

Veterans Affairs Project Cover Sheet

Last edited by: [LAST EDITED BY NAME]

Last edited on: [LAST EDITED DATE]

IRBNet Number – System field

Project Title – System field

1. **PAGE: Introduction**

Welcome to the **Department of Veterans Affairs – Project Cover Sheet**.

Questions with an asterisk (*) **must** be answered. Incomplete submissions will be returned un-reviewed. You have the option to save the application as you progress and complete it at a later time.

Please keep the information in this form accurate and up-to-date. If any future changes to this project affect information in this form, please revise the appropriate sections and submit the form.

(No Response)

2. **PAGE: Project Summary**

a. **Concise Project Summary**

Please provide a brief description (fewer than 500 characters) of the project.

(Rich Text Response)

b. **Significance**

What is the significance and/or value of this research to Veterans or the VHA?

(Rich Text Response)

3. **PAGE: Study Funded**

Is this study funded?

(Radio Buttons)

- a. Yes
- b. No

4. **PAGE: Funding Information** – *This PAGE will only appear if “Study Funded: YES” is selected. This PAGE will repeat for each Funding Source to be entered.*

a. **Funding Source Code**

(Drop-down Menu)

- i. [0000] None
- ii. [9002] BLR&D Research Advisory Group (CC 103)
- iii. [9009] BLR&D Other Designated Research (CC 109)
- iv. [9024] Health Services R&D (Prog 824)
- v. [9003] BLR&D Merit Review (CC 103)

- vi. [9010] BLR&D Research Career Scientist (CC 110)
- vii. [9025] Cooperative Studies (Prog 825)
- viii. [9006] BLR&D Special Research Initiatives (CC 106)
- ix. [9022] Rehabilitation R&D (Prog 822)
- x. [9026] Million Veteran Program (Prog 826-CC160)
- xi. [9008] BLR&D Career Development (CC 108)
- xii. [9023] Agent Orange & Related Herbicides
- xiii. [9050] Clinical Science R&D
- xiv. [9103] National Cancer Institute
- xv. [9117] Natl Inst of Environmental Health Science
- xvi. [9129] Natl Inst on Arthritis, Musculoskeletal & Skin Disease
- xvii. [9105] National Eye Institute
- xviii. [9119] Natl Inst of General Medical Sciences
- xix. [9131] Natl Inst on Deafness & Other Communication Diseases
- xx. [9107] National Heart, Lung & Blood Inst
- xxi. [9121] Natl Inst of Neurological Disorders & Stroke
- xxii. [9133] Natl Inst on Drug Abuse
- xxiii. [9109] Natl Inst of Allergy & Infectious Disease
- xxiv. [9122] Natl Human Genome Research Institute
- xxv. [9135] Natl Inst on Mental Health
- xxvi. [9111] Natl Inst of Child Health & Human Dev
- xxvii. [9123] National Institute of Nursing Research
- xxviii. [9137] Natl Center for Research Resources
- xxix. [9113] Natl Inst of Dental and Craniofacial Research
- xxx. [9125] National Institute on Aging
- xxxi. [9138] Natl Inst of Biomedical Imaging and Bioengineering
- xxxii. [9115] Natl Inst of Diabetes, Digest. & Kidney
- xxxiii. [9127] Natl Inst on Alcohol Abuse & Alcoholism
- xxxiv. [9143] Natl Inst of Health (Inst not listed)
- xxxv. [9202] Centers for Disease Control
- xxxvi. [9213] Environmental Protection Agency
- xxxvii. [9225] National Library of Medicine
- xxxviii. [9203] Dept of Defense
- xxxix. [9215] Food and Drug Administration
 - xl. [9227] National Science Foundation
 - xli. [9205] Dept of Education
 - xl.ii. [9217] Health Resources & Svcs Admin
 - xl.iii. [9229] Rehabilitation Services Admin
 - xl.iv. [9207] Dept of Energy
 - xl.v. [9219] Natl Inst of Occupational Safety
 - xl.vi. [9235] U.S. Public Health Service
 - xl.vii. [9209] Dept of Health & Human Services
 - xl.viii. [9221] Natl Aeronautics & Space Admin
 - xl.ix. [9237] Natl Inst of Disability Rehab. Research
 - l. [9211] Dept of Labor
 - li. [9223] Agency for Health Care Policy Research
 - lii. [9299] Other Federal Government Agency
 - liii. [9301] Affiliated University

