INITIAL REVIEW QUESTIONNAIRE (IRQ)

All research involving humans, regardless of funding, must be reviewed by the IRB. The information in this form will assist the IRB in determining the risks and potential benefits of the proposed research. Complete this questionnaire only if the study involves living human subjects (including organs, tissues, or fluids from living individuals), and/or access to identifiable information from human subjects. *NOTE: If any fields on this IRQ do not allow enough space to provide a thorough answer, state “see attached”, and include the complete answer on a separate page, identifying clearly to which question the answer refers. Unless otherwise noted, all IRQ appendices and other forms referenced in this document are located at:* <http://www.va.gov/portlandresearch/piservices/rd_forms.asp>

**Instructions (OHSU/VA Joint IRB Studies ONLY):**

* Unless noted, all sections of this form and related appendices are required.
* Complete this form using study information for research activities conducted at VAPORHCS (e.g. do not include enrollment numbers for OHSU subjects, and/or related to OHSU subjects only, etc.). If a question does not apply to the research activities conducted at VAPORHCS, provide an explanation in the form of a cover memo (e.g. VAPORHCS only engagement in research is data analysis).
* Once this form is completed, convert it electronically to pdf format. The page with signature should be signed by the PI in one of two ways: 1) electronically using the PI’s PIV card; or 2) signing with a wet signature, scanning and then uploading it into eIRB.
* Submit this form along with any additional documents prompted by the individual questions in the IRQ, and any additional study documents via eIRB.

Please do not complete this IRQ if:

* You haven’t completed the study protocol using the VAPORHCS Protocol/Local Protocol Addendum template located at: <https://www.va.gov/portlandresearch/documents/PIResources/Sample-Research-Protocol.doc> . *NOTE: The protocol must include all required information as indicated in the VARPORHCS Protocol Template instructions. The protocol template is designed to ensure your protocol, informed consent documents, and other protocol-related documents are consistent and in compliance with all State, local, VAPORHCS and general VA/VHA requirements.*
* The sole purpose of this submission is to establish a new research repository; instead, see the IRB Review of Repositories Located at the VAPORHCS policy, under the “HRPP” tab of the VAPORHCS Research website located at: <https://www.va.gov/portlandresearch/hrpp/index.asp?tab=0%20-%20policies1%20-%20top>
* The study fits criteria for an exemption from IRB oversight; instead, complete the Certificate of Exemption form located at: <https://www.va.gov/portlandresearch/documents/irb/certification-of-exemption.doc>
* This is an application for the clinical use of a Humanitarian Use Device (HUD); instead, complete the Humanitarian Use Device (HUD) Application located at: <https://www.va.gov/portlandresearch/documents/irb/hud-application.doc>
* If the study only includes decedent information (i.e. no information regarding living human subjects), please complete the Research on Decedents' Information Application located at: <https://www.va.gov/portlandresearch/documents/irb/hipaa-decedents-research.doc>

Basic Information/Study Personnel :

**Project Title:       Protocol ID:**

**VA Principal Investigator (PI):       Email       Extension**

***NOTE:*** *PI listed must be eligible to serve as VAPORHCS PI, or responsible clinician, as defined in the* ***VAPORHCS IRB P&P*** *located at:* [*https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc*](https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc)

**Study Coordinator:       Email       Extension**

***NOTE:*** *All correspondence will be sent to this person (in addition to the PI)*

**STAFF TABLE (see below):**  List all personnel working on the study **other than** the PI and Study Coordinator. If more space is necessary, use the same table from a clean IRQ. **List all individuals** who will work onsite at the VAPORHCS, need access to CPRS patient records, directly interact with VAPORHCS participants, and/or see identifiable data for VAPORHCS participants. ***NOTE:*** *If the investigator is not a clinician but the protocol requires clinical expertise, a responsible clinician with appropriate expertise and privileges must be named below. 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).*

* Complete all personnel forms and training required for an appointment through Research Service (see **Research Appointment Requirements** located at: <https://www.va.gov/portlandresearch/piservices/hiring/appointmentrequirements.asp> );
	+ - Have a **VA-paid or Without Compensation Appointment at VAPORHCS**, unless this is a multi-site study and staff at other sites will see identifiable information about VAPORHCS participants. In this case, please list staff members with access to the identifiable VAPORHCS information in the table below and submit documentation of IRB approval from those sites in lieu of appointment, training, and education and credentialing forms;
* Be up to date on all applicable **VAPORHCS Education Requirements** (for research and for use of VA computers, as needed) listed at: <http://www.va.gov/portlandresearch/training/index.asp>. *Please direct any questions related to CITI education or other required training to Heather Parman, extension 56619.*

