VA Portland Health Care System (VAPORHCS) Institutional Review Board (IRB)

**CONTINUING REVIEW QUESTIONNAIRE (CRQ)**



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| **VAPORHCS PI:** |  | **Date:** |  |
|  |  | **Study ID#:** |  |
| **Study Contact (if not PI):** |  |  |  |

**Important Instructions:**

* **Do not submit this form if:**
* Do NOT submit this CRQ form if either of the following apply:
* The IRB has determined that the study may undergo an annual check-in rather than a continuing review. Instead, please complete the [Annual Check-In](https://www.va.gov/PORTLANDRESEARCH/documents/irb/Annual-Check-In.docx) or [Repository Annual Check-In](https://www.va.gov/PORTLANDRESEARCH/documents/irb/repository-Annual-CheckIn.docx) form.
* All activities, including data analysis, are complete **OR** all data has been de-identified, no subjects are being followed, and only analysis of de-identified data is ongoing. Instead, submit a [Finalization Report.](https://www.va.gov/PORTLANDRESEARCH/documents/irb/termination-of-project.docx)

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

* Complete this form using study information for research activities conducted at VAPORHCS (e.g., do not include enrollment numbers for OHSU subjects, reportable events that occurred at OHSU and/or related to OHSU subjects only, etc.). If a question does not apply to the research activities conducted at VAPORHCS, provide an explanation (e.g., VAPORHCS only engagement in research is data analysis)
* Submit this form along with any additional documents prompted by the individual questions in the CRQ, and the required additional documents listed below via eIRB by the due date indicated in the Continuing Review Reminder email. ***Unless otherwise noted, all forms/boilerplate referenced in this document can be found at:***<https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp> **OR** <https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp>
* **Archiving VA Documents**: *(If study is closing/closed to subject enrollment and a Mod-CR is being submitted.)*  Please list all VA study documents you are archiving at this review. Be sure to delete these documents as you progress through the questionnaire.

**Examples:** VA Consent form(s) and VA recruitment materials, when enrollment is complete

**SECTION I: Additional Documents Included in this Submission:**

***IMPORTANT: You must check ONE box in EACH of A–F below.*** ***A submission that is missing required documents (or the PI's signature) will be deprioritized, and the study may lapse if the IRB receives a high volume of higher priority submissions.***

**Required for ALL Continuing Reviews:**

1. **Updated Abstract with a current (this year) version date**

Update the Findings to Date section to reflect the current status of the study, enrollment, and any findings to date, including interim analysis. Please account for all parts/phases/subject groups described in the study's IRB-approved protocol.

***REQUIRED:***

[ ]  An updated Abstract has been uploaded for this continuing review.

1. **Conflict of Interest forms (COIs)**

A newly signed and dated [OGE Conflict of Interest in Research Form (OGE Form 450)](https://www.research.va.gov/programs/tech_transfer/model_agreements/conflict_of_interest.pdf) is required at continuing review from each the following individuals:

* PI, Co-PI, study chair, local site PI (if different from the main PI), co-investigator, sub-investigator (including a collaborator with a VAPORHCS research appointment), responsible clinician, and repository director/co-director.
* Any other research/repository staff with a real or perceived conflict of interest per OGE Form 450.

***REQUIRED:***

[ ]  All required COIs have been uploaded for this continuing review.

**Required for CRs that include Personnel Changes:**

1. **Scope of Work forms (SOWs) *Personnel Additions/SOW Revisions ONLY***

An [**IRQ Appendix L – Scope of Work**](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irq-appendix-l.docx) is required for each individual being added to the study or given new duties not indicated in their previously approved SOW.

***REQUIRED – Check ONE:***

[ ]  All required SOWs have been uploaded for this continuing review.

[ ]  N/A – This continuing review submission contains no personnel additions or SOW revisions.

**Required for studies with unreported adverse events/protocol deviations:**

1. **Reportable New Information (RNI)**

If the study has had any events that met the threshold for prompt reporting to the IRB and were not previously reported via a RNI, a RNI describing those events (and, if applicable, why they were not reported within the required timeframe) must be submitted at continuing review.

Requirements and timelines for reporting can be found in [VHA Directive 1058.01](https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number)

***REQUIRED – Check ONE:***

[ ]  A RNI has been uploaded to eIRB

[ ]  N/A – A RNI has already been submitted for all reportable events since the last continuing review.

[ ]  N/A – There have been no reportable events since the last continuing review, and any earlier reportable events have been previously reported via RNIs.

