VA Portland Health Care System (VAPORHCS) Institutional Review Board

Research Project Finalization Report

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

**Grant #:** [ ]  **N/A - Unfunded**

**INSTRUCTIONS:**

***Please request finalization ONLY if:***

1. All research-related interventions and/or interactions with human participants have been completed; and
2. All access to study records, both electronic and hard copy, is completed; and
3. Data collection and analysis of **identifiable** **private information is completed**.
4. **Analysis of de-identified data** may continue after study closure as long as the study is transferred to the R&D Committee for annual review of study activities *(see instructions in Q.,18 below).*
5. If the study is being closed and data analysis will not continue, linking documentation is not required to be submitted to the Research Administration Office. However, the information must be retained per current VA regulations.
6. ***If you would like to de-identify the data and continue to conduct data analysis****,* ***please note the following prior to submission to the IRB:***
* Deliver hard copies of linking documentation in a VHA Internal Privacy Act/HIPAA Envelope to Robb White in Building 101, Room 502, or send it in an encrypted email\*\* to Robert.White2@va.gov if it is available only in an electronic format. ***\*\*NOTE: You must include a copy of the email with this finalization report in order to confirm this step has been completed. Do NOT include a copy of any linking documentation or unencrypted email containing PHI.***
* Do not delete your electronic copies of the linking documentation until you have received confirmation\*\*\* from the VAPORHCS Research Administration Office that it has been received. ***\*\*\*NOTE: You must include a copy of the confirmation you received from the Research Office with this finalization report in order to confirm this step has been completed.***
* By submitting this finalization report you attest that this is the only copy of the linking documentation, all other copies have been destroyed, and any further link back to a participant is impossible. Note that this will finalize the study from the perspective of the IRB, and oversight of the study will continue by the R&D Committee (or other applicable subcommittee) until all data analysis (including analysis of de-identified data) is complete.

**Submit this form along with any additional documents prompted by the individual questions below via eIRB.**

**Unless otherwise noted, all forms referenced in this document can be found at:** [**https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp**](https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp)

**1.** Briefly explain why the study is being finalized:

**2.** Did this study include the review of records and/or specimens covered by a waiver of informed process?

[ ]  Yes

[ ]  No – Subjects in this study were enrolled using an informed consent form or information sheet with a waiver of consent documentation. *If* ***NO****, skip to Q.3.*

1. How many records and/or specimens were reviewed/analyzed to date that were covered under a waiver of informed consent process?
2. If more records were reviewed and/or specimens analyzed than were approved by the IRB, was this previously reported to the IRB?

[ ]  Yes; If **YES**, please describe:

[ ]  No; If **NO**, please explain:

[ ]  N/A – Number of records reviewed and/or specimens analyzed was approved by IRB.

**3.** How many subjects to date were consented using a signed consented form or information sheet with a waiver of consent documentation?

* 1. Of those consented, what was the total number enrolled into this study?
	2. If more subjects were consented and/or enrolled than were approved by the IRB, was this previously reported to the IRB?

[ ]  Yes; If **YES**, please describe:

[ ]  No; If **NO**, please explain:

[ ]  N/A – Number of subjects consented and enrolled was approved by IRB.

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1. Were subjects informed that the study would disclose research findings of any kind (e.g., results of genetic studies, clinically relevant information, or incidental findings) to subjects or their provider(s)? ***NOTE:*** *Please refer to the study’s Informed Consent Form, Research Information Sheet and/or other subject documents to confirm whether subjects were informed research findings would be disclosed.*

[ ]  Yes

[ ]  No *If* ***NO****, skip to Q.4.*

1. If **YES to Q.3.c**, did the study disclose research findings to all applicable subjects as indicated on the Informed Consent Form, Research Information Sheet etc.?

[ ]  Yes

[ ]  No; If **NO**, please explain:

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1. Have progress notes been created for each subject enrolled in this study that required one be entered in CPRS? [ ]  **N/A** (progress notes were not required for this study)

If **NO**, please explain:  | [ ]  | [ ]  |
| 1. Did any subjects withdraw from the study or complain about the research process?
 | [ ]  | [ ]  |
| 1. Were any subjects withdrawn from the research project by the Investigator?
 | [ ]  | [ ]  |
| 1. Did any research subjects claim injury from participating in this study?
 | [ ]  | [ ]  |
| 1. If you answered **YES to questions 5, 6 and/or 7**, did the IRB previously receive and review information regarding the event(s) (e.g., submitted with previous continuing review/annual check-in)? [ ]  **N/A** (questions 5, 6, and 7 answered **NO**)

If **YES**, indicate when the IRB received and reviewed the events(s): If **NO**, describe in detail the circumstances for each subject and explain why the IRB didn’t previously receive and review the events(s):  | [ ]  | [ ]  |
| 1. Have there been events that DID NOT meet the threshold for immediate reporting (as defined on the [**Reportable Event Form**](https://www.va.gov/portlandresearch/documents/irb/reportable-events-form.docx)) and have not been reported since last IRB review (e.g., minor protocol deviations/noncompliance, unanticipated problems, adverse events, subject complaints, etc.)?

