**VAPORHCS Research Protocol/Local Protocol Addendum**

***INSTRUCTIONS:***

1. ***This protocol template must be used for all studies submitted to the VAPORHCS IRB or Joint OHSU/VA IRB. All sections and elements are required. If any section and/or element does not apply to the research, does not provide a checkbox to indicate “N/A” or to “see to sponsor/3rd party protocol” and does not indicate if applicable in the instructions, state that the section/element is not applicable and provide justification****.*

1. *VA regulations require that some elements are specifically addressed. These items are noted with “****VA-SPECIFIC REQUIREMENT****”. Please be sure to address those elements in sufficient detail, so an IRB analyst/reviewer is able to understand what is being described.*
2. *If the study has a 3rd party protocol (i.e. sponsor protocol), note sections/elements addressed in the 3rd party protocol in this protocol and include information only in sections/elements missing/not addressed in 3rd party protocol.*
3. *Page numbering - Page numbering is automatic.*
* *Header and Footer - To complete the header and footer, select “View” in the toolbar at the top of your screen, then “Header and Footer.” The “Protocol version date” is to be used by the research team indicate the version. Please do NOT update the “Research Service Template” date, so that in the future it can be easily identified which template version was used.* ***NOTE:*** *A version date MUST be included on documents such as the protocol, abstract, advertisement, etc., submitted to the IRB. Ideally, the version date will appear in the header or footer of every page.*
1. *Once you feel you have completed all elements of the protocol (or local protocol addendum) that apply to your study,* ***delete all instructions/notes in red italics and hyperlinks in blue italics throughout the template prior to submission to the IRB. Item numbering should also be removed. Do NOT delete black font text, headings or subheadings (except these black text instructions).***

***NOTE:***

* *Revisions -* ***Any*** *revisions to the protocol must be approved by the IRB prior to use.*
* *IRB Contact - If you have any questions or concerns, please contact an IRB Analyst (x55125).*

**Title**

*Indicate the full study title, this must match the title on the grant application*

**Specific Aims/Purpose**

See sponsor/3rd party protocol for information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***Briefly*** *describe the purpose of the study. List the broad, long-term objectives and describe concisely and realistically what the specific research described in your proposal is intended to accomplish, and the hypothesis to be tested.*

 **Hypothesis:** *Explicitly state the study hypothesis, this must match the grant application*

**Scientific Rationale and Significance**

 See sponsor/3rd party protocol for information requested in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***Briefly*** *explain the scientific rationale for the study. Give the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. Cite literature and include a list of references at the end of the protocol.*

***VA-SPECIFIC REQUIREMENT (relevance to VA mission):***

 See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Include a statement(s) to address relevance to mission of VA and Veterans.*

**Preliminary Studies**

 See sponsor/3rd party protocol for information requested in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Provide an account of the PI's preliminary studies pertinent to the protocol and/or any other information that will help to establish the experience and competence of the PI to pursue the proposed project. The titles and complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed.*

**Research Design and Methods**

 See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. (For example, interviews, video/audiotaping, observations, interventions, focus groups, instruction/curricular, retrospective or prospective records review, questionnaires, specimen analysis, obtaining data and/or specimens from a repository, etc.)*

1. *Describe any new methodology and its advantage over existing methodologies (e.g. use of artificial intelligence/algorithm in healthcare).*
2. *Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.*
3. *Provide a planned sequence or time table for the overall study.*
4. *Specify procedures, situations, or materials that may be hazardous to personnel and the precautions to be taken to ensure safety.*
5. *Provide justification of the sampling procedure and sample size.*
6. *Describe the power analysis.*
7. *List all supplements, remedies, drugs and/or devices to be used, if applicable. If the supplement, remedy, drug, or device is considered investigational by the FDA, list the actual IND/IDE number and respective source, supplier, and/or sponsor. If an IND/IDE has* ***NOT*** *been assigned, provide the FDA stage status. As applicable, note the proposed dosage-related information, including instructions for administering, adverse effects, compatibility in infusions, and stability.*
8. *List all procedures that will be used for this research project. If blood is to be drawn, indicate amount to be drawn per single withdrawal, and the total amount of blood to be drawn. If transfusions are anticipated, include assurance that the volume of blood removed for research purposes will not necessitate a transfusion.*
9. *List any research procedures that are optional and/or part of a sub-study and describe them.*
10. *If the protocol involves “usual care,” clearly describe and differentiate the research intervention(s) from “usual care” (whether the “usual care” is limited to one arm of the study or is being delivered to all study subjects).* ***NOTE:*** *The informed consent form must identify which procedure(s) is research and which is usual care and know who (the researcher or the subject’s health care provider) is responsible for the following with regards to each procedure:*
	1. *Explaining risks and benefits to the subject*
	2. *Providing the treatment, service or procedure*
	3. *Monitoring the procedure as applicable*
	4. *Defining whether adverse events result from usual care or research*
	5. *Alerting the subject if there is a problem with a procedure or treatment*
	6. *Documenting the subject’s clinical course while receiving the treatment/service/procedure*
11. *Identify study endpoints.*