- liv. [9307] State Government
- lv. [9360] VA Medical Care Supported Mgmt. Studies
- lvi. [9303] Private Donor
- lvii. [9309] Foreign Government
- lviii. [9305] Local Government
- lix. [9311] SWOG
- lx. [9399] Other Government or Academic
- lxi. [9701] A.H. Robins
- lxii. [9723] Cytogen
- lxiii. [9752] Lorex
- lxiv. [9779] Rhone-Poulenc Rorer
- lxv. [9703] Abbott
- lxvi. [9725] Du Pont
- lxvii. [9754] Marion-Merrell Dow
- lxviii. [9781] Ross
- lix. [9705] Adria
- lxx. [9729] E.R. Squibb
- lxxi. [9756] Mc Neil
- lxxii. [9782] R.W. Johnson Pharm
- lxxiii. [9706] Aventis Pharmaceuticals
- lxxiv. [9731] Eli Lilly
- lxxv. [9758] Mead Johnson
- lxxvi. [9783] Sandoz
- lxxvii. [9707] Alpha Therapeutic
- lxxviii. [9732] Fujisawa
- lxxix. [9760] Merck & Co.
- lxxx. [9784] Schering
- lxxxii. [9708] American Cyanamid
- lxxxiii. [9733] G.D. Searle
- lxxxiv. [9762] Merrell-Dow
- lxxxv. [9785] SmithKline Beecham
- lxxxvi. [9709] Ayerst
- lxxxvii. [9734] G.H. Besselaar
- lxxxviii. [9764] Miles
- lxxxviii. [9787] Sanofi-Aventis
- lxxxix. [9710] Amgen
 - xc. [9736] Genentech
 - xcii. [9765] Novartis
 - xciii. [9789] Stuart
 - xciv. [9711] Beecham
 - xcv. [9738] Glaxo
 - xcvi. [9766] Proctor & Gamble
 - xcvii. [9790] Takeda
 - xcviii. [9712] Berlex
 - xcix. [9740] Hoechst-Roussel
 - c. [9768] Organon
 - ci. [9791] Syntex
 - ci. [9713] Boehringer Ingelheim

- cii. [9742] Hoffman-La Roche
- ciii. [9770] Ortho
- civ. [9792] TAP Pharm
- cv. [9715] Boots
- cvi. [9744] Hybritech
- cvii. [9773] Parke-Davis
- cviii. [9793] Upjohn
- cix. [9717] Bristol-Meyers Squibb
- cx. [9745] Immunomedics
- cxi. [9775] Pfizer
- cxii. [9795] Warner-Chilcott
- cxiii. [9719] Burroughs Wellcome
- cxiv. [9746] Janssen
- cxv. [9776] Purdue Frederick
- cxvi. [9797] Wyeth-Ayerst
- cxvii. [9720] Centocor
- cxviii. [9748] Knoll
- cxix. [9777] Roberts Pharm
- cxx. [9798] Zeneca
- cxxi. [9721] Ciba-Geigy
- cxxii. [9750] Lederle
- cxxiii. [9778] Roche
- cxxiv. [9799] Other Private Proprietary Company
- cxxv. [9803] Alzheimer's Dis & Related Dis Assoc
- cxxvi. [9823] Arthritis Foundation
- cxxvii. [9863] National Dairy Council
- cxxviii. [9805] American Cancer Society
- cxxix. [9827] Council for Tobacco Research
- cxix. [9867] Natl Foundation Ileitis & Colitis
- cxxxi. [9809] American Diabetes Association
- cxxxii. [9831] Cystic Fibrosis Foundation
- cxxxiii. [9871] National Kidney Foundation
- cxxxiv. [9811] American Fed for Aging Research
- cxxxv. [9833] Deafness Research Foundation
- cxxxvi. [9875] National Multiple Sclerosis Society
- cxxxvii. [9812] American Foundation for AIDS Research
- cxxxviii. [9837] Dermatology Foundation
- cxxxix. [9879] Paralyzed Veterans of America
- cxli. [9813] American Heart Association
- cxli. [9839] Disabled American Veterans
- cxlii. [9883] Robert Wood Johnson Foundation
- cxliii. [9815] American Kidney Foundation
- cxliv. [9843] Epilepsy Foundation of America
- cxlv. [9885] Scleroderma Foundation
- cxlvi. [9817] American Legion
- cxlvii. [9847] Juvenile Diabetes Foundation
- cxlviii. [9887] Smokeless Tobacco Research Council
- cxlix. [9819] American Lung Association