***NOTE:*** *If study staff is “transient clinical staff” or a “trainee” and they take TMS3185966, TMS 3192008, or VA 20152 then they DO NOT HAVE TO TAKE the main privacy training VA10203. See training requirements located at):* [*https://www.va.gov/portlandresearch/documents/Education-for-Research.pdf*](https://www.va.gov/portlandresearch/documents/Education-for-Research.pdf)

* Only students and other trainees (including residents and fellows) who are from schools with an academic affiliation, or directly appointed to a VA training program that has no external institutional sponsorship,may work on research to fulfill educational requirements within a VA facility or use data or human biological specimens that have been collected within VA for clinical, administrative, or research purposes.
* If this is a mentored project for which the PI is acting as a mentor for someone in training (e.g. a resident, fellow, student conducting an internship or externship), please attach to this IRQ a NIH bio-sketch for the mentor. If it is determined that the mentor is relatively new to conducting human subjects research, the PI (mentor) must either attend the IRB meeting at which the study is initially reviewed or receive training from the Research Administrative Office.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Degree**  | **Study Role (and Site, if not at VAPORHCS)** | **Service** **(if Co-I)** | **Extension** | **Email** |
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***Each******of the individuals above, as well as the PI and the Study Coordinator must complete (as applicable):***

[ ]  **Scope of Work Form (SOW)**: A SOW is required for each person listed in the staff table, as well as the PI and the Study Coordinator, unless they are an individual at another site who will see VAPORHCS identifiable data, a completed IRQ Appendix L (“Scope of Work Form”) is required with IRB submission and is located at: <https://www.va.gov/portlandresearch/documents/irb/irq-appendix-l.doc>

[ ]  **Conflict of Interest in Research Forms (COI):** A COI in Research form is required for each principal investigator, co-principal investigator, co/sub-investigator, and/or study chair. COI form located at: <https://www.va.gov/portlandresearch/documents/conflict_of_interest.pdf>

**Research Setting:**

1. A. Is this a Collaborative/multi-site study1?

[ ]  YES

[ ]  NO (skip to Q.1.D.)

1If a study is being conducted at the VAPORHCS and any other institution (including OHSU), it is a collaborative/multi-site study. ***NOTE***: *If the only OHSU involvement in the study is the use of their REDCap, and the study is not being submitted to the OHSU/VA Joint IRB, please contact an IRB Analyst for guidance,* ***prior to submission****.*

1. Is the only role of VAPORHCS in the conduct of the study to recruit and consent VAPORHCS subjects to contribute to a repository?

[ ]  YES

[ ]  NO

***NOTE***: *If* ***YES****, “Recruitment or Contribution Only” studies must list the VA as a collection site in the main study protocol and/or repository SOP, and include language that states VA investigators can receive information/biospecimens from the repository.*

If **YES** to B, indicate what section(s) of the main protocol and/or SOP or any other study document(s) that state VAPORHCS is a collection site, and VA investigators will be allowed to receive information/biospecimens from the repository.

1. Is the VAPORHCS the Coordinating Center for this study?

[ ]  YES

[ ]  NO

*If* ***YES****, please complete* ***IRQ Appendix M*** *located at:* <https://www.va.gov/portlandresearch/documents/irb/irq-appendix-m.doc>

D. Will any of the study activities be performed outside of the VAPORHCS or be conducted on non-VA time by a research team member listed in the staff table above?

[ ]  YES

[ ]  NO

*If* ***YES****, please complete* ***IRQ Appendix N*** *to allow the IRB and R&D Committee to distinguish the VA research vs. the non-VA research. IRQ-N is located at:* <https://www.va.gov/portlandresearch/documents/irb/irq-appendix-n.doc>

E. Will this study utilize resources of the Oregon Clinical and Translational Research Institute (OCTRI) at OHSU? ***NOTE:*** *This includes the use of OHSU REDCap. If OCTRI resources include the use of REDCap, and the study is not being submitted to the OHSU/VA Joint* *IRB*, *please contact an IRB Analyst for guidance,* ***prior to submission***

[ ]  YES

[ ]  NO

If **YES**, contact the “OCTRI Navigator”: octri@ohsu.edu or 503-418-9790.

F. Does this study contain an international component?

For example, are any study activities being conducted outside of the U.S.? Are any human biological specimens and/or data (regardless of whether they are de-identified, identifiable or coded) being sent to or received from a country outside of the U.S.?

