

**Repository Director:** **Date:**

**Repository/Project ID#:**

**Checklist for Submission:**

**This completed Repository Annual Check-In form**

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 Repository Annual Check-In submission for any of the following individuals who are involved with the repository:

**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+Form+450)).

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



**1. Repository Director and \*Current\* IRB-Approved Repository Team Members:**

| **Current Repository Personnel**  *Do NOT list anyone being added or removed with this Annual Check-In* | | **Repository-Specific Scope of Work on file Is Accurate ‡** |
| --- | --- | --- |
| **Legal Name** | **Repository Role** |
|  | Repository Director |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

***NOTE: If needed, use the Enter/Return key to expand rows for additional repository 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. Otherwise, please submit a separate Modification.The SOW form is available on the Research Office website:* <https://www.va.gov/PORTLANDRESEARCH/documents/irb/irq-appendix-l.docx>

**1.1. Personnel Changes Included with this Repository 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. ***Addition of personnel who are required to submit a Conflict of Interest in Research Form.***
2. ***Personnel changes that require changes to IRB-approved repository documents.***

| **Personnel Removals** | | |
| --- | --- | --- |
| **Legal Name** | **Repository Role** | **Date Departed** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

***REQUIRED:***

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

| **Personnel Additions/Scope of Work Revisions** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Legal Name** | **SOW Revision\*** | **Repository Role** | **Email Address** | **Add to Mail Groups** | |
| **PIs** | **SCs** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

\*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 repository 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 repository 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/repository or when an individual needs IRB approval to work on a study/repository, please consult the Research 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)



1. Please provide a summary of any changes to the repository since last IRB review/annual check-in (e.g., data/specimen storage location, personnel changes and/or access to identifiable information, funding etc.):



1. Please **list all of the studies** that have **contributed** specimens/data to this repository during the last reporting period (e.g., since the last Annual Check-In or Initial IRB Approval, whichever is more recent):

**N/A – *No studies have contributed during the last reporting period.***

* 1. Please **list all other studies** that have **contributed** specimens/data to this repository since Initial IRB Approval (i.e., studies that contributed prior to the last reporting period):

**N/A – *No studies have contributed since Initial Approval.***

**N/A – *All studies that have contributed are noted in Q.3.***



1. Please **list all of the studies** that have **received** specimens/data from this repository during the last reporting period (e.g., since the last Annual Check-In or Initial IRB Approval, whichever is more recent):

**N/A – *No studies have received specimens/data during the last reporting period.***

* 1. Please **list all other studies** that have **received** specimens/data from this repository since Initial IRB Approval (i.e., studies that contributed prior to the last reporting period):

**N/A – *No studies have received specimens/data since Initial Approval.***

**N/A – *All studies that have received specimens/data are noted in Q.4.***

* 1. Is there an executed **Data Use Agreement (DUA)** between the Repository Director and all studies/recipients that have received specimens/data from the repository?

**YES**

**NO – *Please explain:***

**N/A – *No studies/recipients have received specimens/data.***



1. Have there been any of the following: adverse events, noncompliance, protocol deviations (including initiating changes to the repository without prior IRB approval), complaints, claims of injury, withdrawals, unanticipated problems involving risks to subjects or others, or any other types of incidents since the time of initial approval?  *If* ***NO,*** *skip to Q.6.*
   1. **YES to Q.5.,** have you submitted all 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)?
   2. If **NO to Q.5.1., 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.*



1. Has the repository had any events that **DID NOT** meet the threshold for prompt reporting to the IRB since the time of initial approval (e.g., events that do not require notification to the IRB via a Reportable New Information (RNI)? *If* ***NO,*** *skip to Q.7.*
   1. If **YES to Q.6., ACTION REQUIRED:** *Submit Log of Events* *with this Repository Annual Check-In.*



1. Was any new information discovered since last IRB review/annual check-in that might affect subjects’ willingness to participate in the repository?
   1. If **YES to Q.7.**, provide a detailed explanation of the information and the risks to the subjects:

