

Request to Review Research Proposal/Project (534 - Charleston, SC)

Department of Veterans Affairs

All proposals received in good order in the Office of Research and Development (151) at least **14 working days** before each month's scheduled meeting of the R&D Committee will be considered at that meeting. Submission deadlines and meeting schedules are posted [here](#)

1. Principal Investigator/Program Director

2. Project Title

3. Answer the four questions below in order to determine whether the study should be submitted to the R&D Committee.

3a. Is the Study funded by the VA? Yes No

3b. Will VA patients be recruited? Yes No

3c. Will any VA resources be used in the performance of this research (examples: space, equipment, animal facility?)

Yes No

3d. Will this research be performed on VA time? **Note:** *This committee cannot approve the use of VA time to conduct research. The Service Chief must approve the use of VA time to conduct research.*

Yes No

Note: If you answered 'yes' to any of the four questions above, the proposed research must be submitted to the R&D Committee. If you answered 'no' to all four questions, the proposed research does not meet the definition of VA research and thus does not need to be submitted to the R&D Committee. You do not need to complete the remainder of this form. For documentation purposes, please send this page, with 1-3d completed, to the Research Office.

Note If this study is not VA research and thus not approved by the VA R&D Committee, do not list your VA title on associated publications.

4. Telephone (with extension)

Email

5. VA Appointment

Full-Time Part-Time
 WOC Consultant

6. Status of PI in Proposal

7. If PI is not a VA employee, name of local PI with VAMC Appointment:

8. Type of Submission

New Renewal

If renewal, enter 4-digit # of active project

If renewal, has the title changed?

Yes No

9. Co-Principal Investigators: Definition of Co-PI Role - Co-PIs share equal overall responsibility for the project with the PI. Funding is awarded in PI and CO-PIs names. Enter only if study is funded. Co-PIs must have a VA appointment and must be designated as Co-PI in the application. Please note, this designation is different than Co-Investigator.

Last Name, First Name, MI, Degree	Check if at another VAMC
_____	<input type="checkbox"/>
_____	<input type="checkbox"/>
_____	<input type="checkbox"/>

10. Funding Source and Fund Administration: **A list of codes for funding source and fund administration follows this form.

Source Code	Name if Source Code ends in "99"	Admin Code	Name if Admin Code is "08"
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If Source Code is 9007, 9022, 9024, enter VACO Project Number.

11. Project Uses: (Mark each item and submit completed forms. If Animal Subjects is "Yes", complete item 14)

Human Subjects <input type="radio"/> Yes <input type="radio"/> No	Invest Drugs <input type="radio"/> Yes <input type="radio"/> No	Radioisotopes <input type="radio"/> Yes <input type="radio"/> No
Animal Subjects <input type="radio"/> Yes <input type="radio"/> No	Invest Devices <input type="radio"/> Yes <input type="radio"/> No	Biohazards <input type="radio"/> Yes <input type="radio"/> No

12. Project Focus (Mark each item)

Agent Orange <input type="radio"/> Yes <input type="radio"/> No	Females <input type="radio"/> Yes <input type="radio"/> No	Prisoners of War <input type="radio"/> Yes <input type="radio"/> No
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13. Keywords (Minimum 3, maximum 6. Use MeSH terms only. Enter one term per line.)

14. Animal Subjects: (Species and, if applicable, strain. Enter one species per line.)

15. Abstract: See separate page in application packet.

16. Does this project involve human participants? Yes No

If yes, all applicable signatures below must be obtained prior to submitting protocol to the R&D Office. If the procedure/service beyond routine patient care is required of any VA department to carry out the research protocol, the principal investigator must meet with the Chief of the affected Service to agree on the impact and arrange for reimbursement.

17. Does the research involve the use of Protected Health Information? Yes No

Note: Review the definition of protected health information (PHI) before answering. PHI includes: names, initials, geographic subdivisions smaller than a state, all dates except the year, all ages over 89, telephone numbers, Fax numbers, Emails, addresses, social security numbers (including scrambled), medical record numbers, health plan beneficiary numbers, account numbers, certificate or license numbers, vehicle identifiers, license plate numbers, URLs, IP addresses, biometric identifiers including finger and voice prints, full-face photographs and comparable images and any other unique number characteristic or code. INFORMATION IS NOT DE-IDENTIFIED IF IT CONTAINS ANYTHING IN THIS LIST.

18. Does the proposed research impact any other service? Answer yes or no to each below. If yes, you must obtain the endorsement of the Service Chief or CBOC Manager of the affected service.

