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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: |
| * “*Just in Time*” (JIT) indicates that submission to subcommittee(s) will occur upon notification of a fundable grant score.
* If the **PI named above** 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).
* 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.
* All **submissions to the appropriate subcommittees** (e.g., IACUC, SRS, IRB of Record) must be made **after you receive notification** that the PPQ has been signed and an Internal Reference # has been assigned.
* Unless otherwise noted, all forms referenced below can be found at: <http://www.va.gov/portlandresearch/piservices/rd_forms.asp>
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| *Section 1: Abstract/Keywords* |
| 1. Create a one-page abstract using the [abstract template.](https://www.va.gov/portlandresearch/documents/abstract-template.docx)

 *NOTE: This is required for all proposed research projects, including the creation of a repository.* |
| *Section 2: Health Systems Research* | Yes | No |
| 2. Is this proposed research project being submitted the ORD VA Health Systems Research (HSR) Portfolio or to VA QUERI?*If* ***YES*** *to Q.2, the project must be reviewed by the* ***VAPORHCS HSR (CIVIC) Research Review Committee*** *prior to submission to the funding source. See* [http://www.va.gov/portlandresearch/Committees/index.asp](https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.va.gov%2Fportlandresearch%2FCommittees%2Findex.asp&data=05%7C02%7C%7C160b99452c734aeb4d2a08dc326aeef3%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C638440682050943591%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=u5DTyCam34Vck%2Bmg6KpJl53mdBrNuHgoS7WqZesJkWc%3D&reserved=0). *Submissions are due to the* ***HSR Research Review Committee*** *by the 3rd Friday of each month.* | [ ]  | [ ]  |
| *Section 3: Institutional Review Board (IRB) – IRB of Record* | Yes | No |
| 1. Will this proposed research project, be 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 to Q.3., skip to Q.5.*
 |  [ ]  | [ ]  |
| * 1. If YES to Q.3., use the boxes below to indicate the IRB of Record the project will be submitted to for review and approval.

[ ]  VAPORHCS IRB [ ]  VA/OHSU Joint IRB [ ]  VA CIRB [ ]  NCI CIRB[ ]  External IRB (e.g., Advarra, Sterling, or WCG IRB,) Name of External IRB:        [ ]  Unknown (if unknown, email pvamc-irb@va.gov for guidance)*See links to submission guidance below:** VAPORHCS IRB: <https://www.va.gov/PORTLANDRESEARCH/documents/irb/help_guide_new_project_submission.docx>
* VA/OHSU Joint IRB: See “OHSU IRB3” tab on Research Service website located at: <https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp?tab=3>
* VA CIRB: See “Central IRB” tab on Research Service website located at: <https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp?tab=3>
* NCI CIRB & External IRBs: The External IRB Project Application can be **located by** navigating in the VAIRRS system to Forms and Templates (under Other Tools on left-hand side) and selecting VA Portland IRB - Documents for Researchers from the Select a Library drop-down menu, and selecting External IRB Project Application from the documents list.
 |
| 3.2. Will this proposed research project 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 Q.3.2., complete the* [*Financial Administrative Review form*](https://www.va.gov/PORTLANDRESEARCH/documents/admin-review.docx) *and submit with this PPQ.* | [ ]  | [ ]  |
| *If YES to any of the questions in Section 3, you will need to complete the application for IRB of Record noted in the guidance above. Or check the Just in Time (JIT)\* box.*  | JIT [ ]  |
| *Section 4: Single IRB Requirements*  | Yes | No |
| 1. Are any 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 Section 5.*
 |  [ ]  | [ ]  |
| * 1. Has an exception to the single IRB requirement for this study already been determined and documented?

[ ]  Unknown *If YES to Q.4.1., include documentation with PPQ submission.*  |  [ ]  | [ ]  |
| *Section 5: Research Specimens and/or Data & Biorepositories*  | Yes | No |
| 1. Will this proposed research include collecting biospecimens from research patients/subjects?
 | [ ]  | [ ]  |
| 5.1. Is the purpose of this project to establish a research repository (i.e., storing data and/or biospecimens) at the VAPORHCS? *If NO to Q.5.1., skip to Q.5.3.**If* ***YES*** *to Q.5.1, you will need to complete a Repository IRQ form and create a Repository SOP using the Repository Sample SOP Template* ***located by navigating*** *in the VAIRRS system to Forms and Templates (under Other Tools on left-hand side); selecting VA Portland IRB - Documents for Researchers (from the Select a Library drop-down menu) and selecting the form and template from the document list.*  | [ ]  | [ ]  |
| 5.2. If YES to Q.5.1., use the boxes below to indicate the type of repository to be established. [ ]  Data Repository Only [ ]  Biospecimens Repository Only [ ]  Data & Biospecimens Repository |
| 5.3. Will this proposed research include obtaining/use of data and/or biospecimens from an existing research repository? *If NO to Q.5.3., skip to Q.5.6.* | [ ]  | [ ]  |
| 5.4. If YES to Q.5.3., use the boxes below to indicate what will be obtained from an existing research repository. [ ]  Data Only (including contact info for recruitment) [ ]  Biospecimens Only [ ]  Data & Biospecimens |
| 5.5. If YES to Q.5.3., will you or anyone working on this study be able to link the data/biospecimens to the individual’s identity (i.e., have access to the code book, etc.)? | [ ]  | [ ]  |
| 5.6. Will this proposed research include contributing biospecimens collected from VAPORHCS patients/subjects to an existing biorepository? | [ ]  | [ ]  |
| *NOTE: If you've indicated in Section 5, that this research project will include any use of biospecimens,**you must complete Section 7 below.* |
| *Section 6: Institutional Animal Care & Use Committee (IACUC)* | Yes | No |
| 1. Will any work with animals (breeding/research/etc.) occur at the VA or is any animal work funded by the VA?
 | [ ]  | [ ]  |
| *If YES to Q.6., submit your application for the IACUC 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 Q.6.1., please submit the Project Safety & Hazard Assessment* ***referenced in Q.7.1., below.*** | [ ]  | [ ]  |
| *Section 7: Subcommittee on Research Safety (SRS)* | Yes | No |
| 1. 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?

*If NO to Q.7., skip to Q.8.* | [ ]  | [ ]  |
| * 1. If YES to Q.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 Q.7.1., submit the* [*Project Safety & Hazard Assessment*](https://www.va.gov/portlandresearch/documents/safety/project-safety-assessment.doc)***located by navigating*** *in the VAIRRS system to Forms and Templates (under Other Tools on left-hand side); selecting VA Portland SRS - Documents for Researchers (from the Select a Library drop-down menu) and selecting the form from the document list.*  | [ ]  | [ ]  |
| *If YES to Q.7.1., submit your application for the SRS by the 15th of each month. Or check the Just in Time (JIT)\* box.* | JIT[ ]  |
| *Section 8: Clarification of VA Research Activities* | Yes | No |
| 1. Will every activity in this protocol/grant/application be conducted entirely at the VA? *If YES skip to Q.9.*
 | [ ]  | [ ]  |
| 8.1. If NO to Q.8., will all of the work being conducted outside of the VA be conducted on VA time? *If YES skip to Q.9.* | [ ]  | [ ]  |
| 8.2. If NO to Q.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 questions 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* |
| 1. If no subcommittee reviews are indicated (i.e., all questions in Sections 3, 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).*
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| *Section 10: Just in Time* |
| 1. 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