**Study Population**

 See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

1. *Describe the criteria for inclusion and/or exclusion (diagnosis, lab/path results, age ranges, sex, ethnic background, health status, etc.).*
2. *Explain the rationale for the use of special classes of subjects, such as fetuses\* (in-utero or ex-utero, and including human fetal tissue\*\*), neonates\*, research involving interventional or invasive monitoring of pregnant women\*, children, prisoners\*, persons with impaired decision-making capacity or others who are likely to be vulnerable, especially those whose ability to give voluntary informed consent may be questionable. If any inclusion/exclusion criteria are based on age, gender, racial/ethnic origin, pregnancy or childbearing potential, explain and justify.*

***VA-SPECIFIC REQUIREMENTS (if applicable):***

***\*NOTE:*** *Please see VAPORHCS IRB P&P for additional local, federal and/or VA requirements related to research involving these populations located at* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc) *Please contact the Research Administrative office at 503-273-5125 and ask to speak to an IRB Analyst prior to submission.* ***\*\*NOTE:*** *Per VHA Directive 1200.05, VA research with human fetal tissue must be governed by policy set by NIH for recipients of NIH research funding.*

1. *If any specific classes of persons who might benefit from the research will be excluded from participation (e.g., pregnant women, particular gender, particular races, etc.), provide a scientific and ethical justification for the exclusion.*
2. *If this study focuses on a disease, disorder, or condition that disproportionately affects women and/or members of a minority group, describe the special efforts that will be made, as scientifically appropriate, to include women Veterans and/or Veterans who are members of minority groups affected by the disease, disorder or condition.*
3. *If this study will recruit those who are non-English speakers, what accommodations will be made to assure that these subjects are fully informed during the course of the study.*
4. *How many subjects (i.e. total number) will be consented for this study (including screen failures)? If this is a retrospective records review and/or specimen analysis only, indicate how many records and/or specimens will need to be reviewed/collected, including possible screen failures. If consenting more than one subject group, indicate the number for each group as well as the total number.*
5. *How many subjects will be enrolled (i.e. totally number – after consent, information is used and/or procedures are performed beyond screening)? If enrolling more than one subject group, indicate the number for each group as well as the total number. If this is a retrospective records review and/or specimen analyses only, indicate how many records and/or specimens will be included in the study’s data set.*
6. ***VA-SPECIFIC REQUIREMENT (inclusion of non-Veterans):***

N/A. The study does not include non-Veterans.

 See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*If non-Veterans will be recruited, explain why you cannot accomplish your study aims with only Veterans as research participants.*

**Subject Identification/Recruitment**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

1. *Explain how potential subjects will be identified prior to consent or under a waiver in the case of a retrospective chart review, (e.g., telephone call from potential subjects responding to a flyer, data and/or biospecimens from a repository, CPRS, VINCI, at patient visits with provider (who is also PI of study), CPRS review for list of patients with an upcoming visit in a particular clinic, etc.). If subjects will be identified for recruitment prior to initial contact and consent using data from a repository, include where it is located (e.g. VAPORHCS, OHSU)* ***NOTE:*** *A screening and recruitment waiver of authorization is required for recruitment methods that involve the use and/or collection of identifiable information prior to initial contact and consent/authorization. The waiver form must be completed and included with your IRB submission and is located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/partial-recruitment-waiver-2018.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/partial-recruitment-waiver-2018.doc)

*2. Describe the recruitment strategies that will be used in the study.* ***NOTE:*** *Please see VAPORHCS IRB P&P, Contact with Subjects section, for policy and appropriate recruitment options located at* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)

