DETAILED INSTRUCTIONS FOR PREPARING RESEARCH APPLICATIONS FOR SCIENTIFIC MERIT REVIEW

A. FORMAT

1. Applications must be on Department of Veterans Affairs (VA) Forms 10-1313-1 through 10-1313-5/6, VA Research and Development Programs, and, if applicable, VA Form 10-1086, VA Research Consent Form. ***NOTE:*** *These are available at local VA Research and Development (R&D) offices, through the PROMISE information system and on the ORD website at* http://www.research.va.gov/funding/process/forms.cfm.

2. Applications must follow all the guidelines outlined in "Detailed Instructions for Preparing Applications for Scientific Merit Review". **Any application that does not follow these guidelines will be returned and will not be reviewed (returned proposals will not be counted as one of the three permitted submissions).**

3. Type all pages single-spaced, with at least 1-inch margins on all sides. Use Arial 11-point font to ensure that the proposal is easy to read.

4. Number all pages, in the bottom right-hand margin, showing Principal Investigator's (PI) last name and the page number (e.g., Smith-1 to Smith-87). Number consecutively, starting with the Table of Contents and ending with the last page of the supporting documents.

B. CONTENTS OF THE APPLICATION PACKAGE

1. **Required Items**

(a) VA Form 10-1313, pages 1-5/6, the proposal narrative, and all supporting documents.

(b) **Revised Proposal.** If this is a revised proposal, in a letter (not exceeding three pages, placed in front of the proposal narrative, and addressed to the Director, HSR&D), the PI must indicate how the revised proposal differs from the previous one. Revised applications are expected to respond fully to any previous critiques. All substantive changes and additions to the narrative in the revised proposal must be identified by the use of *italics*. Exact copies of summary statements and critiques from any prior reviews of the application must be attached at the end of the application (after appendix) and referenced in the Table of Contents.

(c) **Just in Time Documents.** Do not submit Just in Time Documents until notification that the application has been approved for funding. Just in Time Documents must be submitted simultaneously in a single package. Just in Time Documents may include (depending on the nature of the research) IRB approval

and VA form 10-1223, Report of Subcommittee on Human Studies, VA Form 10-1086, VA Research Consent form, Certification of Completion of Human Subjects Protection training, Principal Investigator's Certification: Storage and Security of VA Research Information, Animal Research Protocol Statement, Biohazard Statement, and Privacy Information Statement. In addition, requests for exemptions from OMB review (surveys involving 10 or more participants), if applicable, must be submitted with Just in Time Documents. Just in Time Documents must be received in VACO before any research can begin or funds are disbursed for the research. ***NOTE:*** *For multi-site studies, documentation of IRB approval must be received for each site before research can begin at the site and funds in support of the research can be released. For sites not yet identified, IRB approval must be forwarded as soon as the site is selected.*

2. **Optional Items**

(a) Proposed data collection instrument(s).

(b) Appendices.

C. DETAILED INSTRUCTIONS FOR COMPLETING THE MERIT REVIEW APPLICATION PACKAGE

1. <u>Table of Contents.</u> List all sections of the application (including any appendices) and the initial page number for each. Use Table 1 as the format for the Table of Contents. Indicate N/A for items that are not applicable. Consecutively number all pages in the application and place the starting number for each section in the Table of Contents.

Table 1: Table of Contents	
Project ID	
PIs Last name, first name	
Title of Proposal	
Table of Contents	1
VA Form 10-1313-1 - front page	__
VA Form 10-1313-2 - (abstract)	__
VA Form 10-1313-3 - first year budget	__
VA Form 10-1313-4 - all years budget and justification	__
Project Timeline (Gantt Chart)	__
Investigators' Biographic Information	__
Starting with PI (VA Form 10-1313-5/6)	
Description of any overlap	
Follow with complete sets for each Co-PI and Co-investigator	
For Resubmissions: Letter from PI identifying significant changes	__
Text of Proposal:	
Narrative: Parts 1-6 (not to exceed 25 pages)	__
1. Research Objectives	__
2. Background/Context	__
3. Significance	__
4. Methods	__
5. Dissemination/Implementation Plan	__
6. Project Management Plan	__
Literature citations (not to exceed 4 pages)	__
R&D Committee approval memorandum	__
VA Form 10-1086 VA Research Consent form (if applicable, may be draft)	__
VA Medical Center Director's memorandum	__
Other Letters of Endorsement (Institution, Collaborator, Consultant)	__
VA Central Office Approvals: Exceptions, Waivers or Permission Letters (eligibility, acceptance into program, off-site location, exceeding budget cap)	__
Appendix	__
For Resubmissions Only:	
Summary Statements from previous submissions	__
Critiques from previous submissions	__

2. VA Form 10-1313-1, Merit Review Application

(a) **Item 1 (Tab No.).** Leave blank.

(b) **Item 2 (Application Number).** If this is a new proposal (never been submitted for review) enter NEW. For proposals which have been submitted previously for review enter the 3-letter prefix and first 5 digits of the 6-digit project number, as referenced in the notification of review outcomes letter. Enter the 6th digit of the project number to indicate whether this is the second (-2) or third (-3) time the proposal is being submitted for review.

(c) **Item 3 (Review Group).** Leave blank

(d) **Item 4 (Review Date).** Leave blank.

(e) **Item 5 (Facility Number).** Enter the facility number of the PI's and, if applicable, Co-Principal Investigators (Co-PI)'s VA medical center.

(f) **Item 6 (Location of Health Care Facility).** Provide the complete mailing address, including the PI's routing symbol, for the VA facility identified in Item 5. If the project involves multiple sites, list the name of the site PI including mail code and the facility name, number, and complete mailing address on a separate sheet of paper.

(g) **Item 7 (Social Security Number).** LEAVE BLANK. Proposals that include Social Security Numbers will be returned and will not be reviewed.

(h) **Item 8 (Date of Last Submission).** Enter the date (if any) on which this proposal was previously submitted to HSR&D for merit review. If none, enter "N/A."

(i) **Item 9 (Principal Investigator(s), Degree(s), and Telephone Number).** For each, enter the PI's (and Co-PI's) last name in capital letters, followed by first name, middle initial, degree(s), and phone number(s).

(j) **Item 10 (Program Title).** Enter the project title. The title may not exceed 72 characters (including spaces) and should reflect the content of the application as accurately as possible. The title of the proposal must match exactly the title submitted with the Intent to Submit information or a previous submission and the title on the IRB approval. Changes may not be made to the title after the Intent to Submit information has been received.

