

**Date of Personnel Change Form Submission:**

**VAPORHCS PI Name:**

**Study/Project ID#:**



**SUBMISSION INSTRUCTIONS**

* Joint OHSU/VA Studies: This completed form and all other forms required by the instructions on this form should be submitted via [eIRB](https://eirb.ohsu.edu/IRB/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b0A7646F3B149874E902185897C144551%5d%5d).



**Checklist for Submission:**

**Please read this checklist carefully and ensure that you check the correct boxes. This information is necessary to determine the type of review your personnel change requires.**

This completed **Personnel Change Form**

I attest that each required [**Conflict of Interest in Research Form**](https://www.va.gov/Portlandresearch/documents/conflict_of_interest.pdf) has been included with this submission.

**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)).

**N/A** – I attest that none of the personnel being added to this study are required to submit COI forms.

**N/A** – This personnel change involves only the removal of study personnel.

I attest that an [**IRQ Appendix L, Scope of Work (SOW)**](https://www.va.gov/PORTLANDRESEARCH/documents/irb/irq-appendix-l.docx) form for each individual being added to the study has been included with this submission.

**N/A** – This personnel change involves only the removal of study personnel.

I attest that **any additional study documents** affected by the personnel change(s) have been submitted as part of this modification.

Examples: A new study coordinator's name must be added to an advertisement or ICF.

A departing co-investigator's name must be removed from the protocol.

**N/A** – I attest that this personnel change does not require changes to IRB-approved study documents.

I attest that each individual being added to this study has an **active VA research appointment** and has **completed all required training**. *For more information, see the "****Additional Instructions for New Personnel"*** *section at the end of this form.*

**N/A** – This personnel change involves only the removal of study personnel.



1. **ADDITION OF PERSONNEL/CHANGE IN ROLE**

***NOTE: The final written IRB approval or written administrative acknowledgement for a new individual must be obtained before that individual may begin work on the study.***

Individuals should be added to a research team if they will do any of the following:

* Use VAPORHCS resources (including network resources)
* Need access to VAPORHCS patient records (e.g., CPRS, CERNER, etc.)
* Directly interact with VAPORHCS participants
* See identifiable data for VAPORHCS participants

**Please list all personnel being added (or whose roles are being revised) in the table below:**

| **Legal Name** | **Role Revision** | **Study Role** | **Email Address** | **Add to Mail Groups** | |
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| **PIs** | **SCs** |
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***NOTE: If needed, use the Enter/Return key to expand rows for additional study staff.***



1. **ROLE CHANGE/REVISED SCOPE OF WORK**

***NOTE: The final written IRB approval or written administrative acknowledgement of an individual's new duties must be obtained before that individual may begin those duties.***

**Please submit an IRQ Appendix L – Scope of Work (SOW) reflecting the revised role/duties of each study team member and summarize the changes to the SOW in the table below:**

| **Legal Name** | **Change(s) to Previously Approved Scope of Work form**  *Which specific items in the SOW have been revised?* |
| --- | --- |
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***NOTE: If needed, use the Enter/Return key to expand rows for additional study staff.***

**NOTE:** If the individual's new role requires submitting a [**Conflict of Interest in Research Form**](http://www.research.va.gov/programs/tech_transfer/model_agreements/conflict_of_interest.pdf) and their previous role did not, please have them complete the COI form. Upload the COI form in eIRB.



1. **REMOVAL OF PERSONNEL**

**Please list all personnel who are leaving the study in the table below:**

| **Legal Name** | **Study Role** | **Date Departed** |
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**Keep a copy of this form for your records**



**ADDITIONAL INSTRUCTIONS**

**ADDITIONAL INSTRUCTIONS FOR NEW PERSONNEL**

* All individuals working on VA research must have some type of VA appointment (either paid or Without Compensation). Appointment status will be verified prior to approval to be added to the study team. If an appointment is needed, please go to the Research Appointment Requirements page at <https://www.va.gov/PortlandResearch/piservices/hiring/appointmentrequirements.asp> and follow the appropriate checklist prior to submitting this form. Questions regarding appointments should be addressed to the Research Service at [VHAPOR-ResearchWOC@va.gov](mailto:VHAPOR-ResearchWOC@va.gov)
* All new personnel must meet the training requirements outlined at <https://www.va.gov/PortlandResearch/training/index.asp> and have the appropriate certificates on file before approval will be granted to be added to the study team.
* If the individual will be a prescriber for investigational drugs, update [**VA form 10-9012**](https://www.va.gov/Portlandresearch/documents/irb/10-9012.doc), as needed.
* There are two mail groups—VA Clinical PIs and VA Clinical Research Coordinators—on which the Research Office sends out announcements regarding changes in VA regulations, reminders of IRB requirements, and other important news. If you wish to add new personnel to either of these groups, please indicate this by checking the relevant box(es) in the rightmost columns of the personnel addition table above ("PI" for VA Clinical PIs or "SC" for Clinical Research Coordinators).

**ADDITIONAL INSTRUCTIONS FOR NEW PI**

***NOTE:*** *For studies with an SRS and/or IACUC component, there can be only one “VA-responsible PI” per study. If study has an SRS and/or IACUC component, the new PI must meet requirements for all subcommittees (e.g., general trainings, lab access, biohazards training and can assume the responsibility for biohazardous sample processing in a lab, etc.). Be sure all requirements are in place prior to submitting request to change to a new PI. For more information on requirements please see:* [*https://www.va.gov/PortlandResearch/piservices/rd\_forms.asp#new\_investigators*](https://www.va.gov/PortlandResearch/piservices/rd_forms.asp#new_investigators)

* **If this form is indicating a change in** **Principal Investigator, the new PI must:**
  + Sign the last page (assurances) of the most recent [Initial Review Questionnaire](http://www.va.gov/portlandresearch/documents/irb/irq.doc) (IRQ) and include a copy with this submission. ***NOTE:*** *The PI Assurances of the IRQ can be located at:* [*https://www.va.gov/PORTLANDRESEARCH/Documents/irb/irq-OHSU.docx*](https://www.va.gov/PORTLANDRESEARCH/Documents/irb/irq-OHSU.docx)**AND**
  + Submit an [**Investigator Data Sheet** (page 18)](https://www.va.gov/Portlandresearch/documents/investigator-data-sheet.pdf), if one for that individual has not been submitted within the last year or two to [pvamc-irb@va.gov](mailto:pvamc-irb@va.gov).