005	2000	150000					
SUBTOTAL	0	11000	0	0	0	0	0
Expected Expenditures							
CSPCC							
Salaries		0					
AOC		10000					
Travel		5000					
SUBTOTAL	0	15000	0	0	0	0	0
Studies							
Salaries		150000					
AOC		20000					
Travel		10000					
SUBTOTAL	0	180000	0	0	0	0	0
BALANCE	0	11700	0	0	0	0	0

*** All Expenditures need to match salary/AOC/Travel figures on Non-profit pages

Core Study and Forecast Templates

FY07 - CSP Center Core and Study Spreadsheet Instructions

General

Use only these worksheets. An individual study budget sheet needs to be completed for each study, including pilot projects and career developments. Please submit a separate worksheet for each study, including NPC and Reimbursable studies. **DO NOT combine studies on a single worksheet.** Only include items in the study budgets that are in the approved study protocol or have been approved by Central Office after CSSMRB. The study budgets should include all study costs incurred at your Center (personnel & AOC). These costs will be listed under your Center. This year we have asked if you are a Center and ERIC please split the two onto individual worksheets. Indicate your Center or ERIC number on the CSP # line (for example, Palo Alto CSPCC is #145)

New Study Summary Sheet

Please insert the totals for each funding source for each study on this page. As you create your study sheets you can have that figures automatically inserted into the summary sheet.

Allocated FY 2006

You will **no longer have to fill in the previous years funding** on your spreadsheets. We have implemented this due to the limited amount of space left after adding the necessary IT appropriated funding. **I have inserted the necessary calculations on the spreadsheets for you to follow.**

Requested FY 2007 personnel costs

Salaries studies - list all medical centers and indicate .825, 870, IT, and Travel. Ensure .870 funds are used for all study sites where there is a nurse working on a study.

Remember 870 funding is not an option to the field.

Capitated studies that are receiving front-loaded payments - list each medical center and indicate the front-loaded amount in the .825 column. Capitation payments only - do not list the individual medical centers. Indicate one line item - "Estimated capitation payment" and include a total in the .825 column. Do not move line items in the worksheets.

The total should be based on estimated recruitment and the number of medical centers. Include salary costs for the chairs office(s) as a line item.

Requested FY 2007 All Other costs

Indicate costs beyond capitation rate and salaries if applicable for each site

Requested FY2007 Non-Profit

Include total payment requested for sites funded in whole or in part by the non-profit. If column filled, complete NP Details worksheet

Requested FY 2007 Travel Costs

For salaried and capitated studies list out all sites and include a travel estimate using \$900/person/meeting. **On a separate line** you may request travel costs for conferences that study chair(s) if there will be any presentations of study data that a study staff member, such as a SI. These request will be approved based on the availability of funds. **Do not include this in with your regular site travel cost.**

Core Study and Forecast Templates

Forecasting Worksheet

If there is a change in forecast, follow the instruction on the forecast worksheet. **Please be sure you have included the most up to date forecast.**

For each study, estimate costs until study end including the, CO approved, analysis period. Costs should be a lump sum for each entry, inclusive of salaries, equipment, supplies, etc.

CSP line items - including HERC, CSPCRPCC, and CSPCC

Personnel and AOC costs should match the information submitted on the Center Detail worksheet.

HERC and Albuquerque should provide the CSPCCs with their respective personnel and AOC totals to include.

All other costs should be submitted as one total. For explanation on the cost, please insert a comment in the cell.

If there is a lengthy explanation, please add a worksheet explaining the breakdown.

Include a total travel estimate for Center staff/DSMB members based on the total expected meetings and number of attendees.

Submit a narrative explanation for any major changes to a study budget.

The submission for your Center should itemize all non-study costs in the Center - FTE & AOC report. Transfer the totals from the FTE & AOC report to the FY07 Center Core sheet.

On the FY07 Center Core sheet you should list each category on a separate line, such as DF, IT and Admin including the associated personnel & AOC for each category.

