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**For Office Use Only**

Study# : \_\_\_\_\_\_\_\_\_

PROPOSED PROJECT QUESTIONNAIRE (*PPQ*)
VA Portland Health Care System (VAPORHCS)

**All Research Proposals using VA resources (space, equipment, patients, etc.) or conducted on an investigator’s VA time must be submitted to the VAPORHCS 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 (PI) Name:** | **Service:** | **Phone:** | **Email:** |
|       |       |       |       |
| **Study Coordinator Name:** | **Phone:** | **Email:** |
|       |       |       |
| **Mailcode** (For Correspondence)**:**       | **Building(s)/Room(s) where the Research Activities will be Conducted:**       |
|  |  |
| **Project Title:** |       |
| **[ ]  Check this box if the research will be unfunded, and then skip to item 1 below.** | **Funding Agency** *(If NIH, specify Institute; if VA, specify service)***:** | **Funding Period Start:**       | **Funding Period End:**       |
|       |  |  |
| **Grant Administrator:**  |  | **If Other Administrator, List:**       |
| **Submission Type:** |  | **If Resubmission, Date of Previous Submission:**       |
| **If Other Submission Type, Explain:**       |
| Will the work on this research be conducted even if the research is not funded by the funding agency?  | Yes [ ]  | No [ ]  |
| INSTRUCTIONS: |
| * **Unless otherwise noted, all forms referenced below can be found at:** <http://www.va.gov/portlandresearch/piservices/rd_forms.asp>
* **\***“*Just in Time*” (JIT) indicates that submission to subcommittee(s) will occur upon notification of a fundable grant score.
* **Please submit this PPQ, the abstract, the grant and/or protocol (with a version date, whenever allowed), and the conflict of interest forms to** **Research.Grants@va.gov****. *Hard copies should not be submitted.*  If an unsigned PPQ is emailed, fax a signed copy of the signature page(s) to 503-273-5152 and indicate the PI and study title on a cover sheet.**
* If a final copy of the grant/protocol is not yet available, a **draft** should be attached, and a final copy supplied to the research office when available.
* **NCI CIRB STUDIES ONLY:** Please submit this PPQ, abstract, Financial Administrative Review form\* (see ***NOTE\**** below) and copy of the current NCI CIRB study protocol to **Research.Grants@va.gov**
	+ ***NOTE\*:*** *Financial Administrative Review form and Project Safety & Hazard Assessment forms (if applicable) may be submitted after PPQ is signed. For questions, please contact* *Jane.Yates@va.gov*
	+ ***NOTE:*** *Please see the NCI CIRB Project Application for more information on requirements for the local VAPORHCS initial review of NCI CIRB approved projects located at:*[*https://www.va.gov/portlandresearch/documents/irb/NCI-CIRB-ProjectApplication.doc*](https://www.va.gov/portlandresearch/documents/irb/NCI-CIRB-ProjectApplication.doc)
* All paperwork for submissions to the appropriate IRB of record *(including NCI CIRB studies)* should be made ***after*** the PPQ notification is received indicating the PPQ has been signed and MIRB # assigned to the study. PPQ notification will also include any specific instructions needed for submission to the IRB**.**
	+ ***NOTE:*** *All studies submitted to the VAPORHCS IRB and Joint OHSU/VA IRB must include a VA-specific local protocol. Please see the required VAPORHCS IRB Protocol Template located at:* <https://www.va.gov/portlandresearch/documents/PIResources/Sample-Research-Protocol.doc>
	+ Please see the VAPORHCS IRB P&P for additional policies and requirements for review and approval located at: <http://www.va.gov/portlandresearch/documents/irb/irb-sop.doc>
 |
| *Section 1: Abstract/Keywords* |
| 1. Create a one-page abstract using the [abstract template.](http://www.va.gov/portlandresearch/documents/abstract-template.doc)  (for all proposed projects, including repositories) |
| *Section 2: OHSU Knight Cancer Institute & NCI CIRB* | Yes | No |
| 2. Does this study involve any of the following aspects of cancer: treating, preventing, non-curative intent of improving the comfort and quality of life for patients by preventing or managing symptoms or side effects, testing for methods of screening, early detection or diagnosis, epidemiologic, observational or outcome studies of patients with cancer and/or laboratory-based studies using human specimens to assess cancer risk, clinical outcomes, response to therapy? | [ ]  | [ ]  |
| 2.1 Is the PI a member of the OHSU Knight Cancer Institute? | [ ]  | [ ]  |