*If* ***YES****, submit/upload a copy of the event log with this finalization report to eIRB.*  | [ ]  | [ ]  |
| 1. Have any reportable events (as outlined on the [**Reportable Event Form**](https://www.va.gov/portlandresearch/documents/irb/reportable-events-form.docx)) unanticipated problems and/or serious adverse event(s) occurred since the last IRB review?

*If* ***NO****, skip to 8.*If **YES**, has the IRB received, reviewed, and approved the event(s)?*If* ***NO,*** *please submit a* ***Reportable New Information (RNI)*** *via eIRB and explain why the events were not reported within the required time frame.*  | [ ] [ ]  | [ ] [ ]  |
| 1. Were all protocol versions, consent forms and other amendments previously approved by the IRB?

*If* ***NO, STOP HERE. DO NOT SUBMIT THIS FINALIZATION REPORT.*** *You must first submit any that were not previously submitted to the IRB, as a modification, and submit a* ***Reportable New Information (RNI)*** *via eIRB* | [ ]  | [ ]  |
| 1. Were specimens sent to a non-VA facility for analysis, for purposes of this study?

If **YES**, please provide either confirmation that all remaining specimens were returned to the VA or attach a certification from the non-VA facility that the remaining specimens were destroyed, either as certification of destruction of each individual specimen or for the batch of specimens as a whole:       | [ ]  | [ ]  |
| 1. Provide a brief (three sentences or less), lay language summary of the results/findings to date for this study:
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| 1. Was there a research clinic created in Electronic Health Record (e.g., CPRS, CERNER) for this study?

If **YES**, what was the name of the Research Clinic?       | [ ]  | [ ]  |
| **15.** Did the IRB require a Research Flag in Electronic Health Record (e.g., CPRS, CERNER) for this study?If **YES**, what was the name of the Research Flag?       | [ ]  | [ ]  |
| 1. Originals of all hard copies of data/forms/etc., for VA Research must be retained at the VA at the time a study is finalized. In addition, a full electronic copy of any electronic records must be behind the VA firewall. Can you provide an assurance that these items are at the VA/behind the VA firewall?

[ ]  **Electronic data VAPORHCS Network Folder Name (e.g., name requested on IRQ when study was initially submitted):** [ ]  **N/A – No Electronic Data**[ ]  **Hard copies data/forms. VAPORHCS Location (building, room, etc.)**: [ ]  **N/A – No Hardcopy Data/Forms etc.****16.a**. If **NO to Q.16**, when will that transfer occur and how will an assurance be provided to the Research Administration Office that it has occurred?       | [ ]  | [ ]  |
| 1. Will another component, such as wet lab work or work with animals continue after IRB finalization?

If **YES**, explain what component of the study will continue:       | [ ]  | [ ]  |
| 1. Will this study continue with de-identified data analysis after IRB finalization?

*If* ***NO****,* ***STOP HERE****. Do not answer 19 and 20.* *If* ***YES****, attach the e-mail confirming that the linking documentation has been received by the VAPORHCS Research Administration Office (per the instructions on the first page);* **OR** identify the date that the hard copy linking documentation was submitted to the VAPORHCS Research Administration Office and to whom, or where, specifically it was submitted:        | [ ]  | [ ]  |
| ***NOTE:*** *If you answered* ***YES to Q.17., or Q.18.****, this study will remain open under the R&D Committee (or other subcommittee) and continuing reviews for that committee will still be required.* |
| 1. If **YES to Q.18**, will the de-identified data analysis include genetic information?
 | [ ]  | [ ]  |
| 1. If **YES** **to Q.19**, has this study obtained the required Expert Determination as outlined in VHA Directive 1605.01?

If **NO**, please review the information regarding required Expert Determination by navigating to Forms and Templates, selecting VA Portland IRB, and selecting **IRQ Appendix J – HIPAA Statistical Analysis De-Identification Certificate form**. For questions, contact the VAPORHCS Privacy Officer (Brooke Smith). ***NOTE:*** *The* ***IRQ Appendix J - HIPAA: Statistical Analysis De-Identification Certificate form*** *will be required when this study is submitted to R&DC for continuing review after IRB finalization.*  | [ ]  | [ ]  |