[ ]  NO

[ ]  YES:

If **YES**, choose which role the VA serves in this international research:

[ ]  The PI for the study as a whole is not a VA investigator and VAPORHCS is only one of many participating sites; **OR**

[ ]  This study is a collaborative/multi-site trial involving non-U.S. sites where the VA is the study sponsor, a VA investigator is the overall study-wide PI, the VA holds the IND, and/or the VA manages the data collection and data analysis.

***NOTE:*** *If* ***YES to Q.1.E. above****, please contact a VAPORHCS IRB analyst* ***prior to IRB submission*** *to obtain guidance on the required documentation and approvals needed to conduct this research at VAPORHCS.*

G. Will this study use the Computerized Patient Record System (CPRS – current system), VA electronic health record (EHR – new system), or CPRS/EHR data on or after January 2022 (for example: entering progress notes; entering consults; ordering labs, medications, procedures, imaging, etc.; eligibility screening with EHR chart review or CDW; using CDW data; etc.)?[ ]  YES

[ ]  NO

**Study Design, Anticipated Screening & Enrollment Numbers:**

2. What elements of study design are included in this research project? (Check all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  Intervention | [ ]  Interview | [ ]  Video or Audio Taping |
| [ ]  Observational  | [ ]  Use of Focus Groups | [ ]  Instruction/Curriculum |
| [ ]  Retrospective Records/Data (currently existing data) | [ ]  Questionnaire or Survey | [ ]  Specimen Analysis |
| [ ]  Prospective Records/Data (data will be existing in future) | [ ]  Use of Artificial Intelligence/Algorithm | [ ]  Genetics |
| [ ]  Use of information about drug abuse, alcohol abuse, HIV infection and/or sickle cell anemia | [ ]  Disclosure of information to any entity outside VAPORHCS study personnel | [ ]  Other:  |
| [ ]  Receiving from and/or contributing to a data/tissue repository |

**Sources of Subjects:**

3. A. Check all sources of subjects that apply:

[ ]  Veterans

[ ]  Veterans not eligible for VHA Healthcare

[ ]  Non-Veterans (i.e., patient family members, general public, etc.)

 ***NOTE:*** *If subjects will include Non-Veterans, be sure the protocol includes justification.*

 [ ]  VA employees (may be Veterans or Non-Veterans and are a targeted subject population)

 [ ]  Active Duty Military Personnel

[ ]  Deceased Veterans or non-Veterans (i.e. targeted subject population and not incidentally included as part of a retrospective chart review) ***NOTE:*** *If any decedent information will be used as part of this study, please complete the* ***Research on Decedents' Information Application*** *located at:* [*https://www.va.gov/portlandresearch/documents/irb/hipaa-decedents-research.doc*](https://www.va.gov/portlandresearch/documents/irb/hipaa-decedents-research.doc)

B. If Veterans not eligible for VHA Healthcare or non-Veterans will participate, indicate the following (check all that apply):

[ ]  N/A – study will not enroll Veterans no eligible for VHA Healthcare or non-Veterans

[ ]  Study will involve either inpatient or outpatient treatment

B.1. What is the probability or likelihood that research-related injury will occur as a result of participating in the study (i.e. 0 - 100%):

B.2. Who is the responsible party for providing reimbursement to the VA Medical Center for any research-related injury treatment costs of a non-Veteran or a Veteran not eligible for VHA care participating in the study?”

***NOTE:*** *The non-Veteran and his or her insurance or third-party payer cannot be a responsible party.*

[ ]  No responsible party (e.g. study is unfunded)

[ ]  ORD: The study is ORD-funded study and ORD has approved a waiver to allow for the inclusion of non-Veterans.

[ ]  Industry: The study is industry-funded and the CRADA or other agreement outlines responsibilities and reimbursements for research related injury.

[ ]  Other: Please explain:

C. If VA employees will participate as a targeted subject population, indicate when participation will occur (check all that apply):

 [ ]  N/A – study will not enroll VA employees

[ ]  On their personal, non-work time

 [ ]  On their VA time. ***NOTE:*** *VA employee participation during work time should be related to major job*

 *duties and supervisor approval is required. Please work with IRB analysts to determine if Union*

 *approval is required prior to study initiation.*

 [ ]  Participation will be related to their major job duties

 [ ]  Participation will be approved by the supervisor (documentation of approval may be

 requested for IRB review)

D. If active duty military personnel will be enrolled explain how you will assure each of the following:

[ ]  N/A – study will not enroll active duty military personnel

* Explain how you will assure that officers are not permitted to influence the decision of their subordinates:
* Explain how you will assure that officers and senior non-commissioned officers are not be present at the time of recruitment:
* Explain how you will assure that officers and senior non-commissioned officers have a separate opportunity to participate:
* Explain how you will assure that when recruitment involves a percentage of a unit, an independent ombudsman is present:

**Special Classes of Subjects:**

4. Are any of the following subject populations actively recruited and/or directly involved?

[ ]  YES

[ ]  NO

 If **YES**, please check the appropriate population(s).

