



**PROPOSED PROJECT QUESTIONNAIRE (PPQ) – revised 12/26/12
Portland VA Medical Center**

For Office Use Only
Grant No.: _____
MIRB No.: _____

All Research Proposals using VA resources (space, equipment, patients, etc.) **or conducted on an investigator's VA time** must be submitted to the PVAMC R&D Service prior to initiation. For grants managed through OHSU, this does not take the place of the OHSU PPQ or MOU.

PRINCIPAL INVESTIGATOR NAME:		SERVICE:	PHONE:	EMAIL:
STUDY COORDINATOR NAME:		PHONE:	EMAIL:	
MAILCODE (FOR CORRESPONDENCE):		BUILDING/ROOM WHERE THE RESEARCH WILL BE CONDUCTED:		
PROJECT TITLE:				
FUNDING AGENCY (If NIH, specify Institute; if VA, specify service):		FUNDING PERIOD START:	FUNDING PERIOD END:	TOTAL DIRECT COSTS:
				\$
GRANT ADMINISTRATOR:		IF OTHER, LIST:		
SUBMISSION TYPE:		IF RESUBMISSION, DATE OF PREVIOUS SUBMISSION:		
IF OTHER, EXPLAIN:				

Abstract/Keywords

1. **Create a one-page abstract** with the headings **Objectives, Plan, Methods, Clinical Relevance** (for basic science studies) and **Relevance to VA's Mission**. Submit it according to the instructions at the end of this form. Note: *spell out all abbreviations the first time they are used, and do NOT use Greek or other symbols*. At the bottom of the abstract, list **3 keywords which are Medical Subject Heading (MeSH) terms**.

OHSU Knight Cancer Institute

2. If the PI is a member of the cancer center, or if the research is conducted with patients with cancer, please submit the study to the OHSU Knight Cancer Institute's Clinical Research Review Committee (CRRC). Call 503-494-4108 for information.

Health Services Research

3. Is this a Health Services Research project being submitted to a funding source? (i.e., VA HSR&D, QUERI, AHRQ, or Health Services Research Section of NIH)?	Yes	No
If "Yes" to #3, the project must be reviewed by the HSR&D Scientific Review Committee prior to submission to the funding source. See http://www.portland.va.gov/Research/Committees/hsrdreviewcommittee/index.asp . Submissions are due to the HSR&D Project Review Committee by the 3rd Friday of each month.		

Financial Administrative Review

4. Does this proposal use any VA hospital resources such as the pharmacy, imaging or the VA clinical lab, or medical service procedures such as ECGs? Will VA clinic exam rooms or inpatient beds be used for research purposes? Does a for-profit company fund this study? (Answer "Yes" if any one of these items is true.)	Yes	No
If "Yes" to #4, complete and submit the Financial Administrative Review form .		

Institutional Review Board & Research Specimen or Data Biorepositories

5. Will this study, as conducted at the PVAMC , involve obtaining data about any living individuals through intervention or interaction with them, seeing identifiable private information about living individuals (or having access to the code allowing identification), or obtaining informed consent for research? If "No", skip to #5.2.	Yes	No
5.1 If "Yes" to #5, will this study also be engaged in human subjects research at OHSU?		

If "Yes" to #5 **and** #5.1, please submit to the joint PVAMC/OHSU IRB. Instructions on submitting to this IRB can be found on the "PVAMC and OHSU Joint IRB tab" at <http://www.portland.va.gov/Research/hrpp/index.asp>
If "Yes" to #5 **but "No"** to 5.1 please review the [Certification of Exemption](#) to determine if any of the categories apply, and if so, submit the completed form to the PVAMC IRB via email to pvamc-irb@va.gov. If none of the exemption categories apply, please complete an application to the PVAMC IRB, starting with the [Initial Review Questionnaire](#) (IRQ, unless otherwise prompted below).

5.2 Is the purpose of this submission to establish a research repository (storing data and/or biospecimens) at the PVAMC?		
If "Yes" to #5.2, an IRQ is not required. Complete and submit a standard operating procedure (SOP) and Scope of Work (IRQ Appendix L) form(s). If the repository will include biospecimens, please also complete and submit IRQ Appendix G-2 and answer "Yes" to #8 & 8.1 below. SOP guidance can be found at http://www.portland.va.gov/research/documents/hrpp/biorepository-sop-guidelines.doc .		

5.3 Is the purpose of this submission to use data/biospecimens from an existing research repository?		
5.4 If "Yes" to #5.3, will you or anyone working on this study be able to link the data/samples to the individual's identity (i.e. have access to the code book, etc)?		
If "Yes" to #5.4, please complete an application to the PVAMC IRB, starting with the IRQ. If "No" to #5.4, please review the Certification of Exemption and, if any of the categories apply, submit a completed copy to the PVAMC IRB. (If none of the exemption categories apply, complete an application to the PVAMC IRB, as noted above.)		