(k) **Item 11 (Amount Requested each Year).** Enter the total funding requested for each project year and for the entire project. The amounts and duration must agree exactly with the totals on VA Form 10-1313-3 and VA Form 10-1313-4. All budgets and subtotals must be rounded to the nearest $100 (see instructions for VA Form 10-1313-3

and VA Form 10-1313-4). Some IIR solicitations or program announcements may specify a limit on project duration or cost. Please check HSR&D's web site (http://www.hsrd.research.va.gov) for the most current information.

(l) **Item 12 (VA Employment Status).** Indicate current or expected VA employment status for the PI (and Co-PI). PIs and Co-PIs who have less than a 5/8-paid VA appointment do not need an eligibility waiver or a 5/8th appointment to submit a proposal to HSR&D for review. However, the PI and Co-PI must be a 5/8th VA employee or have an eligibility waiver at the time of funding. It is recommended that a request for an eligibility waiver be submitted as soon as possible. (see VHA Handbook 1200.15).

(m) **Item 13 (VA Salary Source).** Indicate salary source for PI (and for Co-PI).

(n) **Item 14 (Type Program).** Leave blank.

(o) **Item 15 (Program or Cost Center).** Enter 824.

(p) **Item 16 (Primary Program Area and/or Primary Specialty Area).** For PI (and Co-PI), indicate primary and secondary research interests, using the options contained in the "Page 18" instructions in PROMISE.

(q) **Item 17 (VA Hospital Service and Section).** Leave blank.

(r) **Item 18 (Academic Rank, Department, Affiliation).** Enter PI's and Co-PI's current academic rank, primary academic department, and the name of the university affiliation.

(s) **Item 19 (Program Use).** Check YES or NO for each item.

1) Human Subjects. This box must be checked if the research has any relation to human beings, even if the institutional review board (IRB) has found the research to be exempt.
   a) Check this box if the human subjects are exposed to manipulations or interventions, interact with researchers, or can be identified from data collected, even if the data already exist.
   b) Check this box if human tissues are obtained. Tissues include, but are not limited to, biopsies, blood, cerebrospinal fluid, urine, feces, saliva, nail clippings, hair, sweat, and tears.
   c) Check this box if human tissue is obtained from surgery or autopsy, tissue banks, other non-profit sources, or commercial sources.
   d) Do not check this box if the research involves immortalized cell lines.

2) Animal Subjects. The animal subjects boxes should be checked for any proposal using animals or animal tissues using the criteria in items (1)

and (2) below. These criteria do not serve as a basis for determining if local Institutional Animal Care and Use Committee (IACUC) approval is required; they should be used only for the purposes of determining if an Animal Component of Research Protocol (ACORP) must be submitted as a prerequisite for receiving VA funding for a Merit Review application.

a) An ACORP must be submitted when requested if any of the following conditions apply (the "Yes" box for animal subjects should be checked):

    1. Animals are requested in the application budget for use in proposed experiments.

    2. Animals purchased with other VA funds or with non-VA funds would be used primarily or exclusively for experiments proposed in the application.

    3. Animal tissues or primary cell lines purchased with other VA funds or with non-VA funds would be derived from animals sacrificed primarily or exclusively for use in the experiments proposed in the VA application.

b) An ACORP is not required for submission if the proposed animal use meets one of the following criteria (the "No" box for animal subjects should be checked):

    1. Immortal animal cell lines or explants would be used in the proposed experiments such that no additional animals would need to be euthanatized to meet application objectives.

    2. Animals on other IACUC-approved projects would be used, but these animals would be utilized for other projects even if the need for the animals by the proposed VA project did not exist.

    3. Animal tissues, blood and other body fluids, or primary cell lines would be obtained from live animals on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

    4. Animal tissues, blood and other body fluids, or primary cell lines would be obtained from animals euthanatized while on other IACUC-approved protocols, but samples from these animals would be collected even if the need for the tissues or cell lines by the proposed VA project did not exist.

5. Animal-derived reagents or products such as serum, antibodies and mediators required in the application are limited to those that would be purchased from a USDA-licensed commercial vendor.

c) If guidance is needed on applying the criteria in paragraphs (a) and (b), the Chief Veterinary Medical Officer (CVMO) should be contacted.

3) Investigational Drugs or Devices. Check the appropriate box if the use of investigational drugs or devices with human subjects is proposed.

4) Radioisotopes. If radioisotopes are used, check the "Radioisotopes" box and include appropriate information in the biohazard form. The local Radiation Safety Committee must approve the use of radioisotopes before any studies contained in the application may be conducted.

5) Biohazard. A checklist of biohazards by category is provided on the first page of Appendix G of VHA Handbook 1200.8. If the research uses any of the products listed in the appendix, the Biohazards box must be checked. Blood, however obtained, cerebrospinal fluid, and all body secretions and excretions, e.g., urine, feces, saliva, sweat, and tears, are biohazards. Most chemicals used in laboratories are biohazards.

a) Questions about research safety documentation are to be directed to the VA Central Office Research Biosafety Officer.

(t) **Item 20 (Summary of Research Support).** Summarize the research support for the last three fiscal years, beginning with the current fiscal year, for the PI (and Co-PI). "Non-VA" includes all other sources of research funding other than VA.

(u) **Item 21 (Date Entered on Duty).** Enter date the PI (and Co-PI) entered or will enter VA duty, if appointment is pending. ***NOTE:*** *If there has been a break in service, give date of most recent appointment.*

(v) **Signature Blocks.** Original, dated signatures of the PI and the Associate Chief of Staff (ACOS) for Research and Development (R&D), Coordinator for R&D, or designee are required. Signatures and dates in this block must be within 6 months before the submission due date. The date the ACOS for R&D signs must be after the approval date of the R&D Committee. **The signature of the ACOS for R&D certifies that the application is administratively complete and that all required reviews have been conducted.** The signature of the PI signifies responsibility for the ethical conduct of the proposed work and agreement to follow VA policies including acknowledging VA support and intellectual property rights. "Per", "by", or "for" signatures are not acceptable.

3. **VA Form 10-1313-2, Summary Description of Program**

(a) **General.** At the top of the form, check "PROJECT**."** Enter the PI's name and the project title.