1. **Log of events that did NOT require prompt reporting**

GCP requires that a study maintain a log of events/protocol deviations that did not require prompt reporting to the IRB via a RNI. This (complete) log must be submitted to the IRB at continuing review if anything has been added since the IRB last saw it (or if it has never been submitted).

***REQUIRED – Check ONE:***

[ ]  An event/protocol deviation log has been uploaded to eIRB with this CR.

[ ]  N/A – The last event/protocol deviation log submitted to the IRB remains current. ***If you are not sure when the study last submitted its log, do NOT check this box. Check the previous box and (re)submit your log with this CR.***

[ ]  N/A – This study has never had an event or protocol deviation that should be recorded in an event/protocol deviation log.

**SECTION II: Study Personnel**

**A. Principal Investigator and Current Research Team Members**

**List all individuals who do any of the following**:

* Use VAPORHCS resources (including network resources) **and/or**
* Access VAPORHCS patient records (e.g., CPRS, CERNER, etc.) **and/or**
* Directly interact with VAPORHCS participants **and/or**
* See identifiable data of participants enrolled by VAPORHCS investigators.

| **Current Study Personnel** *Do NOT list anyone being added or removed with this Continuing Review* | **Study-Specific Scope of Work on file Is Accurate ‡** |
| --- | --- |
| **Legal Name** | **Study Role** |
|       | VAPORHCS Principal Investigator | [ ]  |
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***NOTE: If needed, use the Enter/Return key to expand rows for additional entries.***

***‡*** *If an individual's previously approved SOW is no longer accurate, please list them in the Personnel Additions/Revisions table below and include an updated SOW with this CR.*

***REQUIRED:***

[ ]  Each individual listed above has an active VA research appointment and all required training.

**B. Personnel Changes Included with this Continuing Review**

***NOTE:*** *The tables below eliminate the need to submit a separate Personnel Change Form. However, if you are unfamiliar with the requirements an individual must meet before being added to a study or when an individual needs IRB approval to work on a study, please consult the Personnel Change Form for more information.*

***REQUIRED – Check ONE:***

**[ ]** The personnel change(s) noted below do NOT require changes to IRB-approved study documents.

**[ ]** Personnel change(s) included in this submission require adding/removing names/contact info from IRB-approved study documents. Tracked versions of the following study documents have been uploaded to eIRB for this continuing review:

*Changes to IRB-approved study documents other than those just described must be submitted as a separate amendment.*

| **Personnel Removals** |
| --- |
| **Legal Name** | **Study Role** | **Date Departed** |
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| **Personnel Additions/Scope of Work Revisions** |
| --- |
| **Legal Name** | **SOW Revision\*** | **Study Role** | **Email Address** | **Add to Mail Groups** |
| **PIs** | **SCs** |
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***NOTE: If needed, use the Enter/Return key to expand rows for additional entries.***

**For SOW revisions, please summarize the changes to each SOW:**

***REQUIRED:***

[ ]  Each individual being added to this study, or having their SOW revised, has an active VA research appointment and has completed all required training.

**SECTION III: Current Status of the Study**

Describe the study’s current status (e.g., not yet enrolling, active and open to enrollment, closed to enrollment, active for data analysis only, etc.).

**IMPORTANT:** If the study has parts/aims/subject groups that are at different stages, please describe the status of each part/aim/subject group separately**.**

| **Part/Aim/Subject Group/Etc.** | **Status\***  |
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***\*If the study is closed to enrollment or follow-up, include the date enrollment or follow-up ended. If the intervention is complete but follow-up activities remain, briefly describe the remaining follow-up activities. (This information is used to determine eligibility for expedited review.)***

**SECTION IV: Enrollment**

1. **Review of records and/or specimens covered by Waivers of all HIPAA & Informed Consent requirements:**

***Studies that do not review records or analyze specimens covered by waivers should skip to B.***

1. List the current versions of the waivers under which you are accessing data/specimens for analysis.*(Screening waivers may be omitted.)*

| **Waiver Description** *(e.g., type of waiver & subject group)* | **Version Date** |
| --- | --- |
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1. How many records and/or specimens have been reviewed/analyzed to date under waivers of all HIPAA & informed consent requirements? *If using more than one group of records and/or specimens, indicate the number for each group.*
2. If (for any aim/group/etc.) zero records or specimens have been utilized, please briefly explain why:
3. What is the total number of records and/or specimens approved by the IRB for review/analysis? *If using more than one group of records and/or specimens, indicate the number approved for each group.*
4. **If more records and/or specimens have been reviewed/analyzed than were approved:**

