**HELP GUIDE - Submitting a New Project to the VAPORHCS IRB**

**The VAPORHCS IRB forms are meant to work together and prompt you for all information and forms required for your submission. Please read through all instructions and take advantage of all the provided links to policies, definitions, and other forms when applicable. This will help ensure that you include all required elements for IRB review. It will also provide you with a better understanding of why/what is required for IRB review and approval.**

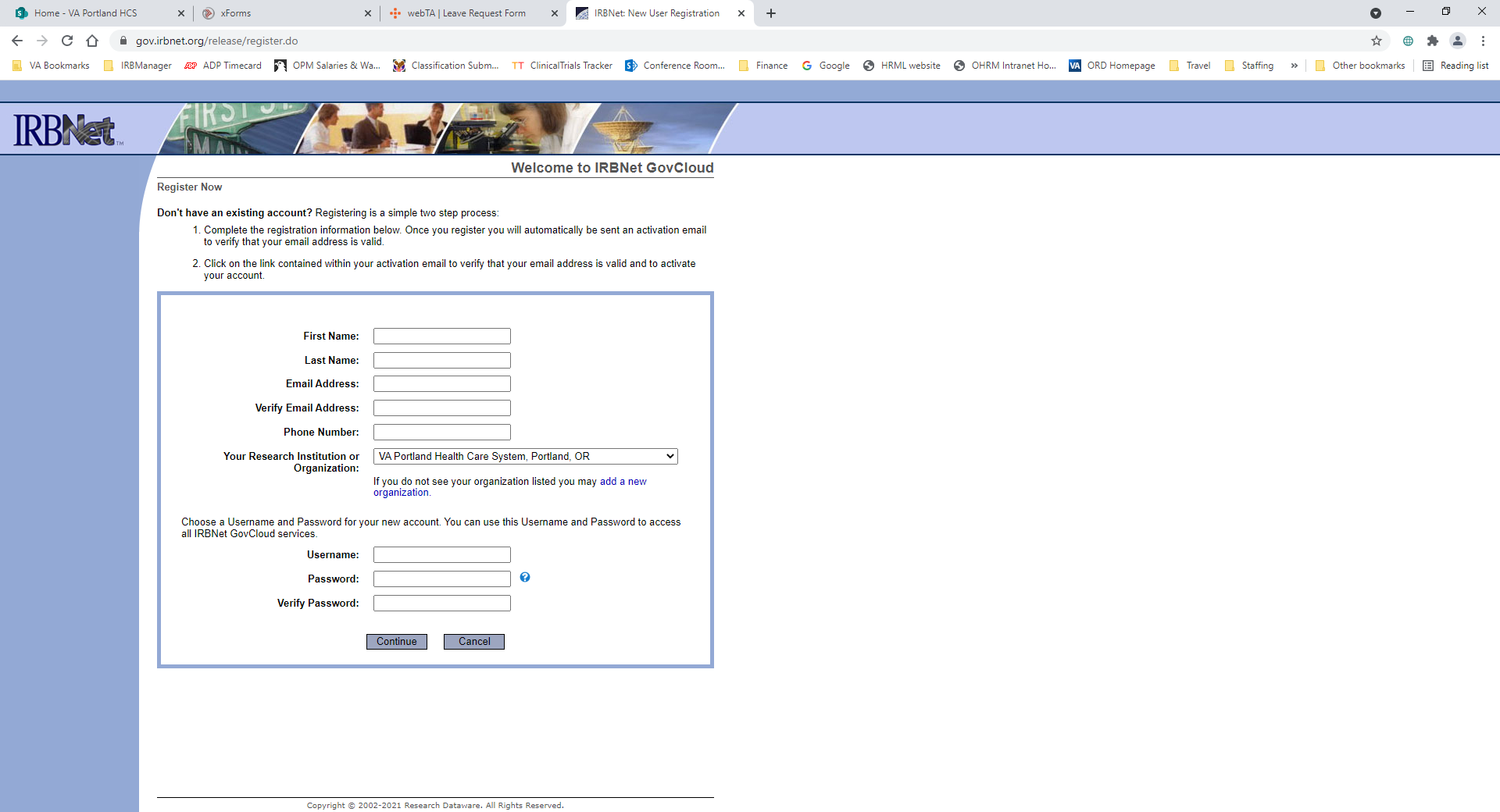
# STEP #1: VAIRRS Account Set-Up

To submit your initial review/new project to the VAPORHCS IRB, you need to first register for an account in the IRBNet electronic protocol management system (The VA version of the system is called “VAIRRS”). ***NOTE:*** *If you already have registered with VAIRRS and/or added VA Portland to your Affiliations in your User Profile, skip to STEP #2.*

**PLEASE NOTE:** Do NOT use the back arrow in your web browser during this process.

1. On the IRBNet GovCloud ([gov.irbnet.org](https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fgov.irbnet.org%2F&data=04%7C01%7C%7C54bea70f079340f31bd708d90b278c23%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637553086749259535%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=CJj1LBAZsOVcj0rnn9rqwz6nfcRoh1TK7bOsEGhkxQs%3D&reserved=0)) homepage (be sure you are on the GOV page and not the general IRBNet homepage), select **Register Now**.
2. Enter your information into the fields (they’re all required) and ensure you select **VA Portland Health Care System, Portland, OR** by scrolling through the list.

**NOTE: Your email address must be your VA email address.**



1. You will be prompted to read and accept the “Terms of Use.”
2. You will be prompted to enter a recovery email (required) and a recovery phone number (not required)
3. A pop-up will appear to enter the verification code that was just emailed to the main (not recovery) address you provided.
4. Once you enter the verification code, you will be taken to a blank workspace.