Children\* [ ]

Fetuses (in-utero or ex-utero, and including human fetal tissue\*) [ ]

Neonates\* [ ]

Pregnant Women\* [ ]

Prisoners\* [ ]

 Individuals with impaired decision-making capacity [ ]

Economical and/or educationally disadvantaged [ ]

*\*****NOTE:*** *Please see the* ***VAPORHCS IRB P&P*** *located at:* <https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc> *for additional federal and/or VA requirements related to research involving these populations.* ***Please contact the Research Administrative office at 503-273-5125 and ask to******speak to an IRB Analyst prior to submission****.*

Subject Identification Prior to Authorization:

5. Will any identifiable information be accessed or utilized in any way when identifying potential subjects and prior to a subject’s signed authorization or under a waiver of authorization and consent documentation (including using data from a “contact” repository)? *NOTE: This does not apply to a study conducted under a complete waiver of consent and authorization.*

[ ]  NO

 [ ]  YES - complete an **2018 Application for a** **Waiver of Authorization for Screening/Recruitment Purposes**, located at: <https://www.va.gov/portlandresearch/documents/irb/partial-recruitment-waiver-2018.doc> ***NOTE:*** *If study will identify potential subjects using data obtained from a repository, a Data Use Agreement (DUA) must be executed prior to accessing the data in any way. Please contact the Repository Director to initiate the DUA process.*

**Informed Consent & Progress Notes:**

6. A. Select which type(s) of informed consent, authorizations and/or waiver(s) will be utilized for this study. ***NOTE:*** *All forms referenced below located at:* [*http://www.va.gov/portlandresearch/piservices/rd\_forms.asp*](http://www.va.gov/portlandresearch/piservices/rd_forms.asp)

[ ]  **Written/documented** informed consent form and, as applicable, HIPAA authorization.

[ ]  **Short form consent form and, as applicable, HIPAA authorization**. Utilized in instances in which informed consent is presented orally to the participant or legally authorized representative (LAR) in a language understandable to the participant. Short form requires signature of participant (or LAR) and witness.

[ ]  **Waiver of documentation of consent and, as applicable, waiver of HIPAA authorization (consent process occurs, but participant signature requirement is waived.)** Scenarios for which this may be appropriate include instances in which participant signature on an ICF document is the only identifying link to study participation and the main risk of study participation is the participant name on the consent document and/or the research is minimal risk and involves no procedures which written consent is normally required outside of the research and/or the research includes members of a distinct cultural group in which signing forms is not the norm.

[ ]  Complete a **2018 Request for Waiver or Alteration of Informed Consent Documentation and Waiver of Authorization to Release Medical Records and Health Information**;

**AND**

[ ]  Submit an **information sheet**/**script** that includes all applicable elements of the informed

consent template (e.g. Key Summary Info and basic elements of consent) minus the signature section

[ ]  **Waiver of informed consent process and, as applicable, waiver of HIPAA authorization**. Scenarios for which this may be appropriate include conducting retrospective records reviews or other minimal research that could not practically be carried out without the waiver or alteration of consent process.

[ ]  Complete a **2018 Request for Waiver or Alteration of Informed Consent Process and Waiver of Authorization to Release Medical Records and Health Information**

B. If more than one consent form will be used, how many different consent forms have been submitted for use in this research project and how individuals (e.g. IRB reviewers) can easily tell them apart (provide different titles here, etc.): ?

[ ]  N/A – study only uses one consent form.

1. *A progress note must be created for all research subjects (Veterans or non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or community living centers).* ***NOTE:*** *See VAPORHCS IRB P&P, section V. Progress Notes, for additional guidance and progress note requirements for research subjects. VAPORHCS IRB P&P is located at:* [*https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc*](https://www.va.gov/portlandresearch/documents/irb/irb-sop.doc)

Given the progress note guidance and requirements indicated above, will subjects enrolled in this research project have progress notes created in CPRS?