***NOTE:*** *If the study will employ the use of a recruitment letter or telephone call(s) for recruitment, please see the VAPORHCS Research Recruiting – Template Phone Script and/or Research Recruiting – Template Recruitment Letter located at:* [*https://www.va.gov/PORTLANDRESEARCH/piservices/rd\_forms.asp*](https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp)

***NOTE: Any letters, including recruitment letters, mailed to potential and/or currently enrolled research subjects must be sent on official VAPORHCS letterhead. VAPORHCS letterhead can be found on the Administrative Support Knowledge (ASK) SharePoint website (note, this is an internal link and only available from behind the VA firewall) located at:*** [***https://dvagov.sharepoint.com/sites/VHAPOR/PSites/EO/ASC/default.aspx***](https://dvagov.sharepoint.com/sites/VHAPOR/PSites/EO/ASC/default.aspx)

*3. Describe any advertisements that will be used, including how they will be used (e.g. flyers posted in VAPORHCS elevators, brochures, ad run in Oregonian newspaper, etc.)* ***NOTE:*** *the VAPORHCS advertisement content requirements:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/advertisement-requirements.docx*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/advertisement-requirements.docx)

*4. Describe recruitment methods that include the use of social media Craigslist, Facebook page etc.* ***NOTE:*** *Please see VAPORHCS IRB P&P, Contact via Social Media and/or Craigslist for policy for requirements located at* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)

**Informed Consent & HIPAA Authorization**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

1. *Describe where, how and who will obtain consent and authorization.* ***NOTE:*** *The VA Informed Consent Form Template and VA HIPAA authorization forms are located at:* [*https://www.va.gov/PORTLANDRESEARCH/piservices/rd\_forms.asp*](https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp)

*1.a. If you plan to have a waiting period between informing the potential participant about the research and obtaining informed consent and authorization explain why.*

1. *List any languages, other than English, you intend to conduct the informed consent and authorization session in. How will you assure the language used is understood by the prospective participant or the legally authorized representative?*
2. *List any additional steps that will be taken to minimize possible coercion or undue influence.*

*4.* ***VAPORHCS-SPECIFIC REQUIREMENT (inclusion of those with impaired decision-making capacity):***

 N/A. The study does not include those with impaired decision-making capacity

*Will subjects have the capacity to give informed consent? If not, address the following:*

1. *Will the required disclosures (i.e., informed consent, etc.) be provided to the subject’s legally authorized representative (LAR) as well as to the subject? If no, explain why not.*
2. *Will the research team explain the proposed research to the prospective research subject even when the LAR gives consent, and assure that the subject will not be forced to participate? If no, explain why not.*
3. *Please explain the process to assure that health care agents (appointed under Durable Power of Attorney for Health Care (DPAHC)) and next-of-kin, or guardians, will be given descriptions of both proposed research studies and the obligations of the person’s LAR? (That is, they will be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.)*

***NOTE:*** *Please see section below titled,* ***Additional Participant Safeguards***

*for information required regarding the inclusion of participants with impaired decision-making capacity.*

*5. If you plan on conducting any portion of the consent and authorization process over the phone and/or using the mail to send signed informed consent form and HIPAA authorization (if applicable,) indicate how it will be done and why it is necessary to use such methods.* ***NOTE:*** *If study will use voice recording as part of the consent process over the phone, consent and authorization for recordings must be documented using a method approved by the VAPORHCS Privacy Officer (PO). Please contact the PO prior to IRB submission and include information regarding approved method of documentation.*

*6. If consent and/or authorization will not be obtained and/or altered, indicate why and whether a complete “waiver of consent and authorization process” or “waiver or alteration of informed consent documentation and waiver of authorization” will be used.* ***NOTE:*** *The appropriate waiver form(s) must be completed and included with your IRB submission and are located at:* [*https://www.va.gov/PORTLANDRESEARCH/piservices/rd\_forms.asp*](https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp)

* *Scenarios for which a complete waiver of informed consent and authorization process 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.*
* *Scenarios for which waiver or alteration of informed consent documentation and waiver of authorization may be appropriate include: instances in which participant signature on an ICF document is the only identifying link to study participation; and/or 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.* ***NOTE:*** *If this method used, include with your IRB submission an information sheet/script that describes the research and includes all general elements and all applicable basic elements of the VA Informed Consent Form Template located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/va-informed-consent.docx*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/va-informed-consent.docx)