**IMPORTANT NOTE:** You now will have access to the help guides, forms, and templates needed to complete your Initial Review submission. To access these documents, select **Forms and Templates (under Other Tools on left-hand side of the package) and select VA Portland IRB - Documents for Researchers (from the Select a Library drop-down menu).**

# STEP #2: Proposed Project Questionnaire (PPQ) Submission and Sign-off

* **Complete a Proposed Project Questionnaire (PPQ)**

The PPQ is located at: <https://www.va.gov/PORTLANDRESEARCH/documents/irb/ppq.docx>

* + The VA PPQ provides basic information necessary for the VA Research Office to evaluate and route the project to the appropriate oversight committees. This form must be completed by a VA PI when submitting a research project that uses VA resources (i.e., VA time, VA patients, VA space, and/or VA equipment).
* **AFTER you receive notice that your PPQ has been signed**, proceed to **Step #3.**

# STEP #3: Creating your Initial Review/New Project in VAIRRS

* Log into the VAIRRS system (IRBNet GovCloud URL: [[gov.irbnet.org](https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fgov.irbnet.org%2F&data=04%7C01%7C%7C54bea70f079340f31bd708d90b278c23%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637553086749259535%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=CJj1LBAZsOVcj0rnn9rqwz6nfcRoh1TK7bOsEGhkxQs%3D&reserved=0)](https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fgov.irbnet.org%2F&data=04%7C01%7C%7C54bea70f079340f31bd708d90b278c23%7Ce95f1b23abaf45ee821db7ab251ab3bf%7C0%7C0%7C637553086749259535%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=CJj1LBAZsOVcj0rnn9rqwz6nfcRoh1TK7bOsEGhkxQs%3D&reserved=0) ). *This will allow you to access the templates and forms needed to complete your Initial Review/New Project Package in VAIRRS.*
* To start your New Project submission, click on "**Create New Project"** located on the left-hand side of your Submission Manager workspace page. ***NOTE: do NOT click "Create A New Package"***

# STEP #4: Completing your Initial Review/New Project Submission in VAIRRS

**NOTE: Most forms required for IRB submissions can be located by navigating** in the VAIRRS system to **Forms and Templates (under Other Tools on left-hand side of the package)**; selecting **VA Portland IRB - Documents for Researchers** **(from the Select a Library drop-down menu).**