[ ]  YES

[ ]  NO

**Investigational Drugs:**

*An investigational drug is a chemical or biological drug that is used in a clinical investigation. An investigational drug can be: (1) a new chemical compound, which has not been approved by the FDA, or (2) an approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an IND application, in a clinical investigation; this includes prescription drugs, over-the-counter drugs, nutritional supplements, herbal preparations, and legend items used for the diagnosis, treatment, cure, mitigation or prevention of disease and meeting the above definition.*

7. Will an investigational drug(s), as defined above, be used?

[ ]  YES

[ ]  NO

*If* ***YES****, complete and submit the* ***IRQ Appendix C (not required for Joint OHSU/VA IRB studies)****, the* ***Investigational Drug Information Record - VA form 10-9012*** *for each investigational drug,**along with the investigator’s brochure(s) or package inserts, and any correspondence with the FDA regarding the study to the IRB. The IRQ Appendix C and form 10-9012 located at:* <https://www.va.gov/portlandresearch/piservices/rd_forms.asp>

**Dietary Supplements, Herbal Remedies, or Complementary/Alternative Remedies:**

8. Will this study include the use or evaluation of dietary supplements, herbal remedies, or other complementary or alternative remedies?

[ ]  YES

[ ]  NO

 *If* ***YES****, contact the Research Pharmacy to determine if* ***IRQ Appendix D (not required for Joint OHSU/VA IRB studies)****, should be submitted to the IRB. Also submit any correspondence with the FDA about the study. IRQ Appendix D located at:* <https://www.va.gov/portlandresearch/documents/irb/irq-appendix-d.doc>

**Devices:**

**Medical Device (FDA definition):** *“An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure of any function of the body and which does not achieve its primary intended purpose through chemical action and which is not depended upon being metabolized for the achievement of its primary intended purposes.”*

* + - *This may include any of the following meeting the definition above: artificial intelligence (AI), algorithms, assays, software and mobile devices/applications (either as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device).*
		- ***NOTE:*** *If any AI, algorithm or Laboratory Developed Test (LDT) will be used and is not cleared or approved by the FDA, please contact the Research Assurance Officer before submission of this IRQ in order to determine which requirements apply.*

9. A. Will any medical device (as defined above) be used in this research project?

[ ]  YES

[ ]  NO (skip to E)

B. If **YES**, will any of these medical devices (as defined above), and/or any of its individual functions (e.g. a new wireless functionality for a previously cleared device), be evaluated for safety and/or effectiveness - either when used alone or in conjunction with another treatment method(s)?

[ ]  YES

If **YES to B, for any of the medical devices**, list those in **Table 1 below.** Then complete a separate **IRQ Appendix E** foreach such deviceand submit to the IRB all documentation prompted on that form. The IRQ Appendix E is located at: <https://www.va.gov/portlandresearch/documents/irb/irq-appendix-e.doc>.

[ ]  NO

If **NO to B, for any of the medical devices**, list those in **Table 2 below.**

**Table 1. Medical devices being evaluated.**

|  |  |
| --- | --- |
| **Manufacturer + Brand name** | **Type of device** *(e.g. hearing aid)* |
|  |  |
|  |  |
|  |  |

**Table 2. Other medical devices being used but not evaluated.**

|  |  |  |
| --- | --- | --- |
| **Manufacturer + Brand name** | **Type of device** *(e.g. hearing aid)* | **Role in study** *(e.g. comparator for device being evaluated, MRI beyond what is scheduled for the individual’s clinical care)* |
|  |  |  |
|  |  |  |
|  |  |  |

C. For each medical device listed in Tables 1 and 2, are all its uses in this study covered by its current labeling and/or FDA determination?

[ ]  YES

[ ]  NO

If **NO**, list each device and explain how each use differs from what is currently covered:

D. Are the results of this study intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit?

[ ]  YES

[ ]  NO

**Mobile Devices:** *include smartphones, tablets, E-readers and other devices using a mobile operating system (e.g. iOS, Android, Windows).* ***Mobile Applications*** *are software that runs on mobile devices.*

E. Will any mobile device or mobile application (as indicated above, including any that are also medical devices listed in Tables 1 and 2) be used in this research project?

[ ]  YES

[ ]  NO (skip to 10)

If **YES to E**, list each separately in **Table 3 below.**

Table 3. Mobile devices and mobile applications being used.

|  |  |  |
| --- | --- | --- |
| **Manufacturer + Brand name of device or application** | **Type of device** *(e.g. tablet; if application, enter “application”)* | **Specify if listed in Table 1 or 2; if not listed there, specify role in study** *(e.g. track participants’ physical activity)* |
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**Radiation:**

10. Does this protocol involve ***any*** use of x-ray and/or radioactive materials? This includes ***any and all procedures,*** such as screening chest x-rays, CT scans, bone scans, etc.)