(b) **Keywords**. From the National Library of Medicine's Medical Subject Headings (MeSH), select at least three that identify the scientific discipline or research area(s) emphasized in the proposed research. The MeSH terms book may be located in the ACOS/R&D's office, or the medical center library, or may be obtained online at http://www.nlm.nih.gov/mesh/meshhome.html. ***NOTE:*** *The accuracy of these codes is very important. The codes assist HSR&D administrators in assigning the proposal to an appropriate review group and research portfolio and in selecting appropriate reviewers.*

(c) **Brief Statement of Research Objectives (Abstract).** Provide a concise (500 words or less), informative description of the proposed study, suitable for dissemination. The summary description (abstract) of the proposal must include enough information so that the proposal can be referred to the appropriate Merit Review Subcommittee and reviewers. Use only the allotted space. Organize the abstract in the following sequence:

1) Anticipated Impacts on Veterans' Healthcare. Describe why this study is important and how it will benefit veterans, impact veterans' healthcare, or represents a unique research opportunity within the VA healthcare system.

For Example:

Our study will provide important insight into the clinical, system, and cultural factors that may account for variations in procedure use in veterans with osteoarthritis. Our study will also provide insight into differences in disease perceptions and values between racially diverse groups of veterans. This insight will help VA providers deliver care that is more culturally sensitive.

2) Project Background/Rationale. Describe the background or rationale for the proposed study. *Address why the study is important and relevant to VA*.

For Example:

Many investigations have confirmed that African-American patients are much less likely than White patients to receive total joint replacement for osteoarthritis of the hip and knee. This variation occurs even though the prevalence of osteoarthritis is similar in African-American and White patients. There is little understanding of the reasons for this variation. Understanding the reason for this variation is of profound importance to veterans because osteoarthritis is both extremely common and a leading cause of disability among veterans.

3) Project Objectives. Outline the major goal(s), specific research question(s) and objective(s).

For Example:

The indications for therapy of osteoarthritis are based on the patient's symptoms and quality of life. Therefore, understanding ethnic variations in the care of patients with osteoarthritis requires an understanding of ethnic differences in clinical severity of osteoarthritis, the impact of osteoarthritis on quality of life, patient perceptions and beliefs about arthritis, and patient interactions with the health system. With this in mind, our objectives are to measure ethnic variation in: 1) the pathways leading from joint destruction to clinical symptoms and from clinical symptoms to impaired quality of life; 2) social and cultural attitudes of patients with osteoarthritis (such as attitudes towards arthritis, pain, and disability, cultural attitudes towards potential treatments, and cultural attitudes about the health system); and 3) patients' interactions with the health system.

4) Project Methods. Describe the study design (e.g., randomized controlled trial, cohort study, case-control, etc.) that will be used. This section should also include major characteristics of the study population (e.g., age, gender, diagnosis, inclusion/exclusion criteria) and size of the sample and any control group; the intervention; and the setting. Please indicate if non-VA sites are included. Finally, include major variables and source(s) of data and the main types of analysis (decision modeling, cost-effectiveness, qualitative techniques, meta-analysis, etc.)

For Example:

This is a cross-sectional study of 600 veterans with chronic hip or knee pain cared for in VA primary care clinics. We are using two primary methodologies: 1) a structured survey with items measuring constructs in each of the above objectives. This includes the severity of the patient's arthritis, the impact of the arthritis on functional status and quality of life, cultural beliefs about arthritis, and the acceptability of different treatments of osteoarthritis. 2) a semi-structured, interview, analyzed with qualitative techniques. This interview focuses on the patient's interaction with the VA health care system, and the reasons for the patient's success or lack of success in obtaining satisfactory treatment for their osteoarthritis symptoms.

4. **VA Form 10-1313-3, Current Funds and First Year Request**

(a) **General.**

1) At the top of the form, check "Project." Enter PI's name and project title.

2) Budget Limits**:** Projects that exceed $300,000 in any one year or a total project budget of $925,000 (including all salary costs) will not be accepted without a previous written waiver approved by the scientific program manager and the Director, HSR&D. In planning project budgets, applicants are reminded to adhere to HSR&D guidelines regarding allowable use of research funds for specific items and restrictions on the use of research funds for equipment and development of computer software (see VHA Handbook 1204.01, Paragraph 8, HSR&D Funding for "Development").

3) Budget Waiver Request**:** In rare instances, a waiver may be granted for projects that exceed $300,000 in any one year or a total of $925,000. A request must be received no later than 30 days prior to the proposal submission deadline. The request must include all budget information from the proposal (VA forms 10-1313-1, 10-1313-2, 10-1313-3, 10-1313-4) and a one-page justification as to why the waiver is being requested. Following approval by the local HSR&D Center (if applicable) and ACOS for Research Development, the request and related documentation should be sent via e-mail to the relevant portfolio manager. An e-mail response will be given within 10 days. If a waiver is granted, a copy of the e-mailed waiver must be included with all copies of the application. A waiver does not guarantee a project will be funded at the level requested.

4) All budget subtotals are to be rounded to the nearest $100. Check the HSR&D website (http://www.hsrd.research.va.gov) for current policy as to budget/duration of project limitations.

5) Table 2 summarizes guidance for budget categories.

Table 2: Budget Item Guidance	
Personnel	
• Physicians	Salary support is not authorized for any VA physician.
• Nurses or Licensed Medical Professionals	Salary support is not authorized for any Title 38 nurse or licensed medical professional with clinical responsibilities in VA unless a waiver has been granted by the CRADO. If waived, salary support is

	allowed only for services beyond usual care.
• Increases in salary over years to account for cost of living or salary increases (HR actions)	Not authorized
• Summer/Graduate students	Not authorized
• IPAs	IPAs must be listed under “All Other”, not personnel. IPAs are not authorized for physicians.
• Consultant	Limit of $500 per consultation and $2,500 per annum. Physicians may not be paid as consultants. Expenses other than professional fee (e.g., travel) should be listed under “All Other”.
Equipment	
• Computers	Computers (and IT expenditures) should not be listed in the “Equipment” section. Computers (and IT expenditures must be itemized in Table 4 (Justification page 1313-4) and the total listed as a line item in the “All Other” section.
• Furniture	Must be justified as necessary for the conduct of this research. Justification must account for disposition of previously funded furniture purchases for projects that are terminated.
• Medical Equipment	Must be required for the conduct of the research project and not be used as part of routine and customary patient care.
Supplies	
• Postage	Not authorized, unless special circumstances require other than ordinary mail
• Phone costs	Special 800 lines may be approved with justification
• Copying	Not authorized
• Construction	Contact ORD for guidance on construction requests
• Books, journals, or reprints	Not authorized
• Professional memberships	Not authorized
• Manuscript preparation	Not authorized
All Other Expenses	
• General Administrative costs	Not authorized
• Access to Austin or PBM database	Not authorized
• Contract for Services	Service contracts are used to obtain a