- cl. [9851] Lupus Foundation of America
- cli. [9891] Spinal Cord Society
- clii. [9821] American Narcolepsy Association
- cliii. [9855] March of Dimes
- cliv. [9895] VA Private Research Corporation
- clv. [9822] Amer Parkinson Disease Assoc
- clvi. [9859] Muscular Dystrophy Association
- clvii. [9899] Other Voluntary Agency/Foundation

b. Funding Source Code – Other

If the specific Source Code is not listed or if Other is selected, please name the funding source.

(Plain Text Response)

c. Merit Award

Is this a Merit Award?

(Radio Buttons)

- i. Yes
- ii. No

d. Administrative Code

(Drop-down Select)

- i. [00] Funded with other than research dollars (e.g., medical dollars, QUERI)
- ii. [01] No funding
- iii. [02] VA Funds
- iv. [03] VA – Reimbursed from another Federal Agency
- v. [04] VA – Direct Grant
- vi. [05] VA – General Post Funds
- vii. [06] VA – Private Research Corporation
- viii. [07] Affiliated University
- ix. [08] Other
- x. [09] Med Care-Supported Studies
- xi. [10] CRADA Partner

e. Service ID

This number is specific to the individual PI per award. Please enter N/A if no service ID is associated with this funding.

(Plain Text Response)

f. Award Number

(eRA Commons award number. Starts with RX, BX, CX, HX)

(Plain Text Response)

g. Funding Start Date

(Calendar Tool)

h. Funding End Date

(Calendar Tool)

5. **PAGE: Contracts/ Agreements**

Will any contracts or agreements be required to be executed specific to the project?

Do not answer yes if there is an agreement such as an institutional agreement for IRB or IACUC reliance. These are not necessarily project specific.

(Radio Buttons)

- a. Yes
- b. No
- c. Unsure (please check the Agreements Algorithm on the ORD webpage – if still unsure, please contact your research office)

6. **PAGE: Contracts/ Agreements Information** – *This PAGE will only apply if “Contracts/ Agreements: YES” is selected.*

Please select all that apply.

(Checkboxes)

- a. Cooperative Research and Development Agreement (CRADA)
- b. Data Use/Sharing Agreement (DUA/DSA)
- c. Material Transfer Agreement (MTA)
- d. Clinical Sharing Agreement
- e. Contract
- f. Business Associates Agreement
- g. Unsure

7. **PAGE: VA Project Lead/ Principal Investigator (if research)**

a. **Name (as it appears in Outlook for VA email)**

(Plain Text Response)

b. **Highest Degree**

(Drop-down Menu)

- i. MD
- ii. DO
- iii. DDS
- iv. DMD
- v. PhD
- vi. DNP
- vii. PsyD
- viii. RN
- ix. PT/DPT
- x. OT
- xi. PharmD
- xii. CSW
- xiii. MSW
- xiv. DSW
- xv. MPH
- xvi. DrPH
- xvii. ScD