[ ]  YES

[ ]  NO

*If* ***YES****, complete* ***IRQ Appendix F*** *located at:* [*https://www.va.gov/portlandresearch/documents/irb/irq-appendix-f.doc*](https://www.va.gov/portlandresearch/documents/irb/irq-appendix-f.doc)

**Human Biological Specimens:**

11. A. Will this project involve collection and analysis of human biological specimen(s) for the purposes stated in the current protocol? ***NOTE:*** *Be sure the protocol describes how specimens are obtained, specimen types(s), methods used to label specimen(s), how specimens will be kept secure and the analyses to be performed on each specimen type at each applicable institution/facility.*

[ ]  YES

[ ]  NO (skip to Q.12.A.)

B. If **YES**, where will specimen(s) be processed, analyzed and/or stored? (select all that apply)

[ ]  VAPORHCS clinical lab

[ ]  VAPORHCS research lab\*

***\*NOTE:*** *The use or storage of specimens in a VAPORHCS research lab must have prior approval from the VA Subcommittee on Research Safety (SRS) for each new project. Contact Jane Yates (Jane.Yates@va.gov, VA ext. 52800) for more information.*

[ ]  VA Facility

[ ]  Non-VA\*\*, non-profit institution/facility (including central labs)

[ ]  Non-VA\*\*, for-profit institution/facility (including central labs)

***\*\*NOTE:*** *Specimens sent to a* ***non-VA* institution/facility** *must be destroyed by the* institution/facility

 *or returned to the VA after the specific tests/analyses have been performed. If the specimens are destroyed by the* institution/facility*, the* institution/facility *must provide certification of destruction of each individual sample, or of the batch of samples as a whole, in writing to the principal investigator. The certification must be retained in the PI’s study files, and a copy will be requested by the IRB at the time of study termination.*

C. Will the specimens be stored at a for-profit institution/facility (including central labs)?

[ ]  NO

[ ]  YES; **AND**

[ ]  The project includes biospecimen storage at a for-profit institution/facility and an **Application for Biospecimen Storage at a For-Profit Institution** waiver is included with this submission.

***NOTE:*** *The PI must obtain a waiver for this from the Associate Chief of Staff/R&D. This waiver allows specimens to be stored to perform batch analyses or to repeat analyses that are described in the protocol and informed consent form. The Application for Biospecimen Storage at a For-Profit Institution**waiver is located at:* [*https://www.va.gov/portlandresearch/documents/irb/biospecimen-storage-forprofit.doc*](https://www.va.gov/portlandresearch/documents/irb/biospecimen-storage-forprofit.doc)*.*

D. Will the data generated from the analysis of biospecimens be linked to clinical data such as diagnosis, comorbidities, prescriptions, etc. (e.g. either from the medical record or from any collected or created research data)?

[ ]  YES

[ ]  NO (skip to Q.11.F)

*If* ***YES,*** *be sure the protocol describes where the data will be analyzed, who will do the analyzing of data and how the link between the clinical data and biospecimens will be maintained and who will maintain it.*

E. If **YES** to D, answer the following:

Will the specimens be linked to clinical data at the Portland VA? [ ]  Yes [ ]  No

Will the specimens be linked to clinical data at another VA(s)? [ ]  Yes [ ]  No

Will the specimens be linked to clinical data at other institutions? [ ]  Yes [ ]  No

If **YES to item above**, justify why the clinical data needs to be viewed by investigators outside the VAPORHCS:

F. Will any laboratory results from analysis of the specimens be used for diagnosis, treatment, and prevention of disease in patients?

[ ]  YES

[ ]  NO

If **YES**, will the tests be performed at the VA (pathology) laboratory?

[ ]  YES

[ ]  NO

*If* ***NO****, include a copy of the* ***Clinical Laboratory Improvement Amendments (CLIA)*** *certification of the lab with this IRQ.*

G. Does this research proposal involve the use of any kind of specimens other than saliva, blood, urine or cerebrospinal fluid (even those collected solely for research purposes, those in addition to what is collected for clinical care, or tissue remaining after a work up by the pathology department is complete)?

[ ]  YES

[ ]  NO

*If* ***YES****, please follow the steps described here:* <https://www.va.gov/portlandresearch/documents/crcresources/tissue-for-research.docx>

**Specimen and/or Research Study Data Banking (Repository Contribution):**

12. A. Will this project contribute specimens and/or data to a research repository for future research not covered by this protocol (i.e. will bank specimens and/or data)?