Professional Development should be strategically planned and well thought out at each Center. On a separate line in the travel column for the Center,

include an estimate for Professional Development travel only. Estimate \$1000 per eligible employee and \$2000/person for

Core leadership(Director, Associate Director, ADO.) Professional Development registration fees should be a separate line on the center AOC page.

Also include an estimate for the Human Rights site visits @ \$900 per person.

CSP #

Forecasting until Study End

	FY08		FY09		FY10	
	.825	.870	.825	.870	.825	.870
Chair office						
Sites - Capitated						
Sites - Salaried						
CSPCC						
HERC						
CRPCC						
Subtotal						
IT - Pay						
IT-Non-Pay						
Subtotal						
Travel						
Grand Total						

Please insert your most current version submitted to CO to start.
 If you deviate/change/modify any number in any out-years, please do a new table below highlighting the changes
 and an explanation must be provided.

GUIDELINES FOR CENTRAL PRINTING

Several years ago, the Perry Point CSPCC was assigned the responsibility of printing study case report forms and other large quantity documents (i.e., *CSP Guidelines* and *CSP Update*) for the whole Cooperative Studies Program. Case report forms can be printed on NCR paper (non-carbon required) or plain bond paper.

Each job must be accompanied by a Print Shop Duplication Request Form (see sample on following page). A job is defined as a document or a form. If you send more than one document or form, fill out a Print Shop Duplication Request for each. We expect to receive "camera-ready copy." We cannot take responsibility for making any corrections, typing, formatting, etc. Our paper stock is 8 ½" x 11". Anything other than this size will constitute a special request and there may be some delay while we procure supplies. We also maintain a large color assortment of cover stock, but if colors are requested that we do not have in stock, a delay in completing your printing request should be expected.

Routinely jobs are printed in the order in which they are received, but we will always look at the due date and there may be occasions when we will have to reorder the priorities. There have been some occasions that we have not been able to complete a job by the requested due date because not enough time was allowed for us to receive the request by mail. In assigning a due date for a job please take into consideration the slowness of the mail and allow at least six weeks for completion. If we are going to have a problem in completing your job by the due date, we will call you so that you can make other arrangements if necessary.

Mail your duplication requests directly to Gary L. Brown, Printer, CSPCC (151E), VA Medical Center, P.O. Box 1010, Perry Point, MD 21902. If you have a reproduction request that may not be routine, please call Mr. Brown in advance at (410) 642-2411, ext. 5273. We will do our best to maintain high quality of reproduction and quick turnaround. If at any time you experience problems with our service, please call Susan Stinnett at (410) 642-2411, ext. 5284.

Print Shop Duplication Request

For Technical Assistance, Contact:
 Gary Brown
 E-mail brown.gary_1@baltimore.va.gov
 or
 gary.brown2@va.gov
 Telephone (410) 642-2411 x 5351 or 5273

CSPCC (151E)
 Print Shop, Bldg. #4
 VA Maryland Health Care
 System, PO Box 1010,
 Perry Point, MD 21902
 410-642-2411 ext. 5273
 (voice mail)

CSPCC _____

Date Sent Mo _____ Day _____ Yr _____

Person To Contact _____

Date Due. Mo _____ Day _____ Yr _____

FTS # _____

SHIPPING OPTIONS (PLEASE SELECT ONE)

E-mail Address _____

Return Ship FedEx # _____
 (Forms will be returned FedEx if number is supplied)

Priority Mail

Regular Mail

Study #. _____

Has anything changed on this document
 since last printing? Yes No N/A

Document Name _____

Total Number of Pages _____ Quantity _____

PRINTING INSTRUCTIONS:

Cover:

Paper:

Print:

Finishing:

White (bond)
 Padded

Bond

One only

Blue (cover stock)

(White)
 2-part
 (White-Pink)

2-sides, head to head

Unpadded (Thin
 set NCR adhesive)

Brown (cover stock)

3-part
 (White-Yellow-Pink)

2-sides, head to foot

Stapled

Green (cover stock)

4-part
 (White-Yellow-
 Blue-Pink)

Color Copier

3-holed punched

Yellow (cover stock)

Other, specify _____

Other, specify _____ **Other, specify** _____

Books: Set(s) - per - Pad(s)

Additional information

(Limit sheet totals per pad between 175-200)

PRINT SHOP USE ONLY:

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 Mo. Day Yr.