| 2.2 If YES to 2 and 2.1, has the study been submitted to the OHSU Knight Cancer Institute’s Clinical Research Review Committee (CRRC)? *Call 503-494-4108 for further information.* | [ ]  | [ ]  |
| *Section 3: Health Services Research* | Yes | No |
| 3. Is this a Health Services Research project being submitted to a funding source (i.e., VA HSR&D, QUERI, or Health Services Research Section of NIH)? |  [ ]  | [ ]  |
| *If YES to 3, the project must be reviewed by the HSR&D Research Review Committee prior to submission to the funding source. See* <http://www.va.gov/portlandresearch/Committees/index.asp> . *Submissions are due to the HSR&D Research Review Committee by the 3rd Friday of each month.* |
| *Section 4: Single IRB Requirements*  | Yes | No |
| 4. Will this study, be submitted to the National Cancer Institute (NCI) Central IRB (CIRB), or VA Central IRB for review, approval and IRB of record oversight? *If YES, please see NCI CIRB specific instructions, if applicable, at the top of this* *form and skip to 5.*  |  [ ]  | [ ]  |
| 4.1. Does the research involve more than one engaged institution in human subject research? *If NO, skip to 5.* |  [ ]  | [ ]  |
| 4.2. Are any of the other participating institutions a federal institution (including another VA) or are any of the participating institutions receiving federal funding or support for the research activity? [ ]  Unknown *If NO or UNKNOWN, skip to 5.*  |  [ ]  | [ ]  |
| 4.3. Has an exception to the single IRB requirement for this study already been determined and documented? [ ]  Unknown*If YES, include documentation and skip to 5.*  |  [ ]  | [ ]  |
| 4.4. Does ORD policy allow the use of the single IRB for this study? [ ]  UnknownIf YES, indicate name of Single IRB of Record for this study.       |  [ ]  | [ ]  |
| *Section 5: Institutional Review Board & Research Specimen or Data Biorepositories* *(including NCI CIRB studies)* | Yes | No |
| 5. Will this study, as conducted at the VAPORHCS and/or using VAPORHCS resources, involve obtaining data about any living individuals through intervention or interaction with them, seeing individually-identifiable information about living individuals (or having access to the code/ identification), or obtaining informed consent for research? *If NO, skip to 5.6.* | [ ]  | [ ]  |
| 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, you may choose to submit to the joint VA/OHSU IRB. Instructions on submitting to this IRB can be found at* [*http://www.va.gov/portlandresearch/hrpp/index.asp?tab=1*](http://www.va.gov/portlandresearch/hrpp/index.asp?tab=1)  *If YES to 4 but NO to 5.1, Instructions on how to submit to the IRB will be provided via email once your PPQ is signed.*  |
| 5.2 Does the protocol require any interventions that would require privileges at the VA? *If NO, skip to 5.4.* | [ ]  | [ ]  |
| 5.3 Is the PI licensed, credentialed, and privileged at the VAPORHCS? *NOTE: If NO to 5.3, if the PI is not a clinician but the protocol requires clinical expertise, a responsible clinician with appropriate expertise and privileges must be named on your IRB submission and grant (if applicable). Such duties might include the review of data, adverse events and new study findings, and who/how required decisions will be made for protecting the health of the subjects (e.g., stopping the participant’s involvement in the study or determining when to notify the subject or their health care provider of information that may affect the health of the subject).* | [ ]  | [ ]  |
| 5.4 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.* | [ ]  | [ ]  |
| *If YES to 5.4, complete and submit the* [*Financial Administrative Review form*](http://www.va.gov/portlandresearch/documents/admin-review.doc)*.* |
| 5.5 Is the purpose of this submission to establish a research repository (storing data and/or bio-specimens) at the VAPORHCS? | [ ]  | [ ]  |
| *If YES to 5.5, your IRB submission will need to include:* [*Repository IRQ*](http://www.va.gov/portlandresearch/documents/irb/repository-irq.doc)*,* [*Standard Operating Procedure*](http://www.va.gov/portlandresearch/documents/hrpp/biorepository-sop-example.doc) *(SOP) and* [*Scope of Work (IRQ Appendix L)*](http://www.va.gov/portlandresearch/documents/irb/irq-appendix-l.doc) *form(s). If the repository will include biospecimens, please answer YES to 7 & 7.1 below. SOP guidance can be found at* [*http://www.va.gov/portlandresearch/documents/hrpp/biorepository-sop-guidelines.doc*](http://www.va.gov/portlandresearch/documents/hrpp/biorepository-sop-guidelines.doc)*.*  |