[ ]  YES

[ ]  NO (skip to Q.12.C.)

B. If **YES,** specify what data and/or specimens from this study will be contributed to that repository:

**AND**, where is the research repository located?

[ ]  At the VAPORHCS. Indicate repository title and ID# (if known):

[ ]  At another VA facility. Indicate VA facility name, repository title and ID# (if known):

[ ]  At a non-VA institution/facility\*. Indicate non-VA institution/facility name, repository title and ID#

(if known):      ; **AND**

[ ]  The project includes banking at a non-VA institution/facility and an**Application for an Off-Site Biospecimen Banking Waiver at a Non-VA Institution** is included with this submission.

***NOTE:*** *If the study includes biospecimen banking at a non-VA* institution/facility*, an* **Application for an Off-Site Biospecimen Banking Waiver at a Non-VA Institution***must be completed and included with your IRB submission and is located at:* [*https://www.va.gov/portlandresearch/piservices/rd\_forms.asp*](https://www.va.gov/portlandresearch/piservices/rd_forms.asp)

C. Will this protocol **establish a new research repository with human biological specimens and/or data at the VAPORHCS** (i.e. repository is covered by this protocol)?

[ ]  YES

[ ]  NO (skip to Q.13)

If **YES**, the following **must** be attached to this form:

[ ]  Research repository Standard Operating Procedure (SOP)

***NOTE:*** *If such a repository does not yet exist, one must be established (as a stand-alone project) in order to bank data and/or specimens after this project is completed. Data/specimens from previously conducted studies may not be used for future research unless they come from a repository. Please see* ***IRB Review of Research Repositories*** *policy under the “HRPP” tab of the VAPORHCS Research website located at:* [*https://www.va.gov/portlandresearch/hrpp/index.asp?tab=0%20-%20policies1%20-%20top*](https://www.va.gov/portlandresearch/hrpp/index.asp?tab=0%20-%20policies1%20-%20top)

**Collection of Sensitive Information & Use of Certificate of Confidentiality (CoC):**

13. Does this research project assess or collect sensitive information from research subjects (such as information about sexual attitudes, use of drugs or addictive products, or information about illegal conduct), which could reasonably lead to social stigmatization, discrimination, or legal proceedings and which would need to be protected against subpoena or forced disclosure in order to protect the participants?

[ ]  YES

[ ]  NO

***NOTE:*** *If* ***YES****, please be sure the study protocol addresses use as instructed in the CoC section of the VAPORHCS Protocol Template located at:* <https://www.va.gov/portlandresearch/documents/PIResources/Sample-Research-Protocol.doc>

**Accessing/Using/Disclosing information (under HIPAA and VA regulations):**

14. A. Will the study utilize any portable device(s) (e.g., audio recorder, video recorder, laptop, tablet, cellphone, digital camera, etc.) to electronically record voice and/or video and/or other biometric readings as part of the research study?

[ ]  YES

[ ]  NO

If **YES**, please contact an IRB Analyst to request initiation for authorization to utilize a portable device to store research data (per VHA Handbook 6500, Appendix F). ***NOTE:*** *If any* ***identifiable*** *research data will be transferred and/or transported* ***outside of the VAPORHCS*** *or the study utilizes a portable storage device (e.g., audio recorder, video recorder, laptop, tablet, cellphone, digital camera, etc.), the study must have written authorization. Please contact an IRB Analyst at extension 55125 to initiate the process.*

B. How is **identifiable** information, research data and/or forms transferred from one location to another?

|  |  |
| --- | --- |
| Electronic Data Transfer | Hard Copy Data |
| [ ]  E-mail with PKI encryption | [ ]  FedEx/UPS (with tracking) |
| [ ]  Encrypted CD/DVD | [ ]  Hand-carried by Research Staff (but never taken home) |
| [ ]  VA-issued Thumb drive (FIPS compliant) | [ ]  Other:  |
| [ ]  Other:  |  |

***NOTE:*** *Protected Health Information must not be transmitted via e-mail unless data and accompanying passwords or other mechanisms are properly secured. Microsoft Outlook is not a secure form of data transmission, unless information is encrypted.* ***REMINDER: VA and OHSU Microsoft Outlook encryption are not currently compatible.***