*7. If consenting and enrolling more than one subject group, will there be any differences in the consent and authorization process? If so, clearly describe the process for each group, including the use of any waiver or alteration of consent and authorization.*

**Risks and Side Effects:**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

1. *Describe any* ***potential risks to subjects or others --physical, psychological, social, legal, or other --*** *and assess their likelihood and seriousness.*
2. *Describe the alternative treatments and procedures that might be advantageous to the subjects.*
3. *Describe the* ***procedures for protecting against or minimizing any potential risks****, including risks to confidentiality, and assess their likely effectiveness.*
4. *Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.*
5. *Describe* ***why the risks to subjects are reasonable in relation to the anticipated benefits*** *to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.*
6. *List all risks that are more than minimal (minimal risks are no greater probability or magnitude than those ordinarily encountered in daily life or during routine medical tests). Include physical, psychological, social, economic, legal or other risks, where present.*
7. *Describe the severity and probability of all material risks, and the implications, in understandable terms. Use a table for Common (21-100/100), Occasional (5-20/100) and Rare (<5/100) risks sorted by Immediate (1-2 days of treatment), Prompt (within 2-3 weeks before next course), Delayed (any later time during treatment) and Late (after completion of treatment) onset wherever possible.*

**Additional Participant Safeguards:**

 N/A. The study does not include vulnerable populations and/or those with impaired decision-making capacity.

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

1. *If the study includes vulnerable populations, what additional safeguards are included to protect their rights and welfare? If no additional safeguards are included, explain why not.*
2. ***VAPORHCS-SPECIFIC REQUIREMENT (inclusion of those with impaired decision-making capacity):***

 N/A. The study does not include those with impaired decision-making capacity

*If the study population includes those with impaired decision-making capacity, describe the following:*

1. *What is the process to determine, after appropriate medical evaluation, that the prospective participants have impaired decision-making capacity and are unlikely to regain it within a reasonable period of time?*
2. *Will this be done once for the population/group as a whole, or for potential participants individually?*
3. *What is the process or tool that will be used to determine how impaired decision-making capacity will be determined?* ***NOTE:*** *Remember that a note must be placed in the medical record for each subject indicating their impaired decision-making capacity. If the determination is based on a diagnosis of mental illness, and the PI is not a psychiatrist or licensed psychologist, a responsible clinician must determine impaired decision-making capacity and place a note in the medical record indicating the subject’s lack of decision-making capacity.*
4. *Explain procedures to ensure that participants’ LAR is well-informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision-making capacity.*

***NOTE:*** *Review related requirements in the VAPORHCS IRB P&P, available at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)

**Suicidality*:***

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***VA-SPECIFIC REQUIREMENT: (if applicable):***

N/A. The study does not include a population of subjects who are potentially suicidal.

*If the population for this study includes those who are potentially suicidal, become familiar with the method of conducting a “warm transfer” when a suicidal participant is on the phone. See the instructions at* [*https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/warm-transfer.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/warm-transfer.doc)*, “Conducting a Warm Transfer.” Include language in your protocol regarding when a “warm transfer” will be conducted. Also include language in the risks section of the informed consent form to inform potential participants that, if they indicate during a phone call that they are suicidal, then a “warm transfer” will take place.*

**Benefits:**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*1. Describe the benefits for participants, if any, and their likelihood. If none, explain.*

*2. Explain how the risks are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge reasonably expected to result.*

**Protected Health Information:**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***VA-SPECIFIC REQUIREMENTS: (entire section, as applicable)***