	deliverable/product from a company or an institution, e.g. service contract with the University of California for statistical analysis of data. You may not contract for clinical services or identify the individual (s) who will provide the service on VA Form 10-1313-3. A non-VA physician may only perform non-clinical work. A detailed description of the services being contracted for, along with the name and credentials of the person(s) who may be providing the services, should be part of the budget justification on VA Form 10-1313-4.
• IPAs	IPAs provide for salary and fringe benefit reimbursements; they do not allow for "overhead" costs. IPAs may not be used for physicians. IPAs should not be used for key personnel (PI and Co-PI).
• Monetary incentives to physicians	Monetary incentives to physicians are not authorized.
• Patient Incentives	Small amounts of money can be offered as a reimbursement for time and/or travel to participate in a study. The incentive must not, in and of itself, constitute an incentive and must be consistent with IRB and ethics policies.
• Travel and registration costs associated with conference attendance	Not authorized. HSR&D will consider requests to travel to present study findings on a case-by-case basis.
• Information Technology	Unusual computer requests should be accompanied by a vendor quote and a strong justification. Shared network charges are not authorized.

(b) **Personnel**. Starting with the PI, list all VA employees who will work on the project, including those for whom no salary support is requested. Enter name and academic or professional degree(s) (list Grade and Step in parentheses).

1) Physicians may not receive salary support from VA research funds.

2) Nurses and other licensed medical professionals (Title 38 employees) with clinical responsibilities may not receive salary support from VA research funds except with the express prior approval of the Chief R&D Officer.

3) Clerical support may not be included as study personnel unless their work can be justified as an integral part of project activities.

4) There are restrictions on who can be paid directly by VA. Check with the local Research Office to ensure that salary is not requested for a person who cannot be paid directly by VA.

5) Interagency Personnel Act (IPA) appointments should not be listed under Personnel. IPAs should be listed under All Other. IPAs may not be used for PIs, Co-PIs, and physicians.

(c) **Role in Program**. Indicate whether the named individual is a Co-PI, investigator, research assistant, etc.

(d) **Percent Effort**. List the percent of time (Full-time Equivalent (FTE)) to be devoted to the project by each named participant. Ensure that no person's individual time commitments total more than 100 percent.

(e) **Current Year Funds**. List all R&D funds disbursed by VHA Central Office to the named individual (s) during the 12 months preceding the requested start date.

(f) **First Year Requested Funds.** List all funds requested for the first 12 months of the proposed project. VA research funds cannot be used to cover the costs of patient care except in very special circumstances.

1) Salary requests are to be proportional to the percent effort listed. Salaries are to include fringe benefits (30%) for all personnel.

2) Nurses and other licensed medical professionals (Title 38 employees) may not receive salary support from VA research funds except with prior approval of the Chief R&D Officer.

3) For the Nursing Research Initiative (NRI) program, the PI, who must be a nurse, can not be paid by research funds.

(g) **Consultant Services**. Consultant payments are limited to $500 per consultation or $2,500 per year, exclusive of expenses. Higher amounts must be approved by the Secretary of Veterans Affairs.

1) Consultation-related costs other than professional fees (e.g., consultant travel) need to be listed under "All Other Expenses."

2) A curriculum vitae and letter from each proposed consultant, indicating the agreement to consult and detailing the nature of the consultation, need to be included in the supporting documents.

(h) **Equipment.** List each item of equipment to be purchased. Estimated equipment costs need to be consistent with current VA procurement policies and contracts.

(i) **Supplies**. Itemize the cost of supplies (expendable items), by major category, e.g., office supplies, printing, etc.

(j) **All Other Expenses.** Itemize all other expenses by major category, e.g., travel, rent, contract fees, IPAs, etc. (see Handbook 1204.5). Refer to guidance in Table 2 for items which can not be purchased with research funds.

1) Travel costs. List the travel costs for year one (derived from Table 3 on Page 1313-4). All requested travel must be related directly to the conduct of the research. Travel and registration costs associated with conference attendance should not be requested. ***NOTE:*** *If the project is funded, HSR&D will consider requests for travel to attend a conference to present study findings, based on the availability of funds, on a case-by-case basis.*

2) Information Technology (IT). List the total planned IT expenditures (derived from Table 4 on Page 1313-4).

5. **VA Form 10-1313-4, Estimated Expenses**

(a) At the top of the form, check “Project."

(b) **Personnel**. All personnel costs should be straight-lined for the duration of the project. Do not request funds for expected cost-of-living increases, within-grade increases, or promotions.

(c) **Consultant Services through Total Operating Expenses**. Enter the totals for each budget category for all additional years of support requested. The total operating expenses for the first year must be identical to the total indicated on VA Form 10-1313-1 and VA Form 10-1313-3.

(d) **Justification.** All items in the budget listed on Form 1313-3 must be clearly justified. Use continuation pages if necessary.

1) Personnel. Fully explain the role and percent effort of the PI and all personnel listed in the Personnel section of form 10-1313-3.

2) Consultants. Clearly explain the expertise of each consultant with regard to the proposed research, the nature of the service to be provided, the number of consultations, and professional status (MD, RN, PhD, etc.). MD consultants may not receive salary compensation.

3) Equipment. For each item, justification should include a discussion of why the equipment is needed and why similar existing equipment at your facility or in a nearby research space cannot be used. Include the cost of maintenance.

4) Supplies. Explain how the costs for each category of supplies were derived (e.g., based on the PI's expense history in performing similar research).

5) All Other Expenses. Items in this category should be explained in the same manner as those in the supplies category.

6) General.

   a) Interagency Personnel Agreements (IPAs) should be fully explained including the basis for the individual's salary.

   b) Contracts for services should describe the services or products that are to be provided. Contracts for Service should not identify the individual(s) who might perform the services.

7) Project Travel. All requested travel must be related directly to the conduct of the research. Project related travel expenses must be fully explained and a cogent justification provided. Explain why e-mails, conference calls, or teleconferencing are not sufficient to accomplish the goals of the requested travel. Provide a table summarizing the requested travel using the format in Table 3. Travel and registration costs associated with conference attendance may not be requested.