- xviii. Bachelor's - Other
- xix. Master's - Other
- xx. Doctorate - Other
- xxi. Other

c. **Phone**

(Plain Text Response)

d. **Alt. Phone** - *This response is optional.*

(Plain Text Response)

e. **VA Email**

(Plain Text Response)

f. **VA Appointment**

(Drop-down Menu)

- i. WOC
- ii. IPA
- iii. Full-time
- iv. Part-time
- v. Contractor
- vi. Fee-basis

g. **Part-time 8ths** - *This response is optional.*

If this individual is part-time, 8ths:

(Plain Text Response)

h. **COI Disclosures?**

Have all VA study personnel serving in an investigator role submitted an OGE-450 Alt VA for review by the COI Administrator?

Note: Bio sketches and COI acknowledgments (from COI administrator) or COI resolution plans (from OGC-Ethics) are required only for study team members serving in an investigator role.

(Radio Buttons)

- i. Yes. Findings by the COI Administrator/OGC-Ethics of all study team personnel serving in an investigator role are attached.
- ii. Yes. However, COI review is pending on one or all. Acknowledgments (by COI Administrator) or resolution plans (from OGC-Ethics) will be forwarded upon completion of review.

8. **Additional Project Personnel** – *This PAGE will repeat for each Additional Personnel entered. This PAGE is optional.*

a. **Name (as it appears in Outlook for VA email)**

(Plain Text Response)

b. **Highest Degree**

(Drop-down Menu)

- i. MD
- ii. DO
- iii. DDS
- iv. DMD
- v. PhD
- vi. DNP
- vii. PsyD
- viii. RN
- ix. PT/DPT
- x. OT
- xi. PharmD
- xii. CSW
- xiii. MSW
- xiv. DSW
- xv. MPH
- xvi. DrPH
- xvii. ScD
- xviii. Bachelor's -Other
- xix. Master's - Other
- xx. Doctorate - Other
- xxi. Other

c. **Project Roles**

(Drop-down Menu)

- i. Co-PI
- ii. Other Investigator (Co-I/Sub-I)
- iii. Study Coordinator
- iv. Project Staff (Statistician, Research Pharmacist, etc.)
- v. Medical Monitor
- vi. Other

d. **Project Roles – Other** – *This RESPONSE is optional.*

(Plain Text Response)

If you selected "Other," please record the Project Role below.

e. **Phone**

(Plain Text Response)

f. **Alt. Phone** - *This response is optional.*

(Plain Text Response)

g. **VA Email**

(Plain Text Response)

h. **VA Appointment**

(Drop-down Menu)

- i. WOC
- ii. IPA

- iii. Full-time
- iv. Part-time
- v. Contractor
- vi. Fee-basis

i. **Part-time 8ths** - *This response is optional.*

If this individual is part-time, 8ths:
(Plain Text Response)

j. **COI Disclosures?**

Has this VA study personnel member serving in an investigator role submitted an OGE-450 Alt VA for review by the COI Administrator?

Note: Bio sketches and COI acknowledgments (from COI administrator) or COI resolution plans (from OGC-Ethics) are required only for study team members serving in an investigator role.

(Radio Buttons)

- i. Yes. Findings by the COI Administrator/OGC-Ethics of all study team personnel serving in an investigator role are attached.
- ii. Yes. However, COI review is pending on one or all. Acknowledgments (by COI Administrator) or resolution plans (from OGC-Ethics) will be forwarded upon completion of review.
- iii. Not Applicable. This individual is not serving in an investigator role.