1. *Describe/list which HIPAA identifiers will be utilized (in any way) in this study and* ***be sure to be consistent with the HIPAA authorization and/or waiver(s) of authorization****, if applicable.* ***NOTE:*** *A list of the 18 HIPAA identifiers is located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/18-HIPAA-identifiers.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/18-HIPAA-identifiers.doc)
2. *Describe/list what data/information/health information will be utilized (in any way) in this study and* ***be sure to be consistent with the HIPAA authorization and/or waiver(s) of authorization****, if applicable.*
3. *List any information (with specificity) covered under 38 U.S.C. 7332 (e.g., regarding drug abuse, alcoholism, alcohol abuse, infection with human immunodeficiency virus [HIV], or sickle cell anemia) that will be included in the study.*
4. *If the study includes any information covered under 38 U.S.C. 7332 include assurance that the purpose of the data is to conduct scientific research and that personnel involved in the study will not identify, directly or indirectly, any individual subject in any report of the research, or otherwise disclose subject identities to anyone outside the IRB-approved VA personnel (****for this study****) in any manner (e.g. manuscript or publication).*
5. *If the study will utilize (in any way) different HIPAA identifiers and data/information/health information across subject groups, include the information above for each group.*
6. *Explain why the identifiers and health information (listed above) that will be utilized for this study are the minimum necessary needed to conduct the research and can’t be further reduced. Indicate in this section if no PHI will be utilized (in any way) as part of the study.*
7. *If real* ***Social Security Numbers (SSNs) (including scrambled and the last 4 digits)*** *are used (including for subject payment), indicate why they are needed and what security measures are in place to ensure they are adequately protected.* ***NOTE:*** *If SSN is ONLY written on the consent form or HIPAA authorization or used to enter progress notes in the Electronic Health Record (e.g., CPRS, CERNER), please state.*

**Collaborative Research**

***VA-SPECIFIC REQUIREMENTS: (entire section, if applicable)***

 N/A. The study does not include Collaborative Research.

***NOTE: Per VHA Directive 1200.05 (Requirements for the Protection of Human Subjects in Research):*** *VA investigators must submit a protocol or other documentation to their VA IRB of Record that clearly delineates which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA investigators on VA time or VA property).*

1. *If the research will be conducted at multiple sites (for example, both VAPORHCS and OHSU), state explicitly what will be conducted at each institution and by whom. This includes identifying what components of the study will be conducted at VAPORHCS (e.g., by VA investigators on VA time and/or on VA property and/or using VA resources) and what components will be conducted elsewhere and by whom. Differentiation must be made if any of the components conducted at other sites, will be conducted by personnel on VA time or while utilizing VA resources.* ***NOTE:*** *See VAPORHCS P&P for definition of “VA Research” located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)
2. *If it is a multi-site study, list the other sites, their contact information, and identify the coordinating center for the overall study.*

***NOTE:*** *Please see section below titled,* ***Information and/or Specimen Management***

*for information required regarding disclosure of research data as part of Collaborative Research.*

**Resources Available**

***VA-SPECIFIC REQUIREMENT:***

*Describe the resources available to conduct the research, including clinic space, office space, PI time, and study coordinator time (as applicable). If the PI and/or coordinator is working on multiple studies, describe the PI and/or coordinator’s overall workload and whether there is adequate time for them to conduct this study, including number of studies the study coordinator is listed on.*

**Subject Compensation/Payment:**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***VA-SPECIFIC REQUIREMENTS: (entire section, if applicable)***

N/A. The study does not include subject compensation/payment.

1. *Explain why the proposed payments are reasonable and commensurate with the expected contributions of the subject.*
2. *The amount of payment and terms of the payment and whether this information is included in the informed consent.* ***NOTE:*** *The FDA encourages a prorated system of payment whereby subjects who do not finish the protocol are paid in proportion to the part completed. The amount of payment must be justified based on time and effort involved and must not be so large as to constitute undue inducement of the subject to participate in the research.*
3. *Explain why the payments are fair and appropriate and do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for or continue participation in the study.*

***NOTE:*** *For research including VA employees and/or under a DOD addendum in which U.S. military personnel are involved, dual compensation is limited. An individual is prohibited from receiving pay or compensation for research during duty hours. U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty.*

**Privacy and Confidentiality:**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Describe appropriate provisions to protect the privacy of subjects and maintain the confidentiality of information and/or biospecimens (e.g. involvement of subject advocates, independent consent monitoring, formal capacity assessment, waiting periods, training, authorization of access, password protection, encryption, physical controls, Certificates of Confidentiality, and separation of identifiers and data).*

**Certificate of Confidentiality**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***VA-SPECIFIC REQUIREMENTS: (entire section, if applicable)***

N/A. The study does not include a Certificate of Confidentiality.