Table 3: Project Travel

Traveler	Status (VA or non VA)	Destination	Number of Trips	Year of Trip	Estimated Cost	Purpose

8) Information Technology. All planned expenditures for IT must be fully justified. Unusual computer requests should be accompanied by a vendor quote and a strong justification. Shared network charges are not authorized. Itemize all planned IT expenditures using the format in Table 4. The total for planned IT expenditures should be listed as a line item "Information Technology" in the "All Other" section of 1313-3.

Table 4: Planned IT Expenditures

Category	Type	Amount Year 1	Amount Year 2	Amount Year 3
Hardware	Purchased			
	Leased			

	Services			
Software	Purchased			
	Leased			
	Services			
Telecommunications	Purchased			
	Leased			
	Services			
IT Supplies and Materials	Purchased			
	Leased			
	Services			
IT Personnel				
	TOTAL			

9) Budget Totals. Budget totals on VA Form 10-1313-3 and VA Form 10-1313-4 must be identical and correspond to the totals in block 11 of VA Form 10-1313-1. The accuracy of these items needs to be checked before submitting the application package.

6. **Gantt Chart.** Present the project timeline in a Gantt Chart form (see Appendix A)

7. **VA Form 10-1313-5/6**. Complete VA Form 10-1313-5/6 for the PI and for each scientist who will participate in the design, conduct, or scientific direction of the proposed research. Do not include any of the above forms for consultants or technical staff. ***NOTE****: VA Form 10-1313-7 and VA Form 1313-8 are no longer required.*

(a) **Education and Training.** Follow the instructions on the form.

(b) **Positions and Honors.** Follow the instructions on the form.

(c) **Selected Peer-reviewed Publications.** List publications in chronological order. Due to space limitations (total for items Positions and Honors and Selected Peer-reviewed Publications may not exceed two pages) select those publications that are directly relevant to the proposed research.

(d) **Research Support.** Total research support is defined as all financial resources, whether federal, non-federal, commercial or institutional available in direct support of the individual's research. Do not include the current application as pending support. Include all currently funded and pending support. Support which was received more than 3 years ago can be listed if the funded project was directly related to the current application. Although the instructions on VA Form 5/6 state "Do not list award

amounts or percent effort in projects", this information DOES NEED to be provided. Use the format in Table 5 to organize the data.

TABLE 5 RESEARCH SUPPORT					
Grant number	**Agency**	**Start-End Dates**	**Total Award**	**Role in Project**	**% Effort**
Title					
Goals of Project					

1) Overlap. After listing all of an investigator's support, on a separate sheet of paper headed "Overlap", summarize any potential overlap between the research in the proposal and any active or pending research with respect to the science, budget, or the investigator's total effort. If the investigator has no active or pending research, do not include the "Overlap" page. Statements such as "there are no budgetary, scientific or administrative overlaps" without any discussion of the science are not acceptable.

   a) Budget overlap occurs when items requested in the current application, such as computer equipment or salary, duplicate, or are equivalent to, items already funded, items requested in a pending application, or items which have been provided from another source.

   b) Commitment overlap occurs when any personnel listed on the project has time or effort commitments (whether salaried or unsalaried) that exceed 100 percent. No individual listed on the project budget form may have more than 100 percent effort.

   c) Scientific overlap occurs when substantially the same research is proposed in more than one application, is submitted to two or more funding sources, or when the research objectives and the research designs are the same or grossly similar in two or more applications, regardless of funding sources.

(e) **Time and effort.** Follow the instructions on the form.

(f) **Significant Life Events.** This section is optional.

8. Proposal Response and Narrative

(a) **General Instructions.** The narrative must include sufficiently comprehensive and detailed information about the rationale for goals and methods of the proposed research

to permit serious consideration of the scientific and technical merit of the proposed research. In a clear, well-organized, self-contained narrative, the applicant must explain what is proposed, how it will be done, and why it is important. ***NOTE:*** *The narrative is expected to address any substantive and methodological concerns identified by reviewers of any previous version of the proposal.*

1) Follow instructions carefully, observing page limits. Use proper English and avoid jargon. For terms that are not universally known, spell out the term for the first time followed by an abbreviation enclosed in parentheses; thereafter the abbreviation may be used.

2) Observe type size specifications and margin requirements throughout the application (see paragraph 1b) or the proposal will not be reviewed. All tables, diagrams, graphs, and charts, must be clear and legible. Proposals that are difficult to read will be administratively withdrawn.

3) All figures and tables must be included in the text. As long as clearly legible, type size for figures, charts, tables, footnotes, and figure legends, may be smaller.

4) Photographs are to be placed in the text of the proposal and are included in the 25-page limit. Unpublished questionnaires may be placed in the appendix. Methods and/or procedures, even if unpublished, are to be incorporated into the Narrative and are not to be placed in the appendix.

(b) **Application Page Limitations, Order, and Content Requirements.** Table 6 summarizes the page limitations, order and guidance on the content requirements of the narrative sections.

TABLE 6: Page Limitations, Order, and Content Requirements

Section	Page Limit	Content
Response to Critiques (Revised applications)	3	Paragraph 8 (b) (1)
Narrative (Total)	25	
• Research Objectives	1 (suggested)	Paragraph 8 (b) (2) a)
• Background/Context	3 (suggested)	Paragraph 8 (b) (2) b)
• Significance	2 (suggested)	Paragraph 8 (b) (2) c)
• Methods	15 (suggested)	Paragraph 8 (b) (2) d)
• Dissemination/Implementation Plan	2 (suggested)	Paragraph 8 (b) (2) e)
• Project Management Plan	2 (suggested)	Paragraph 8 (b) (2) f)
References	4	Paragraph 8 (b) (3) References do not count toward 25 page limit

1) **Response to Reviewers' Critiques (resubmitted applications only, three page limit).** A revised application will not be reviewed if it fails to comply with all of the requirements for resubmission. Prior to submitting a revised application, the PI should have received the summary statement and critiques from the previous review.

a) The revised proposal must address all the concerns outlined in the highlights of the SMRB's discussion on the summary statement as well as major issues in the individual reviewers' critiques.

b) Responses to the reviewers' critiques must be presented in a letter addressed to the Director, HSR&D which is placed before the narrative. Revised applications are expected to respond fully to any previous critiques. The response to reviewers' critiques must describe how the revised proposal differs from the previous submission and how the concerns expressed by reviewers were addressed. The letter should summarize the substantial additions, deletions, and changes based on the comments and suggestions in the summary statement. A justification must be provided if changes suggested by the reviewers are not made.

c) All substantive changes and additions to the narrative must be identified by the use of *italics*. The Work Accomplished section needs to include any new work accomplished since the prior submission. Acceptance by HSR&D to review a revised application automatically supersedes previous submissions and the revised application becomes the document of record.

