

VA Pittsburgh Healthcare System (VAPHS)
Research and Development
Part I: Request to Conduct Research

This form and all associated materials are required in order to initiate Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), Research Scientific Evaluation Committee (RSEC), and R&D Committee review of projects at VAPHS. No work may begin until you have received written notification from the Associate Chief of Staff for Research and Development (ACOS/R&D) that the project may begin.

SECTION A:

Principal Investigator:

Project Title:

Service Line:

VA Mail Code/Address to which Correspondence should be sent:

Phone:

Fax:

Pager:

Email Address:

VA Appointment Status (Check One):

Full Time

Part-Time; please provide number of eighths:

Contract

Without Compensation (WOC)

University of Pittsburgh Appointment (Check One):

None

Professor

Associate Professor

Assistant Professor

Other, Please Specify:

Does the proposed research involve any of the following?

Yes*

No**

VA funding

Yes*

No**

VA funded personnel effort

Yes*

No**

VA patients or their private health information

Yes*

No**

Other VA resources including (check all that apply):

VA Central IRB

VA equipment

VA property (including space leased to, or used by VA)

VA databases

*If you answered "Yes" to **any** of the above, proposal must be submitted to the Research Office. Complete this form and all associated documents.

If you answered "No" to **ALL items above, the proposed research does not meet the definition of VA research. Submit Section A for documentation purposes only

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SECTION B: PROJECT INFORMATION

1. Please indicate the type of proposal you are submitting to the Research Office (check all that apply):

- Animal Research → Requires submission of Parts I and IV.
- Human Subjects Research → Requires submission of Part I & additional materials outlined in Part III.
- Laboratory Research → Requires submission of Parts I and II.
- Other, Please Specify: _____ → Requires submission of Part I.

2. Does the project involve any of the following (check all that apply*):

- Biological hazards (including human biological specimens)
- Chemicals
- Animals and/or animal blood, body fluids, organs, tissues, cell lines, or cell clones?
- Ionizing radiation or use of radioactive materials outside of clinical standard of care

***If any of the boxes in item 2 above are checked, Part II is also required.**

3. Funding Source (Check One – See Funding Source Codes):

- Department of Veterans Affairs*; please specify code:
- National Institutes of Health*; please specify code:
- Other Federal Government Agency*; please specify code:
- Private Proprietary Company*; please specify code:
- Voluntary Agency/Foundation*; please specify code:
- None/Intramural

4. Attached Forms:

- DMAP – for VA-funded research*
- Resource Sharing Information/Plan - for externally funded research*
- Other, Please Specify:

***The Data Management and Access Plan (DMAP) or Resource Sharing Plan Form from your VA or externally funded grant application must be included with this study submission. Please see R&D Policy #22, Research Data Management and Access Plan (DMAP) Policy.**

5. Anticipated Start Date:

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6. Project Focus (Check if applicable):

Traumatic Brain Injury (TBI)

Post Traumatic/Post Deployment Stress Disorder (PTSD/PDSD)

Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

7. Are you collaborating with a non-VA investigator or institution?

No

Yes; please describe the collaborations and attach agreement below*:

**When a VA investigator wishes to send data and/or specimens obtained during the conduct of VA-approved research to a non-VA entity, an appropriate access agreement should first be in place that clearly defines the terms of data/specimen use by the named party(ies), data/specimen ownership and control, and oversight. Please see VAPHS Research Guidance: Written Agreements.*

The following agreement(s) is attached:

VAPHS Research Written Agreement (RWA)

Research Data Use Agreement (RDUA)

Material Transfer Agreement (MTA)

8. VAPHS Privacy and Data Security Plan: This form must be included with all new submissions to the IBC, IACUC, and Research Scientific Evaluation Committee (RSEC).

9. VA data, such as scientific data obtained directly from scientific instruments, may be stored on computers connected to the Pitt Network. Is VA research information from this project stored on non-VA IT equipment (i.e., on lab equipment computer connected to the Pitt network)?

No

Yes*

**If yes, please certify the following by initialing each statement:*

1. The components connected to the air-gapped network will never touch the VA network
2. VA sensitive data or limited data sets (as defined below) will not be transferred or transmitted over the Pitt Network connection or stored on University devices connected to the Pitt Network
3. Final VA research data will be stored on the VA network
4. VA research data collected on non-VA equipment connected to the Pitt network will be transferred to the VA network via secure methods, such as VA-issued encrypted thumb drive or email

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DEFINITIONS:

VA Sensitive Information or Data: All Department information and/or data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes not only information that identifies an individual, but also includes other information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, and records about individuals requiring protection under applicable confidentiality provisions.