<u>Service</u>	<u>Applicable?</u>	<u>Signature of Service Chief</u>	<u>Cost Per Patient</u>
Medicine	Yes <input type="checkbox"/> No <input type="checkbox"/>	William Groh, MD	
Psychiatry	Yes <input type="checkbox"/> No <input type="checkbox"/>	Donald L. (Hugh) Myrick, M.D.	
Surgery	Yes <input type="checkbox"/> No <input type="checkbox"/>	Mark Lockett, M.D.	
Laboratory	Yes <input type="checkbox"/> No <input type="checkbox"/>	Avtar Singh, M.D.	
Pharmacy	Yes <input type="checkbox"/> No <input type="checkbox"/>	Sharon Castle, PharmD	
Radiology/Nuclear Med	Yes <input type="checkbox"/> No <input type="checkbox"/>	Alexander Dibona, M.D.	
Nursing	Yes <input type="checkbox"/> No <input type="checkbox"/>	Letha C. Rogers MSN, R.N.	
Outpatient (Primary Care)	Yes <input type="checkbox"/> No <input type="checkbox"/>	Christopher D. Blasy, M.D.	
CBOC	Yes <input type="checkbox"/> No <input type="checkbox"/>	CBOC Manager	

19. Briefly indicate which components will be conducted as VA research or non-VA research.

VA research activities (must be reviewed and approved by R&D Committee)

Non-VA research activities (not to be reviewed or approved by the R&D Committee)

VA Site

Description of activity

Non-VA Site

Approvals and Signature Page

20. Institutional Approvals (*Signatures as appropriate*)

Date:

Signature of Service Chief

22. Conflict of Interest: It is recognized that the potential for conflict of interest exists when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results or reporting of research activities or findings.

Does your participation in this project present the potential for a conflict of interest? (i.e. personal or private)?

Yes No

If your response is "YES", please see VA Research Office for additional direction and guidance. VA Research Office staff can provide you with a copy of the VA Conflict of Interest Policy.

23. Acknowledgement of VA in Presentation of Research Results. I agree to insure that proper acknowledgement of the Department of Veterans Affairs' research support is always given by me in any scientific publications, presentation, media interviews, and other professional activities. As a VA investigator, I agree to initiate and document references to VA where either direct or indirect support for the research emanated from VA, either in the form of research funding, resources (e.g. facilities or patients), or as a result of my full-time, part-time, or without compensation (WOC) employment status.

24. Assurance. My signature below certifies that all of the information provided is true and accurate. As the designated Principal Investigator for the described research study, I will insure the protocol is carried out in full compliance with all local, agency and other regulatory bodies' policies and procedures. I have read and understand the [QA Manual](#) as well as all applicable [VA Publications](#).

Date:

Signature of Principal Investigator

25. Original protocol received in the VAMC R&D Office (Room 149) by:

Date:

Signature
Research & Development Service

FUNDING SOURCE CODES

1. Department of Veterans Affairs (Use only Administrative Code 02.)

[9002] = Research Advisory Group (Prog 821; CC 103) [9023] = Agent Orange & Related Herbicides (Prog 823)
[9003] = Merit Review (Prog 821; CC 103) [9024] = Health Services (Prog 824)
[9006] = Special Research Initiatives (Prog 821; CC 106) [9025] = Cooperative Studies (Prog 825) [9092] = Musculoskeletal Research
[9008] = Career Development (Prog 821; CC 108) [9050] = Clinical Science R&D (Prog 825, CC 150)
[9009] = Other Designated Research (Prog 821; CC 109) [9090] = Office of Academic Affairs
[9022] = Rehabilitation R&D (Prog 822) [9091] = Health Care System & VISN Supported Research

2. National Institutes of Health and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)

[9103] = Natl Cancer Institute [9122] = Natl Human Genome Research Institute
[9105] = Natl Eye Institute [9123] = Natl Center for Nursing Research
[9107] = Natl Heart, Lung, & Blood Institute [9125] = Natl Inst on Aging
[9109] = Natl Inst of Allergy and Infectious Diseases [9127] = Natl Inst on Alcohol Abuse and Alcoholism
[9111] = Natl Inst of Child Health & Human Development [9129] = Natl Inst on Arthritis, Musculoskeletal and Skin Diseases
[9113] = Natl Inst of Dental and Craniofacial Research [9131] = Natl Inst on Deafness & Other Communication Disorders
[9115] = Natl Inst of Diabetes, Digestive & Kidney Disease [9133] = Natl Inst on Drug Abuse
[9117] = Natl Inst of Environmental Health Sciences [9135] = Natl Inst on Mental Health
[9119] = Natl Inst of General Medical Sciences [9137] = Natl Center for Research Resources
[9121] = Natl Inst of Neurological Disorders & Stroke [9138] = Natl Inst of Biomedical Imaging and Bioengineering