	Yes	No
5.5 Is the purpose of this submission to contribute samples collected from PVAMC patients/subjects into an existing biorepository/bank?		
If "Yes" to any of questions in this section (5), complete an application, Certification of Exemption or repository submission (as directed) to the PVAMC IRB or PVAMC/OHSU Joint IRB. PVAMC IRB applications and repository submissions are due by the 2 nd Monday of each month to pvamc-irb@va.gov , or check the Just in Time* box.	Just in Time	
PI Appointment & Privileges	Yes	No
6. Does the PI have clinical privileges at the PVAMC? (If "Yes", skip to 7.)		
6.1 If "No" to #6, does the protocol require any interventions that would require privileges at the VA?		
If "Yes" to #6.1, a "responsible VA clinician" must be identified here: The responsible VA clinician is responsible for any procedures/interventions for which the PI is not qualified and/or privileged and for all study-related health care decisions. The PI is responsible for the overall conduct of the study, the Administrative Review and the application to the IRB.		
Institutional Animal Care & Use Committee (IACUC)	Yes	No
7. Will any work with animals (breeding/research/etc) occur at the VA or is any animal work funded by the VA?		
If "Yes" to #7, send your electronic application for the IACUC to PVAMC-IACUC@va.gov . Applications are due by the 15 th of each month, or check the Just in Time* box.	Just in Time	
7.1 Did you answer "Yes" to question 8 in Appendix 3 of the ACORP (Test Substance Appendix)?		
If "Yes" to #7.1, please submit the Project Safety & Hazard Assessment referenced below.		
Subcommittee on Research Safety	Yes	No
8. Will any of the work include radioisotopes, biohazards (such as chemicals, microbiological agents, cell/tissue cultures, recombinant DNA, and/or controlled substances) or de-identified biospecimens, or will you establish a research repository storing biospecimens?		
8.1 If "Yes" to #8, will any of these reagents be used in VA space, or will you establish a repository at PVAMC?		
If "Yes" to #8.1, submit the Project Safety & Hazard Assessment required by the Subcommittee on Research Safety. Applications are due by the 15 th of each month or check the Just in Time* box.	Just in Time	
Clarification of VA Research Activities	Yes	No
9. Will all of the work described in the protocol be conducted on VA time, in VA space, and/or use VA resources (patients, equipment, etc.)?		
If "No" to #9: <ul style="list-style-type: none"> Complete IRQ Appendix N if human subjects are involved (#5 or #5.4 = "Yes"). If animals and/or wetlab work are (also) involved, complete the Clarification of VA Research Activities form. If the research does not include human, animals or wetlab work, complete the final section of the "Clarification of VA Research Activities" form. 		
Conflict of Interest in Research	Yes	No
10. Would any of the following 7 statements be true for the PI, any co-investigator, a responsible VA clinician, and/or any member of the research staff, for themselves or for their spouse or dependent child?		
1. They have equity interests, including stock options, of any amount in a non-publicly traded business that has financial interests in this research project	2. They receive any payments (e.g., bonuses or "finder's fee" payments) in connection with this study that are not directly related to the reasonable costs of the project	
3. They are an inventor, or have made a disclosure of intellectual property to the VA, of technology or work that is directly related to this research project	4. They serve as an officer, director, or in any other executive position (paid or unpaid) for a business that has financial interests in this research project	
5. They have equity interests in aggregate (including your spouse and dependent children) of more than \$10,000 or more than 5% ownership in a publicly traded business that has financial interests in this research project	6. They receive or expect to receive in aggregate (including your spouse and dependent children) more than \$10,000 in a 12 month period from consulting fees, honoraria, gifts or other "in kind" compensation from a business that has financial interests in this research project	
7. They have a financial interest which would reasonably appear to be affected by the outcome of this project		
If "Yes" to #10, each person with a potential conflict must complete the " Conflict of Interest in Research " form. The completed form(s) must be submitted with this PPO. If any changes occur to the conflict of interest status of the PI or any member of the research staff after the initiation of the study, please notify the Research & Development Office immediately.		
<ul style="list-style-type: none"> Unless otherwise noted, all forms referenced here can be found at http://www.portland.va.gov/Research/piservices/rd_forms.asp *"Just in Time" indicates that submission to subcommittee will occur upon notification of grant funding. Instructions for Submission: Email this PPO, the abstract and the protocol (with a version date, whenever allowed) to Research.Grants@va.gov. If an unsigned PPO is emailed, fax a signed copy to 503-273-5351. In the body of the email and in any fax cover sheet, please include the study title. If a final copy of the protocol is not yet available, a draft of the proposal should be attached, and a final copy should be supplied to the research office when available. 		

Principal Investigator _____

Date _____