TOTAL SHEETS _____

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DATE PRINTED _____
 Mo. Day Yr.

TOTAL BOOKS _____

NUM. PAGES _____

DATE SHIPPED _____
 Mo. Day Yr.

BOXES SHIPPED _____

OTHER INFO. _____

WHITE - Original Return Copy
 YELLOW - Print Shop Copy
 PINK - Originating Office Copy

REV. 9/02

**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date:

From: [Assistant Director for Administration or Administrative Officer], [medical center name]
CSPCC (#00/000)

Subj: Quarterly Travel and Meeting Information

To: [NAME], CSP Deputy Director (125A), VA Central Office, 810 Vermont Ave., NW,
Washington, DC 20420

The following list consists of CSPCC travel for [LIST NEXT THREE MONTHS]:

<u>CSP#</u>	<u>BIostatistician OR OTHER</u>	<u>TYPE OF TRAVEL</u>	<u>CSPCC CONTACT PERSON</u>	<u>DATE</u>	<u>LOCATION</u>
#000	[NAME OF TRAVELER(S)]	[LIST TYPE OF MTG, i.e., DMC, HRC, STUDY GROUP, etc.]	[CSPCC TRAVEL CLERK NAME]	[DATES OF MEETING]	[LOCATION Of MEETING]

NOTE: List type of
Funding requested
(Use codes below)

- ¹Not yet requested
- ²General Post Funds
- ³Reimbursable Funds
- ⁴Non-Profit Funds

[NAME OF ASSISTANT DIRECTOR/ADMINISTRATIVE OFFICER]

cc: CSPCRPCC
Chief, GCP Monitoring Unit

CSP CENTER REPORTS SUMMARY

Report Names	Description	Due Dates
Travel Projection	List of upcoming travel for CSP personnel & funding source	Oct 1, Jan 1, April 1, July 1
OMB Performance Reports	Data on site performance & overall CSP trial patient accrual by study	20th of each month for data through the previous month
Quarterly Budget Status Reports	Updates on study expenditures compared to original projected budget	Oct 15, Jan 15, April 15, July 15
NPC Reports	Statements on NPC activities for CSP studies	Oct 15, Jan 15, April 15, July 15
Capitation Reports	Report on status of capitation payments needed	Oct 15, Jan 15, April 15, July 15
Study Profile Updates	Confirmation that study profiles have been fully updated	Oct 1, Jan 1, April 1, July 1

GLOSSARY OF ABBREVIATIONS

ACOS	Associate Chief of Staff
ADO	Assistant Director - Operations
AO	Administrative Officer
BECC	Biomedical Engineering and Computing Center
BRDP	Biostatistical and Research Data Processing Procedure
CERC	Clinical Epidemiology Research Center
CRADA	Cooperative Research and Development Agreement
CRADO	Chief Research and Development Officer
CRP	Clinical Research Pharmacist
CSR&D	Clinical Science Research and Development
CSSMRB	Cooperative Studies Scientific Merit Review Board
CSP	Cooperative Studies Program
CSPCC	Cooperative Studies Program Coordinating Center
CSPCRPCC	Cooperative Studies Program Clinical Research Pharmacy Coordinating Center
CTA	Clinical Trial Agreement
CTAA	Cooperative Technology Administration Agreement
CTSC	Clinical Trials Support Center
CV	Curriculum Vitae
DIR	Drug Information Report
DTHP	Drug Treatment and Handling Procedures
DMC	Data Monitoring Committee
ERIC	Epidemiological Research and Information Centers
FDA	Food & Drug Administration
FDAR	Final Drug Accountability Report
FTE	Full Time Equivalent
FTEE	Full Time Equivalent Employee
GCP	Good Clinical Practices
GCPRG	Good Clinical Practices Review Group
GS	General Schedule
HERC	Health Economics Resource Center
HRC	Human Rights Committee
HSP	Human Subjects Protection
HSS	Human Studies Subcommittee
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IPA	Intergovernmental Personnel Act
IRB	Institutional Review Board
IT	Information Technology
LOA	Letter of Agreement
MAVERIC	Massachusetts Veterans Epidemiology Research and Information Center
OMB	Office of Management and Budget
ORD	Office of Research and Development
PPM	Pharmaceutical Project Manager
QAS	Quality Assurance Specialist
R&D	Research and Development
RDIS	Research and Development Information System
RREP	Regional Research Equipment Program
SI	Site Investigator
SMART	Site Monitoring, Auditing and Resource Team
SOPs	Standard Operating Procedures
VA	Veterans Affairs
VA HQ	VA Headquarters
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration

WEBSITE RESOURCES

<http://www.csp.research.med.va.gov/findex.cfm> - CSP Website

<http://www.fda.gov/>: FDA requirements, debarment list, recent audits, recent news

<http://www.clinicaltrials.gov/ct>: This website provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details.

<http://www.irbforum.org>: Resource for Project Managers to pose questions related to human subject protection

<http://www.hhs.gov/ohrp>: Office for Human Research Protection (OHRP) - regulations related to human subject protections.

<http://vaww1.va.gov/ohrm/pay/payrate1.htm>: Pay rates can be found at this website.

http://vaww1.va.gov/ohrm/pay/lps_1.htm: Nurse locality pay scale

Check FDA sanctions listings:

http://www.fda.gov/ora/compliance_ref/debar/default.htm

http://www.fda.gov/ora/compliance_ref/bimo/dis_res_assur.htm

http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm

Check DHHS, Public Health Service, Office of Research Integrity, Administrative Actions Listings:

<http://silk.nih.gov/public/cbz1bje.@www.orilist.html>

http://www.research.va.gov/resources/ORD_Admin/CO_Contact_List.cfm: VA Central Office Contact Listing

http://www1.va.gov/resdev/resources/ORD_Admin/national_directory_AO_ACOS.pdf: R&D AO/ACOS Directory

www.va.gov/vaforms: Directory of government forms

<http://www.forms.gov/bgfPortal/citizen.portal>: The US government official Hub for Federal Forms

Check on processed funding transactions - will give you the TDA#'s and dates of funding transactions:

<http://vaww.arc.med.va.gov/>

~ click on **AACS website** under "Related Sites"

~ click on **AACS Main Menu**

- User name = STA### (Use your Station #)
- Password = sta### (Use your Station #)

www.gpoaccess.gov/cfr/index.html: Main page of Code of Federal Regulations

<http://www.gpoaccess.gov/>: Main page of GPO Access

<http://vaww1.va.gov/vhapublications/>: Veteran's Health Administration (VHA) documents home page. Policies, procedures, brochures, handbooks, etc.

www.hhs.gov/ocr/hipaa: Health Human Services, Office for Civil Rights – HIPAA information



UNITED STATES DEPARTMENT OF VETERANS AFFAIRS

[Resources](#) > [Policies](#)

VA Research & Development

ORD Policies and Directives Sorted by Number

NOTE: The handbooks listed on this page are provided as general reference, but please note that the contact information and dates in the handbooks may be out-of-date. However the basic guidance and processes are largely unchanged. For current dates, forms, and contacts for the upcoming funding round, please refer to the [Applications & Submissions](#) section.

For other handbooks and directives **not** listed on this page, please visit the [VHA publications site](#). Please note that the **most current** copies of Service policy documents are on the ORD website.

Show/Hide All Descriptions [+] / [-]

Number	Title	Service
1058.2	[+] Research Misconduct (136 KB, PDF)	All ORD
1108.4	[+] Investigational Drugs and Supplies (165 KB, PDF)	All ORD
1200	[+] Veterans Health Administration Research and Development Program (120 KB, PDF)	All ORD
1200.1	[+] Research and Development Committee Handbook (119 KB, PDF)	All ORD
1200.2	[+] Research Business Operations (224KB, PDF)	All ORD
1200.3	[+] Centralized Positions of Research Scientists, GS-14 and Above (150 KB, PDF)	All ORD
1200.4	[+] NEW! Research Career Development Program (61 KB, PDF)	All ORD
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