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| **VAPORHCS PI Name:       Date:** **Study/Project ID#:** |  |  |  |

**Checklist for Submission:**

**[ ]  This completed Annual Check-In**

[ ]  A [**Conflict of Interest in Research Form**](http://www.va.gov/portlandresearch/documents/conflict_of_interest.pdf) **(newly signed and dated)** must be uploaded to eIRB with this Annual Check-In submission for any of the following individuals who are involved in the study at the VAPORHCS:

**COI Form Required:** PI, Co-PI, study chair, local site PI (if different from main PI), co-investigator, sub-investigator (including a collaborator who has a VAPORHCS research appointment), responsible clinician, and repository director/co-director. A COI form is also required for ANY other research/repository personnel with a real or perceived conflict of interest as outlined in OGE Conflict of Interest in Research Form ([OGE Form 450](https://www2.oge.gov/Web/OGE.nsf/Resources/OGE%2BForm%2B450)).

***NOTE: Unless otherwise stated, all forms referenced in this document can be found at:****<http://www.va.gov/PortlandResearch/piservices/rd_forms.asp>*

1. What is the study’s current status (e.g., study has not begun enrolling, is active and open to enrollment, is closed to enrollment, is active for data analysis only, etc.,)?If the study's aims/subject groups are at different stages, please describe the status of each aim/subject group separately**:**

1. Please provide a summary of any changes to the study since last IRB review/Annual Check-In (e.g., data/specimen storage location, personnel changes and/or access to identifiable information, funding etc.).

**3.** **Principal Investigator and \*Current\* VA IRB-Research Team Members:**

| **Current Study Personnel** *Do NOT list anyone being added or removed with this Annual Check-In* | **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 study staff.***

***‡*** *If an individual's Scope of Work (SOW -- IRQ-L) is no longer accurate, a revised SOW must be submitted. If the individual is NOT required to submit a COI form, please list them in the Personnel Additions/Revisions table below. The SOW form can be found at:* <https://www.va.gov/PORTLANDRESEARCH/documents/irb/irq-appendix-l.docx>

**3.1. Personnel Changes Included with this Annual Check-In**

***NOTE: The following personnel changes CANNOT be done as part of an Annual Check-In and must be submitted as a separate Modification:***

1. ***Additions of personnel who are required to submit a Conflict of Interest in Research Form.***
2. ***Personnel changes that require changes to IRB-approved study documents.***

| **Personnel Removals** |
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| **Legal Name** | **Study Role** | **Date Departed** |
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***REQUIRED:***

**[ ]** I attest that the personnel removal(s) noted above do NOT require changes to IRB-approved study documents.

| **Personnel Additions/Scope of Work Revisions** |
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| **Legal Name** | **SOW Revision\*** | **Study Role** | **Email Address** | **Add to Mail Groups** |
| **PIs** | **SCs** |
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\*For each individual whose SOW is being revised, please summarize the changes to the SOW:

***REQUIRED:***

**[ ]** I attest that the personnel change(s) noted above do NOT require changes to IRB-approved study documents.

**[ ]** I attest that the personnel listed in the personnel additions/revisions table above are NOT required to submit a Conflict of Interest in Research Form.

[ ]  I attest that each individual being added to this study has an active VA research appointment and has completed all required training.

***NOTE:*** *A Research Personnel Change Form is NOT required for personnel changes submitted with an Annual Check-In. However, if you are unfamiliar with the requirements that 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. The Research Personnel Change Form can be found at:* [*https://www.va.gov/PORTLANDRESEARCH/documents/irb/personnel-change-form.docx*](https://www.va.gov/PORTLANDRESEARCH/documents/irb/personnel-change-form.docx)

**4. Review of records and/or specimens covered by a Waiver of All HIPAA & Informed Consent requirements:**

***For studies that do not review records and/or analyze specimens covered by such waivers, skip to Q.5.***

**4.1.** How many records and/or specimens have been reviewed/analyzed to date that were covered under a Waiver of all HIPAA & Informed Consent requirements? If using more than one group of records and/or specimens, indicate the number for each group as well as the total number of records and/or specimens, as applicable.

**4.2.** What is the total number of records and/or specimens approved by the IRB? If using more than one group of records and/or specimens, indicate the number for each group as well as the total number of records and/or specimens, as applicable.