2) **Narrative.** The full narrative [i.e., see following subparagraph (2)(a) 1) through (2) (f) 4)] may not exceed 25 pages. The Narrative must be comprehensible without references to any other document, including the appendix. The narrative is organized into 6 major sections with suggested page limits as summarized in Table 2. Specific guidance as to issues to address in each section follows:

a) <u>Research Objectives</u>. Describe:

1. The hypothesis(es) or key research question(s).

2. The immediate and long-term objectives.

b) <u>Background.</u> The background information must be sufficiently complete to demonstrate that the PI is aware of the critical issues related to the proposal. It need not be exhaustive. Provide evidence from the literature and any pilot studies addressing:

1. The scientific rationale and theoretical framework for the proposed research. Discuss relevant research, completed or underway, inside and outside VA.

2. The context in which the study will be conducted and results applied.

3. How or why this study will succeed in answering questions that have eluded other researchers (e.g., better design, larger sample, longer follow-up, etc.).

c) Significance. Explicitly state how the proposed research will provide new knowledge, advance the scientific field, and/or address gaps in knowledge. Explain how the results will be useful to VA and veterans (and if applicable, outside VA). Consider the following questions:

1. How common, serious, or urgent is the problem this research addresses?

2. What are the potential contributions of the proposed research? For example, how will the proposed research extend knowledge and/or contribute to improved quality, effectiveness, or efficiency of VA health care or the health of eligible veterans? How will it enhance health care management or clinical decision-making? How does this research represent a unique opportunity for VA?

3. What or who are the audiences for the results of the research, and how might they use the information or product(s)?

d) Methods. Describe the research plan completely and in detail, including the basic study design, sampling plan, control or comparison groups, methods for data collection and analysis, and specific techniques and measures. Specify the kinds or sources of data to be used, how hypotheses will be tested, aggregate and subgroup analyses, and provisions for ensuring data quality and adherence to the study protocol. Address:

1. How is the study design suited to the specific research question(s) and population? What are the advantages and disadvantages of this approach? Describe new methodologies to be used and why they are preferred over existing methods. Discuss potential problems and limitations

to the proposed methods and/or procedures and possible alternative approaches to achieve specific aims.

2. Where will the study take place? Why is this setting or geographic location appropriate? Will the results be applicable to other places or populations?

3. What are the characteristics of the study population? How will the sample be selected and what steps will be taken to secure and retain the needed number of subjects (and controls, if applicable)? What steps will be taken to ensure adequate representation of women and minorities? What is the estimated sample size and how was it derived? What assumptions were made regarding the magnitude of the expected treatment effect? At what level of power can inferences be drawn?

4. Identify and define the dependent and independent variables and explain their selection. How will the major variables be measured and how will they be linked in the analysis? Comment on the reliability, validity, and appropriateness of the proposed measures for the study population. ***NOTE:*** *If new or unpublished measures are to be used, the data collection instruments must be submitted as part of the appendix.*

5. What is the data collection strategy and timeline? What are the potential problems in collecting data and controlling data quality? How will these problems (e.g., missing data, respondent drop-out, interviewer bias) be addressed?

6. What is the strategy for data analysis? Outline the planned analyses, indicating which variables will be used in which analyses and the order in which analyses will be done (do not merely name proposed statistical tests). What are the strengths and limitations of this analytic strategy? Include power calculations as appropriate. Power calculations should be described in terms of clinical significance, if appropriate, as well as statistical significance.

e) Dissemination and/or Implementation Plan. A conceptual plan must be included that indicates how and when research findings will be disseminated and, if appropriate, implemented. Discuss conditions or barriers to implementing the eventual findings or products, and identify any plans and promising mechanisms

(beyond professional publications) to facilitate dissemination and implementation. Describe:

1. Timelines. Be sure to include dissemination and implementation timelines into the Gantt chart for the project.

2. Intended audiences for the research and identify what channels will be used to reach these audiences. A clearly delineated strategy for dissemination and, if appropriate, implementation for each intended audience must be included.

3. An estimated budget. Funds will not be disbursed until findings for the intended audience are validated.

f) Project Management Plan. Describe:

1. The project management plan and timeline (refer to paragraph 6 Gantt Chart).

2. The facilities and resources required, indicating which are available and which would be obtained if the project is funded. Include space, data processing capacity, access to subjects, access to VA staff, and major equipment and/or supplies.

3. The role and tasks of each member of the research team and how their work will be coordinated.

4. Any proposed collaboration with institutions or investigators outside the PI's facility and how the work will be coordinated. Include a description of the role of consultants, contractors, and other non-VA employees. Along with the letters of endorsement, include a letter from each person who is from outside the PI's facility, indicating their agreement to participate.

3) **References.** List complete bibliographic information for all cited references. ***NOTE:*** *Reference pages do not count as part of the twenty-five page limit.*

9. Administrative Support Documents

(a) **R&D Committee Approval.** Provide a memorandum signed by the Chair, R&D Committee stating the application was reviewed and approved for submission to VA Central Office (include the date of approval) by the R&D Committee. If the PI is the

chairperson of the R&D Committee or a subcommittee, an appropriate alternate must sign. This responsibility may not be delegated to the Administrative Officer or the ACOS for R&D.

(b) **Just-in-Time Submission of Compliance and/or Assurance Documents.** Do not submit any IRB, human subjects, animal subjects, biosafety forms and/or approvals, documentation of human subjects protection training, Certification: Storage and Security of VA Research Information, or the Privacy Information Statement with this application. It is a local facility decision whether subcommittee review for human subjects, animal subjects, and/or biosafety is conducted prior to the submission of the application, after the submission, or after notification of funding. However, these documents will not be accepted in VACO before notification of funding. Research offices will be notified of proposals that are being considered for funding and the specific Just-in-Time documentation needed to complete the review process. All required documentation must be submitted to CO simultaneously, as a single package. No project will be funded until the requested documentation has been provided to VACO.

(c) **Draft of VA Form 10-1086 VA Research Consent Form.**

1) VA Form 10-1223 Report of Subcommittee on Human Studies is no longer required to be submitted with the application package (see Just in Time Documents, paragraph 14). However, a draft of VA Form 10-1086 must be submitted if the proposed research requires evidence of a subjects' informed consent.

2) The title on the informed consent form must be the same as the title of the application (VA Form 10-1313-1, box 10).

3) The VA informed consent form (VA form 10-1086) must be used, even if the affiliated university's IRB is the IRB of record.

(d) **Letters of Endorsement.** All letters of endorsement must include the PI's name, project title, and VA facility. They need to be addressed to the Director, HSR&D, and are to be signed and dated. Letters of endorsement need to be included with the application at the time of submission and will not be accepted after the deadline. Letters are required from:

1) **The Director of the PI's VA facility and, if the research has Network implications, the Network Director.** The letter must indicate the Director's recognition of the potential impact of the proposed research on the facility (including, for example, use of space, equipment, or release time) and that the necessary support, including space, described in the application will be available. It needs to document the Director's understanding that employee appointments and funding for projects supported by R&D are only for the duration of the project, and that the PI is (or will be at the time the proposal is funded) at least a 5/8th

FTEE employee of the medical center. This letter must certify that the proposal is not being submitted to any VA funding source other than HSR&D.

2) **Participating institutions and persons.** Each participating or affected organizational element, institution, collaborator, and consultant must provide a letter. These letters must indicate concurrence of the affected person or institution with their specific role or contribution as described in the application. Consultants need to include their curricula vitae (4 page limit). Collaborators do not need to include their curricula vitae.

10. Appendix. Information that is critical to the review of the application must be contained in the proposal narrative. The Appendix is for material that was prepared by the applicant or others, independent of the current proposal.

(a) **General.**

1) The appendix pages are to be numbered consecutively with the rest of the application and included in the Table of Contents.

2) The appendix must be submitted at the same time as the rest of the application.

(b) **Data Collection Instruments.** For HSR&D applications proposing the use of unpublished data collection instruments, copies of the instrument(s) need to be submitted whenever possible. There is no page limit for instruments; however, if they are multiple or long, applicants may submit sample questions or partial instruments.

(c) **Other Selected Material.** Other selected material that explains or documents a proposed method that is new or unpublished. Total length may not exceed 10 pages.

11. Summary Statement and Critiques

Exact copies of summary statements and critiques of any prior reviews of the application must be attached at the end of the application (after appendices), numbered consecutively with the rest of the application, and referenced in the Table of Contents.

12. Application Checklist

The "HSR&D Application Checklist" (see Appendix B) is included to assist the ACOS/R&D office in preparing a complete and properly formatted merit review application package. The ACOS or Administrative Officer for R&D **must sign the checklist** certifying that the application package is complete and conforms to all the guidelines. The signed checklist must be included in the application package before submission to VACO.

13. Submission of HSR&D Application Packages

(a) The most current information regarding submission procedures can be found at HSR&D's website (http://www.hsrd.research.va.gov/funding/ or in communications from CO to the ACOS/R&D's office. Proposals must be submitted as a single PDF file on a CD (see website for PDF-creation tips). Please label the PDF document as follows:

If a resubmission -LastName_FirstName_ProjectID.pdf
If a new submission (no ProjectID) -LastName_FirstName.pdf

For materials or correspondence being submitted via U.S. mail or commercial delivery, the address is:

Health Services Research and Development Service (124R)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

(b) The contact number for courier delivery is: 202-254-0207.

(c) Directions for electronic submission of application packages will be provided via HSR&D's website (http://www.hsrd.research.va.gov) and in communications from CO to the ACOS/R&D office.

14. Withdrawal of Application from Consideration. Withdrawal of an application once Intent to Submit information has been submitted requires formal notification by the ACOS/R&D to CO. The contact person for this communication is the Merit Review Program Manager (124R).

15. Site Change during Review Cycle. All information given to reviewers must reflect the PI's circumstances and research site. If a PI transfers to another VA, or the facilities available to the project change, the Merit Review Program Manager (124R) must be notified immediately and updated information supplied, if requested.

16. Post Submission Communication. After the proposal has been reviewed, the originating VA medical center will receive notification of the Merit Review Board score. Within six weeks of the review meeting, formal notification of the Merit Review Board recommendation, funding decision, summary statement, and individual critiques will be provided to the originating VA medical center, the ACOS/R&D, and the corresponding PI.

17. Just-in Time Receipt of Compliance and Assurance Documentation.

(a) **General.** The PI should not submit Just-in-Time documents with the application package. It is a local facility decision whether subcommittee review for human subjects, animal subjects, and/or biosafety is conducted prior to the submission of the application,

after the submission, or after notification of funding. However, these documents will not be accepted in VACO before notification of funding. Research offices will be notified of proposals that are in consideration for funding and the specific just-in-time documentation needed to complete the review process. All required documents need to be submitted to CO simultaneously, as a single package. No project will be funded until the required documentation has been provided to VACO. A check list for Just in Time documents is provided in Appendix C.

(b) **VA Form 10-1223, Report of Subcommittee on Human Studies**

1) Proposals for studies involving human subjects will be reviewed without VA Form 10-1223, but will not be funded until approved by the VA facility's Subcommittee on Human Studies or, if none, by the Institutional Review Board (IRB) of the affiliated university. A current (not older than 1 year) VA Form 10-1223 must be submitted in addition to the university IRB approval form. Review by the Subcommittee on Human Studies is to include consideration of compliance with VA policy requiring the inclusion of minorities and women unless an exception has been approved. If the IRB or the VA Subcommittee on Human Studies has found the proposal exempt from review for human subjects' considerations, this finding must be noted in the section "8" comments of VA Form 10-1223. The chair of the IRB must sign the form and the date must be current.

2) For multi-site studies, documentation of IRB approval must be received for each site before research can begin at the site and funds in support of the research can be released. For sites not yet identified, IRB approval must be forwarded as soon as the site is selected.

3) If the human subjects review requires evidence of the subjects' informed consent, submit VA Form 10-1086 or a VA-approved university informed consent form.

(c) **VA Form 10-1086 VA Research Consent Form.** Unless the proposed research was granted a waiver, VA Form 10-1086 is required.

1) The title on the 10-1086 must be the same as the title of the proposal.

2) Each page of each consent form must be dated and the date on the consent form must be current. Forms from a previous submission of the application may be used if the dates of approval have not expired and if the proposed research has not changed.

3) The VA informed consent form (VA Form 10-1086) must be used even if the IRB is at the affiliate university.