 ***If this project will be protected by a Certificate of Confidentiality, describe the following:***

1. *Whether information about the subject’s participation will be included in the subject’s VHA medical record.*
2. *If applicable, the type(s) of information that will be included in the medical record.*
3. *Assurance that the informed consent document will include a statement that the study has a Certificate of Confidentiality and, if applicable, will describe the type of information that will be included in the subject’s VHA medical record.* ***NOTE:*** *The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included in informed consent documents describing Certificates of Confidentiality.*

*Further information can be found about NIH Certificates of Confidentiality at:* [*http://www.grants.nih.gov/grants/policy/coc/*](http://www.grants.nih.gov/grants/policy/coc/)*.*

*For VA specific policy and guidance, please see the VAPORHCS IRB P&P, Certificate of Confidentiality section located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irb-sop.doc)

**Information and/or Specimen Management**

***VA-SPECIFIC REQUIREMENTS: (entire section, as applicable):***

***NOTE:*** *Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1 (VHA Directive 12005.05 §15.b(1)).*

1. *Explain how the information* ***and/or biospecimens*** *will be identified throughout the study (e.g., fully identifiable when initially accessed, coded when recorded, de-identified when shared with collaborator).* ***NOTE:*** *A plan to destroy research-related data, including identifiers, must comply with the VA VHA records control schedule (RCS) 10-1 located at:* [*https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf*](https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf)
2. *If information and/or biospecimens will be de-identified after it is initially accessed and/or recorded, indicate the method to be used to de-identify (e.g. removal of all 18 HIPAA identifiers).* ***NOTE:*** *A list of the 18 HIPAA identifiers is located at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/18-HIPAA-identifiers.doc*](https://www.va.gov/PORTLANDRESEARCH/documents/hrpp/18-HIPAA-identifiers.doc)

***NOTE:*** *Depending on the method used to de-identify information/biospecimens and type of disclosure(s) a Safe Harbor De-Identification Certification or Statistical Analysis De-Identification may be required and are located at:* [*https://www.va.gov/PORTLANDRESEARCH/piservices/rd\_forms.asp*](https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp) *Please contact the VAPORHCS Privacy Officer for questions regarding requirements.*

1. *Indicate where electronic, hard copy information and/or biospecimens will be stored. Identify location (e.g. general location such as: VAPORHCS, OHSU, etc.), and what measures will be used to secure the information/specimens (e.g., locked office, locked filing cabinet, etc.).* ***NOTE:*** *For electronic VA records stored behind the firewall on the VAPORHCS network, a folder will be created for you by the VAPORHCS Research Administration Office (see Initial Review Questionnaire (IRQ). Keeping records/data on a computer desktop and/or hard drive is not permissible.*

**Disclosure/Sharing:**

***VA-SPECIFIC REQUIREMENTS: (entire section, as applicable):***

N/A. The study does not include disclosure/sharing outside the IRB-approved VAPORHCS study personnel.

***NOTE:*** *VA requires PKI or RMS encryption whenever transmitting PHI using email. However, PKI encryption is only available within the VA system. All research using Azure RMS encryption for transmitting PHI must meet all VHA ORD and OIT requirements. Additional information about VHA privacy and information security requirements may be accessed on the OIT FAQ about Azure Rights Management Services (RMS) Guidance Document located on the OIT SharePoint site (only assessible behind the VA firewall) located at:* [*https://vaww.portal2.va.gov/sites/AIP/\_layouts/15/WopiFrame2.aspx?sourcedoc=/sites/AIP/Shared%20Documents/Azure%20RMS%20Frequently%20Asked%20Questions.docx&action=default*](https://vaww.portal2.va.gov/sites/AIP/_layouts/15/WopiFrame2.aspx?sourcedoc=/sites/AIP/Shared%20Documents/Azure%20RMS%20Frequently%20Asked%20Questions.docx&action=default)

*Additional information can also be accessed on the Frequently Asked Questions: Institutional Review Board (IRB) and VA Research and Development (R&D) Committee Considerations for Use of Azure Rights Managements Services (RMS) in VA research guidance document (original release date: 10/25/19) and posted on the ORD policies and guidance webpage at ORPP&E website https://www.research.va.gov/resources/policies/default.cfm*