| 5.6 Is the purpose of this submission to use data/biospecimens from an existing research repository? | [ ]  | [ ]  |
| 5.7 If YES to 5.6, 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 5.7, please submit the PPQ following the instructions at the top of this form. Additional instructions on how to submit to the IRB will be provided via email.*  |
| 5.8 Is the purpose of this submission to contribute samples collected from VAPORHCS patients/subjects into an existing biorepository/bank? | [ ]  | [ ]  |
| 5.9 Is the purpose of this submission to use information obtained about decedents (i.e. subjects who are deceased)? | [ ]  | [ ]  |
| *If YES to 5.9, please complete a* [*Research on Decedents’ Information Application*](https://www.va.gov/portlandresearch/documents/irb/hipaa-decedents-research.doc)*.* |
| *If YES to any of questions in this section (5), you will need to complete the indicated application for submission to the VAPORHCS IRB, VA/OHSU Joint IRB or External IRB. Or check the Just in Time (JIT)\* box.*  | JIT [ ]  |
| *Section 6: Institutional Animal Care & Use Committee (IACUC)* | Yes | No |
| 6. Will any work with animals (breeding/research/etc) occur at the VA or is any animal work funded by the VA? | [ ]  | [ ]  |
| *If YES to 6, send your electronic application for the IACUC to* *PVAMC-IACUC@va.gov**. Applications are due by the 15th of each month. Or check the Just in Time (JIT)\* box.* | JIT [ ]  |
| 6.1 Did or will you submit ACORP Appendix 3 (Biosafety)? | [ ]  | [ ]  |
| *If YES to 6.1, please submit the Project Safety & Hazard Assessment referenced below.* |
| *Section 7: Subcommittee on Research Safety* | Yes | No |
| 7. Will any of the work include chemicals, biospecimens, cells/tissue cultures, microbiological agents, recombinant DNA, controlled substances or radioisotopes, or will you establish a research repository storing biospecimens? | [ ]  | [ ]  |
| 7.1 If YES to 7, will any of these reagents or specimens be used in VA research space, or will you establish a repository at VAPORHCS? | [ ]  | [ ]  |
| *If YES to 7.1, submit the* [*Project Safety & Hazard Assessment*](https://www.va.gov/portlandresearch/documents/safety/project-safety-assessment.doc) *required by the Subcommittee on Research Safety. Applications are due by the 15th of each month or check the Just in Time (JIT)\* box.*  | JIT [ ]  |
| *Section 8: Clarification of VA Research Activities* | Yes | No |
| 8. Will each and every activity in this protocol/grant/application be conducted entirely at the VA? *If YES skip to 9.* | [ ]  | [ ]  |
| 8.1 If NO to 8, will all of the work being conducted outside of the VA be conducted on VA time? *If YES skip to 9.* | [ ]  | [ ]  |
| 8.2 If NO to 8.1, will all of the work conducted outside of the VA on non-VA time involve VA resources (participants, records, equipment, etc.)?  | [ ]  | [ ]  |
| *If NO to 8, 8.1 and 8.2:** *If animals and/or wetlab work are (also) involved, complete the* [*Clarification of VA Research Activities*](http://www.va.gov/portlandresearch/documents/clarification-of-VA-research.doc) *form.*
* *If there will be no human, animal or wetlab work, complete the final section of the* [*Clarification of VA Research Activities*](http://www.va.gov/portlandresearch/documents/clarification-of-VA-research.doc) *form.*
 |
| *Section 9: List of Personnel for Studies without Subcommittee Review* |
| 9. If no subcommittee reviews are indicated (i.e., all questions in sections 4, 5, 6 and/or 7 were answered NO) please submit a list of all research team members, including their roles, who will be involved in VA Research *(*at the VA, using VA resources and/or on VA time). *NOTE: A* [*Conflict of Interest in Research Form*](http://www.va.gov/portlandresearch/documents/conflict_of_interest.pdf) *is also required for any of the following individuals that work at the VAPORHCS: PI, Co-PI, study chair, local site PI (if different than main PI) and each co-investigator or sub-investigator, who will be involved in VAPORHCS Research (i.e., at the VA, using VA resources and/or on VA time).* |
| *Section 10: Just in Time* |
| 10. If the research will only be conducted in the event that funding is awarded or you indicated above that the research will be conducted even if funding is not awarded, check the Just in Time (JIT)\* box and submit a Conflict of Interest in Research Form for the individuals listed in #9 once a funding determination has been made and/or at the time of the submission of other subcommittee paperwork | JIT[ ]  |

Principal Investigator Date