**ACTION REQUIRED:** *Add this information to your* ***log of events that do not meet the threshold for prompt reporting via an RNI****. A separate amendment will need to be submitted to VeIRBt to request approval for an increase in the total number of records and/or specimens reviewed/analyzed.*

**B. Subjects consented using a signed Informed Consent Form (ICF) and HIPAA Authorization and/or a Research Information Sheet with Waivers of HIPAA and Documentation of Consent:**

***Studies that do not consent subjects should skip to Section V.***

***Studies that are closed to enrollment may skip the first of the two tables below.***

|  |
| --- |
| **ICFs, Info Sheets, and HIPAA Authorizations Currently In Use:** |
| Description *(e.g., type of document & subject group)* | Version Date |
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|  | **Consent & Enrollment at VAPORHCS:** | **During the last approval period** | **Since initial IRB approval** |
| a | How many subjects were consented at VAPORHCS? |  |  |
| b | How many VAPORHCS subjects withdrew **prior** to collection of any research data? *Do not include screen failures (see d).*  |  |  |
| c | How many VAPORHCS subjects withdrew or were withdrawn by the research team from the study **after** data collection began? |  |  |
| d | How many VAPORHCS subjects failed eligibility screening after consent? |  |  |
| e | Total # VAPORHCS subjects consented **and** enrolled in study: **a - b - d = e** ***NOTE:*** *Subjects noted in c count towards total enrollment.* |  |  |

1. If you reported withdrawals in b and/or c, please summarize the main reasons for withdrawal:
2. If (for any aim/group/etc.) zero subjects have been enrolled, please briefly explain why:
3. What is the total number of subjects approved by the IRB for informed consent? *If consenting more than one subject group, indicate the number approved for each group.*
4. What is the total number of subjects approved by the IRB for enrollment? *If enrolling more than one subject group, indicate the number approved for each group.*
5. **If more subjects were consented and/or enrolled than were approved:**

**ACTION REQUIRED:** *Add this information to your* ***log of events that do not meet the threshold for prompt reporting via an RNI****. A separate amendment will need to be submitted to eIRB to request approval for an increase in the total number of subjects to be consented and/or enrolled.*

**SECTION V: Data and Safety Monitoring**

1. Since the last continuing review, has this study received all data and safety reports from outside entities (such as DSMB, DSMC ,monitors and/or sponsors) that are required by the study's data and safety monitoring plan?

**[ ]  YES**

**[ ]  NO** – Briefly explain why required reports are missing and any corrective actions taken and/or planned:

**[ ]  N/A** – This study's data and safety monitoring plan does not require reports from outside entities **OR** the study has progressed to a point at which these reports are no longer required.

***If you selected N/A, skip to Section VI.***

1. Have all data and safety reports received since the last continuing review been submitted to the IRB?

*Check all that apply.*

**[ ]  YES** – previously

 Approximate date(s) of submission:

**[ ]  YES** – with this continuing review

*Upload safety reports to eIRB for this continuing review submission.*

**SECTION VI: Complaints, Problems, and Risk/Benefit Assessment**

1. During the last approval period, have any subjects filed complaints regarding participation or claimed injury for participating at VAPORHCS?

**[ ]  NO**

**[ ]  YES** – Provide a brief description of the complaint(s) and any action(s) taken or planned in response to the complaint(s):

*If this information is available in an RNIF or event/protocol deviation log included in this continuing review submission, you may refer to that document here rather than repeat the information.*

1. Was any new information discovered since the last continuing review that substantially changes the risk/benefit ratio for subjects and/or may affect subjects’ willingness to participate?

**[ ]  NO**

**[ ]  YES** – Provide a brief description of the new information and any action(s) taken or planned in light of this information:

*If this description is available in an RNI or event/protocol deviation log included in this continuing review submission, you may refer to that document here rather than repeat the information.*

1. Since the last continuing review, has the study encountered any serious or systemic obstacles that are not described elsewhere in this continuing review submission?

*E.g., Difficulty recruiting subjects or reimbursing them in a timely fashion*

**[ ]  NO**

**[ ]  YES** – Provide a brief description:

**SECTION VII: Assurances**

**By signing the eIRB submission of this continuing review, the PI indicates that they have reviewed this CRQ, and all other documents included in the submission, for accuracy and completeness. The PI further indicates their continuing commitment to abide by the PI Assurances signed at the initial submission of this study to the VAPORHCS IRB.**