3. Other United States Federal Government Agency

[9202] = Centers for Disease Control [9213] = Environmental Protection Agency [9225] = Natl Library of Medicine
[9203] = Dept of Defense [9215] = Food and Drug Admin [9227] = Natl Science Foundation
[9205] = Dept of Education [9217] = Health Resources & Svcs Adm [9229] = Rehabilitation Svcs Admin
[9207] = Dept of Energy [9219] = Natl Inst of Occupational Safety [9235] = U.S. Public Health Service
[9209] = Dept of Health & Human Services [9221] = Natl Aeronautics & Space Adm [9237] = Natl Inst of Disability Rehabilitation Res.
[9211] = Dept of Labor [9223] = Agency for Health Care Policy Research [9299] = Other (Specify Name)

4. Other Government, Private Donor, or Academic Institution

[9301] = Affiliated University [9305] = Local Government [9309] = Foreign Government
[9303] = Private Donor [9307] = State Government [9360] = VA Medical Care-Supported Mgt
Studies
[9399] = Other (Specify Name)

5. Private Proprietary Company

[9701] = A.H. Robins [9725] = Du Pont [9752] = Lorex [9781] = Ross
[9703] = Abbott [9731] = Eli Lilly [9754] = Marion-Merrell Dow [9782] = R.W. Johnson Pharm
[9705] = Adria [9732] = Fujisawa [9756] = McNeil [9783] = Sandoz
[9707] = Alpha Therapeutic [9733] = G.D. Searle [9760] = Merck & Co. [9784] = Schering
[9708] = American Cyanamid [9734] = G.H. Bessalaar [9764] = Miles [9785] = SmithKline Beecham
[9710] = Amgen [9736] = Genetech [9766] = Proctor & Gamble [9787] = Sanofi-Winthrop
[9712] = Berlex [9738] = Glaxo [9768] = Organon [9789] = Stuart
[9713] = Boehringer Ingelheim [9740] = Hoechst-Roussel [9770] = Ortho [9791] = Syntex
[9715] = Boots [9742] = Hoffman-LaRoche [9773] = Parke-Davis [9792] = TAP Pharm
[9717] = Bristol-Meyers Squibb [9744] = Hybritech [9775] = Pfizer [9793] = Upjohn
[9719] = Burroughs Wellcome [9745] = Immunomedics [9776] = Purdue Frederick [9795] = Warner-Chilcott
[9720] = Centocor [9746] = Janssen [9777] = Roberts Pharm [9797] = Wyeth-Ayerst
[9721] = Ciba-Geigy [9748] = Knoll [9778] = Roche [9798] = Zeneca
[9723] = Cytogen [9750] = Lederle [9779] = Rhone-Poulenc Rorer [9799] = Other (Specify Name)

6. Voluntary Agency/Foundation (For Local Chapters of National Organizations, use Agency/Foundation code, not 9899.)

[9803] = Alzheimer's Dis & Rel Dis Assoc [9823] = Arthritis Foundation [9863] = National Dairy Council
[9805] = American Cancer Society [9827] = Council for Tobacco Research [9867] = Natl Foundation Ileitis & Colitis
[9809] = American Diabetes Association [9831] = Cystic Fibrosis Foundation [9871] = National Kidney Foundation
[9811] = American Fed for Aging Research [9833] = Deafness Research Fndn [9875] = Natl Multiple Sclerosis Society
[9812] = American Fndn for AIDS Research [9837] = Dermatology Foundation [9879] = Paralyzed Veterans of America
[9813] = American Heart Association [9839] = Disabled American Veterans [9883] = Robert Wood Johnson Fndn
[9815] = American Kidney Foundation [9843] = Epilepsy Foundation [9885] = Scleroderma Foundation
[9817] = American Legion [9847] = Juvenile Diabetes Foundation [9887] = Smokeless Tobacco Research
Council
[9819] = American Lung Association [9851] = Lupus Foundation [9891] = Spinal Cord Society
[9821] = American Narcolepsy Assoc [9855] = March of Dimes [9895] = VA Non-Profit Research Corp (CRI)
[9822] = Amer Parkinson Disease Assoc [9859] = Muscular Dystrophy Association [9899] = Other (Specify Name)

7. None (Enter 0000) (Use only Administrative Code 01.)

ADMINISTRATIVE CODES

[01] = No funding (Valid only for Funding Code 0000) [06] = VA Non-Profit Research Corp (Charleston Research Institute)
[02] = VA funds (Valid only for Funding Codes beginning with 90) [07] = Medical University of South Carolina
[03] = VA - Reimbursed from another Federal Agency* [08] = Other Agency
[04] = VA - Direct grant [09] = Medical Care-Supported Studies
[05] = VA - General Post Funds

*Administrative Code 03 is valid only for Funding Codes beginning with 91 and 92.

*Administrative Code 09 is valid only for Funding Code 9360.