1. *List any information (with specificity) covered under 38 U.S.C. 7332 (e.g., regarding drug abuse, alcoholism, alcohol abuse, infection with human immunodeficiency virus [HIV], or sickle cell anemia) that will be disclosed outside of the VA. Indicate whether or not such transfer is addressed in the informed consent form and the HIPAA authorization or if this study will use a waiver of consent and authorization documentation or process.*
2. *If the study is part of Collaborative Research (e.g. multi-site research), describe the following:*
3. *data to be disclosed to collaborators;*
4. *the entities to which the data are to be disclosed;*
5. *how the data are to be transmitted;*
6. *how the transmitted data will be stored, retained, destroyed (e.g., per RCS 10-1 for the copy of data that VAPROHCS maintains ownership of), and/or further disclosed and to whom. This includes data from individual subjects as well as other secondary data developed during the research such as the analytic data and the aggregate data.*

***NOTE: A plan to destroy research-related data, including identifiers, must comply with the VA VHA records control schedule (RCS) 10-1 located at:*** [*https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf*](https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf)

1. *If the study information and/or biospecimens will be maintained/stored outside the VAPORHCS, and information is not covered above, specify the location and institution that will maintain information and/or specimens. Specify the type of information and/or specimens, and if any of the 18 HIPAA identifiers will be included. Indicate how the information and/or specimens will be transferred, how long they will be kept, for what purpose, and who will view/use the information and/or specimens. Indicate whether or not such transfer is addressed in the informed consent form and the HIPAA authorization or if this study will use a waiver of consent and authorization documentation or process.*
2. *If the study information and/or biospecimens will be used and maintained/stored outside the VAPORHCS as part of a sub-study, and information is not covered above, specify location and institution that will use and maintain information and/or specimens. Specify whether or not the sub-study is optional, the type of information and/or specimens, and if any of the 18 HIPAA identifiers will be included. Indicate how the information and/or specimens will be transferred, how long they will be kept, for what purpose, and who will view/use the information and/or specimens. Indicate whether or not such transfer is addressed in the informed consent form and the HIPAA authorization or if this study will use a waiver of consent and authorization documentation or process.*

***NOTE:*** *If the study includes biospecimen storage at a for-profit institution, an application for biospecimen storage form 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)

1. *If study information and/or biospecimens will be contributed to a repository (i.e. banked), specify the location (e.g., VAPORHCS, OHSU, etc.), of the repository that will maintain information and/or specimens. Specify whether or not the contribution to the repository is optional, the type of information and/or specimens, and if any of the 18 HIPAA identifiers will be included. Indicate how the information and/or specimens will be transferred to the repository and for what type of future research. Indicate whether or not contribution to a repository is addressed in the informed consent form and the HIPAA authorization or if this study will use a waiver of consent and authorization documentation or process.*

***NOTE:*** *If the study includes biospecimen banking at a non-VA institution, an application for off-site biospecimen banking waiver 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)

**Transfer of Data Ownership**

***VA-SPECIFIC REQUIREMENTS: (if applicable)***

N/A. The study does not include transfer of data ownership.

***NOTE:*** *The protocol, informed consent, HIPAA authorization and/or waivers must be consistent with regards to how and to whom ownership will be transferred.*

*If ownership of the information will be transferred away from VAPORHCS, indicate one of the following options:*

* *Ownership of a copy of the following information <list specific: identifiers, including dates of visits; information; forms; etc.> will be transferred to <specify individual, agency, company, affiliate, etc.> and will be the responsibility of <specify individual and/or PI at the receiving agency, company, affiliate> and <specify individual, agency, company, affiliate, etc.>.*

***NOTE:*** *Transfer of ownership language is only to be used when transferring data to a coordinating center for a multi-site study. Once ownership of a copy of the data is transferred, work on that copy of the data can no longer be done on VA time, in VA space or using VA resources.*

***OR:***

* *The electronic copies and originals of paper records will be returned to VAPORHCS at the time of study closure.*

**Web Application(s), Mobile Device(s) and/or Mobile Application(s):**

***VA-SPECIFIC REQUIREMENTS: (if applicable)***

N/A. The study does not include web application(s), mobile device(s) and/or mobile application(s).