(d) **Human Subjects Training.** For research involving human subjects or human tissue, all investigators, research coordinators, and research assistants involved in the research must receive and document training in the ethical principles and accepted practices by which human studies research should be conducted. Documentation that the PI and Co-PI have received training in the Protection of Human Research Subjects and Good Clinical Practice must be submitted as part of the just-in-time package. Documentation may be in the form of a certificate from an approved training program such as the one at www.citiprogram.org or the VA Learning Center's online web site. Documentation must be dated within one year of submission of the just-in-time materials. It is the responsibility of the ACOS/R&D to maintain training documentation of all the personnel involved in the project and to ensure that all requirements for maintaining certification are met, for the duration of the project.

(e) **Privacy of Information Statement.** All applications must include a letter from the facility Privacy Officer (usually the Chief, Health Administration Service) identifying the PI's name and project title and providing evidence of due regard for the Privacy Act of 1974 (Public Law 93-579) and intent by the PI to comply. The statement must be signed, dated, and the signer identified by name, title, and affiliation.

(f) **Certification of Storage and Security of VA Research Information.** The Principal Investigator and Co-PI must certify that the use, storage and security of all research information collected for, derived from, or used during the conduct of the research will be in compliance with all VA and VHA requirements. A copy of the "Principal Investigator's Certification: Storage and Security of VA Research Information" is required prior to funding and is available on the ORD website at: http://www.research.va.gov/resources/policies/cybersecurity.cfm.

(g) **Registration of Clinical Trials with the National Library of Medicine.** Projects which are identified as clinical trials must register with the National Library of Medicine at clinicaltrials.gov prior to enrolling patients to ensure compliance with VA regulations and for funding to be allocated. The VA Office of Research and Development (ORD) defines a clinical trial as "any research that prospectively assigns human subjects or groups of subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome". **It is the principal investigator's responsibility to register the project**. HSR&D will assist investigators with registration through an automated process which includes a confirmation of registration; contact the HSR&D representative at ART@va.gov .

(h) **OMB Requirements for Survey Approval.** Studies involving the collection of information or data from 10 or more individuals require prior OMB approval. The PI must provide the documentation for OMB review as specified in the funding letter. If the research is exempt from OMB review, the PI must submit a request for OMB exemption describing the basis for exemption and a justification. Studies may be exempt from OMB review if the information that is being collected is part of one or more of the following: clinical trial, clinical examination, direct treatment, prevention of clinical disorder, interpretation of biological analyses. The request for OMB exemption must be approved by the Director, HSR&D.

(i) **Studies Involving Animals, Biosafety Issues, or Radiation.** Studies involving animals, potential biohazards, or radiation have special requirements. Refer to VHA Handbooks 1200.7 and 1200.8 for instructions related to animal protocols and required committee approvals.

SAMPLE GANTT CHART

Project Title: Comprehensive Outcomes of Smoking Cessation in VA					
	Project Period (Fiscal Years)				
	Dates: October 1, 2006 through March 31, 2009				
Activity	**2006**	**2007**	**2008**	**2009**	**2010**
Design questionnaire	---				
Identify respondents	--				
Initial data collection	-------	--			
Analyze results		--------			
Write report		-----			
Refine procedures (based on survey results)		-----			
Collect follow up data		-	----		
Analyze results			-----		
Write articles				----	
Write final report				---	

APPENDIX B

HEALTH SERVICES RESEARCH AND DEVELOPMENT APPLICATION CHECKLIST

Prerequisites:

- ❑ Eligibility of Principal Investigator (PI)(s) established or waiver requested
- ❑ All sites covered under a current Assurance of Compliance with Common Rule
- ❑ PI and/or Co-PI not on Department of Health and Human Services (DHHS) Office-of Research Integrity sanctions list

Format:

- ❑ All pages are numbered consecutively, and with the PI's last name, starting with Table of Contents and ending with Appendix in the lower right hand corner. For example, Smith-24
- ❑ No Social Security numbers should appear in the application (please check CVs)

Merit Review Application Package includes, in the following order:

- ❑ Table of Contents
- ❑ For multi-site studies, a separate page that lists all sites in the study
- ❑ VA Form 10-1313-1, Merit Review Application
- ❑ VA Form 10-1313-2, Summary Description of Project
- ❑ VA Form 10-1313-3, Current Funds and First Year Request
- ❑ VA Form 10-1313-4, Estimated Expenses
- ❑ Project Timeline (Gantt Chart)
- ❑ VA Form 10-1313-5/6, Investigator's Biographical Sketch
- ❑ If a resubmission, letter from PI identifying significant changes (no more than 3 pages)
- ❑ Proposal Narrative (font style Arial, minimum font size 11, no more than 25 pages)
- ❑ Research and Development (R&D) Committee Review of Proposal (original signature required)
- ❑ VA Form 10-1086 (DRAFT), VA Research Consent Form, if applicable
- ❑ Endorsement Letters:
  - (1) Transmittal, from VA medical center Director (original signature required)
  - (2) Endorsement, from each participating organizational element or institution (original signature required)
  - (3) Endorsement, from each collaborator (original signature required)
  - (4) Endorsement, from each consultant including CV (limit-4 pages) (original signature required)
- ❑ Appendices, including data collection instruments (s) OPTIONAL
- ❑ **If the proposal is a resubmission**: include a copy of the notification letter, summary statement, and critiques from previous submissions **after** appendices

I certify that I have reviewed this application and that it adheres to the guidelines specified in "Detailed Instructions for Preparing Research Applications for Merit Review"

_____, _____ _____

Name Title Date

APPENDIX C

Just in Time Documents
(to be provided after proposal is approved for funding and submitted to CO as one complete package)

- ❑ VA Form 10-1223, Report of Subcommittee on Human Studies, dated and signed (within one year)
- ❑ IRB approval for all project sites (subject enrollment may not commence at secondary sites until site IRB approval is received in CO)
- ❑ VA Form 10-1086, VA Research Consent Form, if applicable
- ❑ Certification of completion of human subjects protection training for PI and Co-PI, if applicable
- ❑ Certification: Storage and Security of Research Information (PI and Co-PI)
- ❑ Animal Research Protocol Statement, if applicable
- ❑ Biohazard Statement, if applicable
- ❑ Privacy of Information Statement (original signature required)
- ❑ Certification of registration of Clinical Trials with the National Library of Medicine
- ❑ Documentation required for OMB review
- ❑ Request for exemption from OMB review, if applicable