9. **PAGE: Project Characteristics**

What does this project involve? *Check all that apply.*

(Checkboxes)

- a. Data and/or biospecimens from living human individuals . [Upload your form 10-250 with your submission for review by the Privacy Officer] [Determination] [You indicated your project involves data and/or biospecimens from living human individuals.]
- b. Data and/or biospecimens from deceased individuals [Upload your form 10-250 with your submission for review by the Privacy Officer]
- c. Animals [You indicated your project involves animals and will require review by your local IACUC.]
- d. VA research laboratory [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]
- e. Non-VA research laboratory [You indicated that your study involves a non-VA laboratory, please attach a copy of the agreement for review or contact your research office for how to establish an agreement.]
- f. Viruses, toxins, bacteria [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]
- g. Recombinant DNA [You indicated that your study involves recombinant DNA.]
- h. Chemicals [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]
- i. Radiation or radioisotopes [You indicated that your project involves radiation or radioisotopes and therefore will require review by the radiation safety committee.]

- j. Non-Veterans as research subjects [You indicated that non-veterans may be recruited as research subjects. R&D Committee approval is required to enroll non-veterans.]
- k. Institutional Support (i.e., EKG, Psychiatry, Medicine, Nursing, Surgery, Pharmacy, etc.) [One Service Impact Form for each area in which Institutional Support is required.]
- l. Controlled Substances [You indicated that your project involves the use of prescribed drugs or other controlled medical substances and you will need to complete the pharmacy impact statement and the safety forms to accompany your submission.]
- m. Physical Hazards (i.e., Noise, Vibration, extremes of temperature and pressure, explosive hazards, electrical hazards, mechanical hazards) [You indicated that your project involves a physical hazard and therefore will require completion of the VHA Form 10-0398 and SRSS review.]
- n. Other

10. PAGE: Project Characteristics – Other – *This PAGE will only appear if “Project Characteristics: Other” is selected.*

Since you indicated that the project involves characteristics that were not listed on the previous page, please explain.

(Rich Text Response)

11. PAGE: Determination Requests – *This PAGE will only appear if “Project Characteristics: Data and/or Biospecimens from living/deceased human individuals” OR “Project Characteristics: Other” is selected.*

Are you seeking any of the following determinations:

- Exemption
- Not Research Determination (QI, EBP)
- Non-human subject Research Determination

(Radio Buttons)

- a. Yes
- b. No

12. PAGE: Human Research Multi-Site Study – *This PAGE will only appear if “Project Characteristics: Data and/or biospecimens from living human individuals” is selected.*

Is this a multi-site study involving human research?

Note: Human research is a systematic investigation designed to contribute to generalizable knowledge where the investigator obtains, uses, studies or analyzes information or biospecimens about living individuals either through access to their identifiable information/specimens or through interaction or intervention with the individuals.

(Radio Buttons)

- a. Yes
- b. No
- c. Unsure (discuss with your research office)

13. PAGE: Cooperative Human Non-Exempt Study– *This PAGE will only appear if “Human Research Multi-Site Study: Yes” is selected.*

Is this a Cooperative Human Non-Exempt Study (CHNE – a multisite non-exempt study engaging more than one federal institution and requiring single IRB review)?

(Radio Buttons)

- a. Yes
- b. No
- c. Unsure - [You indicated that you are unsure if this study is a multisite study requiring single IRB review. Please clarify with your research office whether this study requires an exception to the single IRB provision before proceeding.]

14. PAGE: Single IRB Exception – *This PAGE will only appear if “Cooperative Human Non-Exempt Study: Yes or Unsure” is selected.*

All VA Non-Exempt Human Subjects Research that has more than one institution engaged in the research must use a single IRB, unless one of the following conditions are met:

- An exception to the Single IRB provision has been granted
- The project was not approved or transitioned to follow the 2018 Requirements of the Common Rule
- The VA facility is the only federal site involved in the project and no other site is receiving federal funds

If another institution already obtained an exception (either from ORD or another Federal Agency), there is no requirement to apply for one. Simply upload a copy of the exception for your institution’s records.

Note: If you need instructions on how your institution can request an exception, or if you are unsure if your project has already been granted an exception at another VA site, visit the ORD’s webpage on single IRBs: https://www.research.va.gov/programs/orppe/single_irb.cfm

Which of the following best describes your project?