* **Create a VAPORHCS Local Protocol**
* The protocol template prompts for the information the IRB needs in order to verify that your proposed project is in compliance with all applicable federal, state, and VA requirements. Please read the directions carefully and ensure that you have addressed all applicable prompts.
* **If the protocol you would like to propose was written by a third party (i.e., the sponsor, the coordinating center, etc.),** please use the protocol template to create a local protocol addendum that addresses specifically how the required items will be conducted/addressed at the VA Portland Health Care System (VAPORHCS).

***NOTE:*** *Sponsor's protocols typically contain a lot of information that the IRB does not need to review. A well-constructed local protocol addendum will significantly expedite IRB review of your project by making the information the VAPORHCS IRB needs easy to find. (Please note that VAPORHCS has an all-volunteer IRB made up primarily of VA clinicians and staff who have little (if any) protected time for their IRB work.)*

* Complete the Initial Review Questionnaire (IRQ)

***NOTE:*** *Follow the Checklist for Submission section and instructions throughout the form carefully. The IRQ includes specific prompts for other required forms and how to locate them.*

* To upload the **VAPORHCS Local Protocol Addendum, Initial Review Questionnaire (IRQ)**, and any other documents required for your submission, click the **Attach New Document** button at the bottom of the page (of the New Project submission you are working on).

# STEP #5: Required “Wizards”

* All New Projects submitted to the IRB must include a **VA Project Cover Sheet** and **VA IRB Information Sheet**. VAIRRS includes a **Wizard** for each sheet that is used to complete them within the system.
* To locate and complete the two required wizards, click the **Start a Wizard** button at the bottom of the page (of the New Project submission you are working on). and select the sheet you need to complete.

***NOTE:*** *Be sure your study staff entered in the VA Project Cover Sheet matches the staff listed on the IRQ.*

# STEP #6: How to Submit Your Completed New Project Package:

* Once the submission materials are complete, **the PI must sign the package in VAIRRS.** No other study staff is required to sign the package. **Study staff may submit the package (see instructions below) on the PI's behalf, but they may NOT sign on the PI's behalf.** 
  + PIs can access additional instructions for how to sign a package by navigating in VAIRRS to **Forms and Templates** (under **Other Tools** on left-hand side of CR package) and selecting **VA Portland IRB - Documents for Researchers** from the **Select a Library** drop-down menu, and selecting **0-HELP GUIDE\_Signing A Package** from the documents list.
* **Submit** the package by navigating to **Project Administration** on the left-hand side of the package and clicking on **Submit this Package.**

# ADDITIONAL RESOURCES AND GUIDANCE:

**VAIRRS and submission Help Guides:**

Study teams can access additional instructions for how to make pre-review requested revisions and **Mark Revisions Complete** (i.e., re-submit the package) by navigating in VAIRRS to **Forms and Templates** (under **Other Tools** on left-hand side of package) and selecting **VA Portland IRB - Documents for Researchers** from the **Select a Library** drop-down menu, and selecting **0-HELP GUIDE\_STUDY-TEAMS\_Minor Revisions-Finding Approval-Ltr-Docs** and/or **0-VAIRRS FAQ-For Study Teams** from the documents list.

PI resources can be found at the following links:

<https://www.va.gov/PORTLANDRESEARCH/piservices/index.asp>

[http://www.portland.va.gov/Research/hrpp/index.asp?tab=3](https://www.va.gov/PORTLANDRESEARCH/hrpp/index.asp?tab=3)

<https://www.research.va.gov/resources/policies/human_research.cfm>

[http://www.portland.va.gov/research/crcresources/](http://www.portland.va.gov/research/crcresources/ )

<https://www.va.gov/PORTLANDRESEARCH/piservices/rd_forms.asp>

**QUESTIONS?**

Email the IRB Inbox at [pvamc-irb@va.gov](mailto:pvamc-irb@va.gov)