C. Identify the institution and location where **any electronic records** will be stored(including scanned consent forms, records, de-identified research records, any databases with electronic data/records, etc.) ***NOTE:*** *For VA records stored on the VAPORHCS network, a folder will be created for this study by the VA Research Office. Please explain below what name you would like the network folder to have, using the naming convention “PI Last Name XXX”, where XXX indicates your brief method of identifying the study (i.e., study acronym, study ID number, etc.). For the OHSU “location” prompt, please be as specific as possible, including network and server names if possible.* ***NOTE:******Keeping records/data on a computer desktop and/or hard drive does NOT equate to storing the records/data on a server****.*

|  |
| --- |
| [ ]  VAPORHCS network folder. VAPORHCS Network Folder Name:       |
| [ ]  OHSU secured network. Location at OHSU:       |
| [ ]  Other institution: Location:       |

**Investigator Assurances**

1. I will initiate this study, and any proposed changes in the research, only **after** receiving written approval from the IRB.
2. I will report and submit written notification to the IRB for all problems, adverse events, and apparent serious or continuing noncompliance, including local research deaths, in accordance with VHA Handbook 1058.01, local VA Facility requirements, IRB P&P and IRB SOPs.
3. I take responsibility for maintaining IRB approval and will submit all required information according to required timelines.
4. Unless the IRB has granted a waiver of all informed consent/authorization requirements, or a waiver of documentation of informed consent and a waiver of the master list requirement, I assure that I or a qualified research staff member will:
	1. Create a progress note within 24 hours containing all required elements in the Computerized Patient Record System (CPRS), when appropriate (see section XVII.P of the VAPORHCS IRB P&P).
	2. Give a copy of the informed consent form to each participant.
	3. Forward each original signed consent form and signed HIPAA authorization as soon as possible, preferably within three business days, of obtaining consent to the Research Administration Office for review by the Research Compliance Officer (RCO). I will keep a copy until the original is returned and will then maintain the original on file.
	4. Activate an electronic research flag for all patients consented in this study, unless the IRB determines that this requirement does not apply to my study. If participants do not meet enrollment criteria, the flag will be removed.
	5. Maintain a master list of all consented subjects; this list will include participant’s names and the date(s) of their informed consent and, if applicable, reconsent.
	6. If the study involves the enrollment of non-Veteran subjects, or Veterans who may not be enrolled in VHA healthcare, I will obtain a signed VA FORM 10-0483 (i.e. Notice of Privacy Policy acknowledgement form located at: <https://vaww.va.gov/vaforms/medical/pdf/vha-10-0483-fill.pdf> ) from each non-Veteran and/or Veteran (if applicable) who provides informed consent to participate in the study. I will then send the signed VA Form 10-0483 to the Research Administration Office with the signed ICF and HIPAA authorization (if applicable). I will keep a copy until the original is returned and will then maintain the original on file.
5. I will promptly report any changes in PI or research staff and will obtain written IRB approval prior to implementing those staff changes. If I know I will be absent more than one month, I will notify the IRB at least two months prior and provide a mechanism to assure that the safety and treatment of human subjects will not be compromised.
6. I will maintain research files based on standards of good clinical practice.
7. I will report to the IRB when the study is completed. If this study includes investigational drugs, I will inform the Chief of Pharmacy Service when the study is terminated.
8. I will maintain an accounting of disclosures of PHI to all non-VA entities. ***NOTE:*** *Disclosure of identifiable information made to a non-VA entity must be produced upon request by the VAPORHCS Privacy Officer. Should you receive such a request from the Privacy Officer, MIRB #, study title, and information in columns A through J for each individual subject that had identifiable information disclosed will be needed. You are not required to use this spreadsheet to account for your disclosures. This spreadsheet is intended as a guide and is located at:* [*http://www.va.gov/portlandresearch/documents/irb/acctg-of-disclosures.xls*](http://www.va.gov/portlandresearch/documents/irb/acctg-of-disclosures.xls)
9. I am aware of how and to whom to report a suspected or confirmed loss of VA information and I take responsibility for the security of the information and who has access to it.
10. I am aware that, when scientifically appropriate, special efforts must be made to include women Veterans and Veterans who are members of minority groups in studies of diseases, disorders and conditions that disproportionately affect these Veteran groups.
11. I will be responsible for the ethical conduct of this project and for protecting the rights and welfare of the subjects.
12. As the PI/responsible Clinician, I assume responsibility for all study-related health care decisions related to this research project.
13. I affirm that all responses provided to the IRB, including information in all IRQ appendices, are true and that this study will be conducted according to the information provided here.

**My signature below indicates I have reviewed for accuracy and completeness all information submitted in and with this form and have read and agree to the above assurances.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

Principal Investigator Date Responsible Clinician (if applicable) Date

**Keep a copy of this form for your records.**