Limited Data Sets: A limited data set is protected health information from which certain specified direct identifiers of the individuals and their relatives, household members, and employers have been removed. These identifiers include name, address (other than town or city, state, or zip code), phone number, fax number, Email address, Social Security Number (SSN), medical record number, health plan number, account number, certificate or license numbers, vehicle identification, device identifiers, web universal resource locators (URL), internet protocol (IP) address numbers, biometric identifiers, and full-face photographic images. The two patient identifiers that can be used are dates and postal address information that is limited to town or city, State, or zip code.

10. Keywords (Provide a minimum of 3, maximum of 6; Use MeSH terms- see the following link for more information on MeSH terminology <http://www.nlm.nih.gov/mesh/MBrowser.html>):

SECTION C: RESOURCES

1. Do you currently have adequate resources (e.g., staff, physical space, information technology, etc) to protect the safety of participants, staff and the confidentiality of subjects' data during the conduct of this study?

Yes No*

*If No, please explain how the resources will be obtained before the study is initiated:

2. Will off-site ancillary service facilities (e.g., radiology services, central labs, non-VA space, etc) be used for this study? Yes* No

*If Yes, please provide the location and a brief description of the project activities to be conducted at off-site ancillary facilities:

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SECTION D: INSTITUTIONAL SUPPORT

Please indicate which of the following services, if any, will be used to conduct this research.

Note: Any item marked yes will require a letter of support/collaboration

Clinical Support	Yes	No	Investigational Drug Service	Yes	No
Imaging	Yes	No	Patient Care Services	Yes	No
Behavioral Health	Yes	No	Surgical Services	Yes	No
Critical Care	Yes	No	Surgical Specialty	Yes	No
Research Registry	Yes*	No	Clinical Trials Center (CTC)	Yes	No

*If Yes, please specify registry administrator:

*If Yes, please specify which of the following CTC services will be utilized:

Other, please specify: Yes* No

- Regulatory Coordinator Support Core
- Clinical Coordinator Support Core
- Ancillary Services Support Core
- Decision Support Core

SECTION E: HUMAN SUBJECTS RESEARCH *Check here if not applicable:*

1. Does the research involve any of the following (check all that apply):

Yes* No **Investigational Drugs**

*If Yes, submit the Investigational Drug Information Record Form (10-9012) and list all applicable Investigational New Drug (IND) numbers:

Yes* No **Investigational Devices**

*If Yes, please list all applicable Investigational Drug Exemption (IDE) numbers:

Yes* No **Human exposure to radiation other than that associated with procedures that are consistent with the customary standard clinical care, including:**

- X-rays
- PET scans
- CT scans
- Radioactive Materials Administered without Imaging
- Radio-pharmaceutical Therapy
- Radiation Therapy
- Nuclear Medicine (e.g., MUGA, bone scans)

*If yes, contact the VAPHS Radiation Safety Officer at 60-3221 for the procedures necessary for approval by the VA Radiation Safety Committee. See the document Human Subject Exposure to Ionizing Radiation for assistance.

2. Will study participants receive any payment in association with this research project?

No.

Yes. Please submit a financial letter of support from Business Service line or the Veterans Research Foundation of Pittsburgh (VRFP)

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INVESTIGATOR'S ACKNOWLEDGEMENT & CERTIFICATION

My signature below certifies that all of the information provided is a true and accurate statement. 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 agree to insure that proper acknowledgement of the Department of Veterans Affairs' research support is always given by me in any scientific publications, presentations, media interviews and other professional activities. As 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. I understand that failure to acknowledge VA support or employment, may result in discontinuation of current VA R&D funding and/or ineligibility to receive future R&D funding for up to 5 years. In extreme circumstances, it may also result in the revocation of the privilege to conduct research at the VA.

I recognize that I have an obligation to protect the rights and welfare of research participants.

Principal Investigator Signature

Date

INSTITUTIONAL APPROVAL:

The Principal Investigator is responsible for obtaining the signatures below to verify appropriate institutional approval.

The resources necessary for the performance of these proposed studies are available and adequate, and I approve their use for this project.

The PI has requested _____ % effort to devote to this project. I approve this allocation to the Principal Investigator's time for this project.

Section Chief Name, if applicable
(TYPE OR PRINT)

Signature

Date

Service Line VP (or Chief of Staff)
(TYPE OR PRINT)

Signature

Date