(Radio Buttons)

- a. All the study sites are already under the oversight of a single IRB – [You indicated that your Cooperative Human Non-Exempt project is under the oversight of a single IRB].
- b. We have already obtained an exception to the Single IRB provision – [You indicated that your Cooperative Human Non-Exempt project has received an exception to the Single IRB provision. Please include a copy of the exception with your submission for your institution’s records.]
- c. Our institution requires an exception to the Single IRB provision, and we will apply for an exception with ORD – [You indicated that your Cooperative Human Non-Exempt project requires an exception to the Single IRB provision, and that you will apply for an exception with ORD. An exception must be granted before your project is reviewed by the IRB.]
- d. None of the above, or unsure - [You indicated that you are unsure if your Cooperative Human Non -Exempt project requires single IRB review. Please clarify with your research office whether this study requires an exception to the single IRB provision.]

15. PAGE: No Single IRB Review or Exception Explanation – *This PAGE will only appear if “Single IRB Exception: None of the above, or unsure” is selected.*

You indicated that your Cooperative Human Non-Exempt project may not require Single IRB

review or an exception to the Single IRB provision. Please clarify with your research office on whether this study requires an exception to the Single IRB provision, and explain below why the provision may not apply to your project. In your explanation, please address the following:

- When was your project first approved by an IRB?
- Is your VA facility the only federal site in the project?
- Are any other sites in the project receiving federal funds?

(Rich Text Response)

16. **PAGE: IRB of Record Type** - *This PAGE will only appear if “Human Research Multi-Site Study: YES” is selected.*

Which of the following facility types is the IRB of record? If more than 1 IRB will review this study, please select the IRB type for the IRB reviewing your project.

(Radio Buttons)

- PI’s VA Medical Center IRB
- Other VA Medical Center IRB
- VA Central IRB
- DOD – Defense Health Agency (DHA) Medical Center
- DOD – Defense Health Agency (DHA) Uniformed Services University
- DOD – Army
- DOD – Navy
- DOD – Air Force
- DOD – Marines
- NIH - All of Us IRB
- NIH - NCI IRB
- Other Federal IRB
- Affiliate University IRB
- Commercial IRB
- Non-affiliate University IRB
- Other IRB

17. **PAGE: IRB of Record Name** - *This PAGE will only appear if “Other Federal IRB” OR “Affiliate University IRB” OR “Commercial IRB” OR “Non-affiliate University IRB” OR “Other IRB” is selected*

What is the name of the IRB of Record?

(Plain Text Response)

18. **PAGE: Additional IRBs** - *This PAGE will only appear if “Human Research Multi-Site Study: YES” is selected.*

Will any additional IRBs (other than the IRB of record) be reviewing the study?

(Radio Buttons)

- Yes
- No

19. **PAGE: Additional IRB Information** – *This page will only appear if “Additional IRBs: YES” is selected. This PAGE will repeat for each Additional IRB.*

Please enter the name and facility type of each Additional IRB that is not the IRB of record.

- IRB Facility Type**
(Drop-down Menu)

- i. PI's VA Medical Center IRB
- ii. Other VA Medical Center IRB
- iii. VA Central IRB
- iv. NCI IRB (NIH)
- v. All of Us (NIH)
- vi. Other Federal IRB (DOD/DHA, NIH, DOE, NIST, etc.)
- vii. Affiliate University IRB
- viii. Commercial IRB
- ix. Non-affiliate University IRB
- x. Other
- xi. Unknown

b. IRB Name
(Plain Text Response)

20. PAGE: Form Complete

Thank you for completing the **Veterans Affairs – Project Cover Sheet**.

Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

Additional required documentation:

[SMART LIST]

Please click Preview to review the information you have provided in this form.

Refer to the end of the document for this checklist as you continue to prepare this submission.

Please use this checklist to ensure that you have attached all the necessary documentation for complete IRB review.

(No Response)