1. *Identify any web application, as well as its security features, that will be used for such purposes as recruiting, completing questionnaires, sending data to sponsor (e.g. web-based or online case report forms) or processing data (other than Craigslist and Facebook).*
2. *If mobile device(s) and or application(s) will be used as part of the study, indicate the brand name/model, whether or not the device(s) are encrypted and if the encryption is FIPS 140-2 validated.* ***NOTE:*** *All mobile devices and media and any information transmitted to and from a wireless device must be protected with VA approved encryption technology that is FIPS 140-2 validated (see: VA Handbook 6500, Appendix D)*

**Data and Safety Monitoring Plan (DSMP)**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

***VA-SPECIFIC REQUIREMENTS: (entire section, as applicable):***

*For retrospective studies, including studies involving pre-existing data and biological specimens, focus on the safety and monitoring of the collected study data. Also, indicate if there are potential study outcomes that may have an effect on the subject’s health or well-being and a procedure to determine when and how to notify individual subjects or their health care providers of findings that may affect the subjects’ health. If there are not outcomes that may have an effect on the subject’s health or well-being, indicate why this is the case (e.g. the study has the potential to yield only generalizable results).*

*For interventional studies include, all items that apply below.*

1. *What safety information will be collected, including serious adverse events and unanticipated problems involving risk?*
2. *How the safety information will be collected, e.g., case report forms, at study visits, by telephone, etc.*
3. *The frequency of data collection, including when safety data collection starts.*
4. *The frequency or periodicity of review of cumulative safety data (e.g., at a Data Safety Monitoring Board quarterly meeting, by the PI weekly, etc.).*
5. *Describe the statistical tests for analyzing the safety data to determine if harm is occurring.*
6. *Describe the individual or group that will monitor the data and safety of the protocol and provide general description of the expertise of the person/membership and/or board/group as a whole.*
7. *If there will not be a data monitoring committee or equivalent, and if applicable, what statistical tests will be used to analyze safety data and determine if harm is occurring?*
8. *Describe the mechanisms in place to assure the independence of judgment of those monitoring the study (e.g., PIs or monitoring group members verify absence of conflict of interest, or they may not be individuals from the same department or division as the PI, etc.).*
9. *Describe in what manner and how frequently the PI will verify the data are being collected according to the protocol (e.g. participation in all study procedures, periodic review of patient records for protocol compliance, meetings with study staff, etc.).*
10. *Which conditions would trigger an immediate suspension of the research? For example, efficacy proven, halted by DSMB due to unforeseen safety data, etc. (if applicable).*
11. *If there are stopping rules for individual subject participation/interview, indicate what they are and how they will be monitored/identified throughout the study (if applicable).*
12. *Indicate if this study is being conducted under a Department of Defense (DoD) Addendum. If the study is greater than minimal risk, name the independent research monitor who will have the authority to stop the study, remove individuals from the study, and take any steps necessary to protect safety and well-being of subjects until the IRB can assess (if applicable).*

***NOTE:*** *VA guidance regarding pregnancy and outcome data as part of safety monitoring:* [*https://www.research.va.gov/resources/policies/guidance/pregnancy.pdf*](https://www.research.va.gov/resources/policies/guidance/pregnancy.pdf)

**Step-by-Step Guidance on Conducting the Study**

 See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Take the opportunity here to outline, in a step-by-step manner, how this project should be conducted. Include steps such as recruitment, consent, follow-up phone calls, etc. If it is written in the manner of a standard operating procedure, it can serve as a guide to all members of the research team. Be sure to be consistent with other sections of the protocol. Format this section as appropriate, which may include tables of which procedures get conducted at which research visit, etc.*

**References & Literature Cited**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Compile a judicious list of relevant literature citations. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication.*

**Appendix** **– Supporting Documents List**

See sponsor/3rd party protocol for requested information in this section. Indicate what heading/subheading in the 3rd party protocol that the information is located:

*Please list any case report forms, letters and/or study materials given to subjects, questionnaires, scales, tables, charts, diagrams, manufacturer’s brochures, etc. that will be used as part of the study. Then, include copies as separate supporting documents with your IRB submission. If laboratory tests for treatment, diagnosis and/or prevention of disease will be conducted outside of the VAPORHCS pathology laboratory, provide a copy of the Clinical Laboratory Improvement Amendments (CLIA) certification of the lab as one of the supporting documents.*

|  |
| --- |
|  **PLEASE REMEMBER TO ADD A FOOTER WITH THE DATE AND PAGE NUMBER ON EACH PAGE OF THE ENTIRE DOCUMENT** |