**4.3.If more records and/or specimens have been reviewed/analyzed than were approved,**

**ACTION REQUIRED:** *Add information to a Log of Events that do not meet the threshold for immediate reporting (e.g., events that do not require notification to the IRB via a Reportable New Information (RNI)**report submitted to eIRB) and upload it with this Annual Check-In submission.* ***NOTE: A separate Modification will need to be submitted to eIRB to request approval for an increase in the total number of records and/or specimens.***

**5. Consent using a signed Informed Consent Form (ICF) and HIPAA Authorization and/or a Research Information Sheet used with a Waiver of HIPAA and Documentation of Consent:**

***For studies using ONLY waivers of HIPAA & informed consent, skip to Q.6.***

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|  | **Consent & Enrollment #s at VAPORHCS:** | **During last approval period** | **Since initial IRB Approval** |
| 5a | How many subjects were consented at VAPORHCS? |  |  |
| 5b | How many VAPORHCS subjects withdrew **prior** to collection of any research data? *Include information in Section 6 & 7, if applicable.* |  |  |
| 5c | How many VAPORHCS subjects withdrew or were withdrawn by the research team from the study **after** data collection had begun? *Include information in Section 6 & 7, if applicable.* |  |  |
| 5d | How many VAPORHCS subjects failed eligibility screening after consent? |  |  |
| 5e | Total # VAPORHCS subjects consented **and** enrolled in study:5**a - 5b - 5d = 5e** ***NOTE:*** *Subjects in 5c count towards the total enrollment.* |  |  |

**5.1.** If you reported withdrawals in 5b and/or 5c, please summarize the main reasons for those withdrawals.

**5.2.** How many subjects were IRB-approved for informed consent? If consenting more than one subject group, indicate the number for each group as well as the total number of subjects, as applicable.

**5.3.** How many subjects were IRB-approved for enrollment? If enrolling more than one subject group, indicate the number for each group as well as the total number of subjects, as applicable.

**5.4. If more subjects were consented and/or enrolled than were approved,**

**ACTION REQUIRED:** *Add information to a Log of Events that do not meet the threshold for prompt reporting to the IRB (e.g., events that do not require notification to the IRB via a Reportable New Information (RNI) report to eIRB) and upload it with this Annual Check-In submission.* ***NOTE:******A separate Modification will need to be submitted to eIRB to request approval for an increase in total number of subjects to be consented and/or enrolled.***

**6. Since initial approval,** have there been any events that met the threshold for **prompt reporting** to the IRB in accordance with [VHA Directive 1058.01](https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number) and as outlined in the VA [Reportable Event Form (REF)](https://www.va.gov/portlandresearch/documents/irb/reportable-events-form.docx)? *If* ***NO,*** *skip to Q.7.*

**6.1.** If **YES to Q.6.,** have you previously submitted all of these events to the IRB via an RNI submission in eIRB?

**6.2.** If **NO to Q.6.1., ACTION REQUIRED:** *Submit a* ***Reportable New Information (RNI)*** *report to eIRB for the event(s) and explain why the event(s) were not reported within the required time frame.*

**7.** **Since initial approval**, has the study had any events that **DID NOT** meet the threshold for prompt reporting to the IRB (i.e., events that do not require notification to the IRB via a Reportable New Information (RNI))? *If* ***NO,*** *skip to Q.8.*

**7.1** If **YES to Q.7.,** check one**:**

[ ]  An event/protocol deviation log has been uploaded in eIRB for this annual check-in. ***NOTE: This log may not contain PHI.***

[ ]  The last event/protocol deviation log this study submitted to the IRB staff 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 annual check-in.***

**8.** Was any new information discovered since last IRB review/Annual Check-In that might affect subjects’ willingness to participate in the study? (e.g., Data Safety Monitoring Board [DSMB]/Data Safety Monitoring Committee [DSMC] reports, published or unpublished information)?

If **YES,** please include a copy of all applicable new information with this form’s submission to eIRB. ***NOTE: Please include a copy of all DSMB/DSMC reports not previously submitted to the IRB, even if no problems were identified.***

**8.1** If **YES to Q.8.**, provide a detailed explanation of the information and the risks to the subjects:

