**HELP GUIDE - Submitting a New Exempt Human Subjects Research Project at VAPORHCS**

To qualify as exempt research, every study activity involving human subjects or the use of identifiable data must fit into one of the categories listed at the end of this document.

# STEP #0: For PIs New to Human Subjects Research at VAPORHCS

If this is your first human subjects study at VAPORHCS, you will need to make sure A - C below are complete before you submit your study to a VAPORHCS research oversight committee.

1. **Apply for a VAPORHCS research appointment**. Instructions may be found [here](https://www.va.gov/PORTLANDRESEARCH/piservices/hiring/appointmentrequirements.asp).

*If you have no existing (paid or WOC) appointment at VAPORHCS, the process of obtaining one can be quite lengthy. If you have a (paid or WOC) appointment at VAPORHCS in a service other than R&D, the process of obtaining a VAPORHCS research appointment is much quicker.* ***Questions about research appts should be sent to VHAPOR-ResearchWOC@va.gov.***

1. **Complete VAPORHCS human subjects training**. Instructions may be found [here](https://www.va.gov/PORTLANDRESEARCH/documents/irb/citi-instructions.doc).

*As noted in the linked instructions, you must complete the VAPORHCS-specific CITI human subjects training. OHSU CITI human subjects training is not sufficient.*

1. **Register for an account in IRBNet.**

The VA version of IRBNet is called VAIRRS. It is the electronic protocol management system you will use to submit your project to VAPORHCS research oversight committees. It is also where you will find many of the forms you will need to submit.

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

1. On the IRBNet GovCloud homepage ([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)), select **Register Now**.

*Be sure you are on the GOV page, not the general IRBNet homepage.*

1. Enter your information into the fields (they are all required) and ensure you select **VA Portland Health Care System, Portland, OR** by scrolling through the list.

**NOTE: The PI's email address must be their VA email.**

1. Read and accept the Terms of Use.
2. Enter a recovery email (required) and phone number (not required)



1. A pop-up will appear prompting you to enter the verification code that was just emailed to the main (not recovery) address you provided.
2. Once you enter the verification code, you will have successfully registered, and you will be taken to a blank workspace.

# STEP #1: 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 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).
	+ The instructions at the beginning of the PPQ prompt for additional documents (an abstract, conflict of interest form, and protocol draft or grant application).
* **Email your completed PPQ and all supporting documents to** **Research.Grants@va.gov**.
* After you receive notice that your PPQ has been signed, proceed to **Step #2.**

**EXCEPTION: If the PI or any other investigator on the study has a potential financial conflict of interest to disclose, complete Steps #2 and #3 as soon as possible. Do NOT wait for the PPQ to be signed.**

Potential COIs must be reviewed by OGC Ethics before the project can begin. Review by OGC Ethics can take many months.

# STEP #2: Creating your Initial Review/New Project in VAIRRS

* Log into the VAIRRS/IRBNet system ([[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.*
* 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 #3: Submitting Required COI Disclosures in VAIRRS

**Each investigator (principal, co-, sub-) on your study must submit a financial conflict of interest (COI) disclosure before the project may begin. These disclosures must be completed in VAIRRS and must be submitted in a separate package from your other study documents.**

**Basic Steps:**

1. **Ensure each of your co-/sub-investigators has a VAIRRS/IRBNet account. (Unless a person is a new investigator at VAPORHCS, they likely already have an account.)**
2. **"Share" the project you created in Step 2 with each of your investigators.**
3. **Have each of your investigators use the My COI tab in VAIRRS to complete a COI disclosure for your project.**
4. **Create a package, link your investigators' COI disclosures, and submit the package to the VA Portland Conflict of Interest VAIRRS workspace.**

***For detailed guidance on how to complete these steps, please consult the HELP GUIDE\_Submitting COI Disclosures document in the VA Portland IRB - Documents for Researchers VAIRRS library (see beginning of Step #4 below).***

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

* **Locate the forms "Libraries"**

**Under Other Tools** on left-hand side of package, select **Forms and Templates**. At the top of the page, you will see a **Select a Library** drop-down menu. The forms required for exempt submissions are located in two "libraries":

**VA Portland IRB - Documents for Researchers**

Protocol Template/Local Protocol Addendum

IRQ-L Scope of Work (SOW)

Additional Help Guides

**VHA ORPP&E, Washington, DC - Documents for Human Subjects Researchers**

Exemption Request Form

Request for a Waiver of HIPAA Authorization

VA Form 10-0493

Enterprise Research Data Security Plan (ERDSP)

* **Create a VAPORHCS Protocol using the VAPORHCS Protocol Template**
* Please read the directions in the VAPORHCS Protocol Template carefully and ensure that you have addressed all applicable prompts.
* **If your protocol was written by a third party (i.e., the sponsor, the coordinating center, etc.),** please use the VAPORHCS Protocol Template to create a local protocol addendum that makes clear which study activities will occur at VAPORHCS and addresses all applicable prompts for those study activities.
* Complete an **Exemption Request Form**

**IMPORTANT:** Please make sure every part of your study (at VAPORHCS) is accounted for on the Exemption Request Form. (You may select more than one exempt category.) **For your project to qualify as exempt, every study activity involving either (i) interaction with human subjects or (ii) use of identifiable data from human subjects must fit an exempt category on the Exemption Request Form.**

*Section IV of the Exemption Request Form will prompt you to submit either a* ***Request for a Waiver of HIPAA Authorization*** *or a* ***VA Form 10-0493*** *if your study will access any of the 18 HIPAA identifiers. The 18 HIPAA identifiers are listed in Section IV of the Request for a Waiver of HIPAA Authorization form.*

***NOTE:*** *Exempt studies are exempt from the Common Rule's informed consent requirements, so no Waiver of Informed Consent is needed.*

* Complete an **Enterprise Research Data Security Plan (ERDSP)**

*The VAPORHCS Information Systems Security Officer (ISSO) will sign this form after completing his review of the submission.*

* Complete **all subject-facing documents** to be used in the study (e.g., surveys, recruitment materials, interview scripts).

***NOTE:*** *Records review studies will not have subject-facing documents.*

* Complete an **IRQ-L Scope of Work (SOW)** form for each individual who will be working on the project at VAPORHCS.

*Each of these individuals must have a current VAPORHCS research appointment and have completed all required training (see Step #0 above).*

* To upload these documents, click the **Attach New Document** button at the bottom of the page (of the New Project submission you are working on).
	+ Please also add the **Abstract** you submitted with your PPQ to the VAIRRS/IRBNet package.

# STEP #5: Required “Wizards”

* All new human subjects research projects must include a **Project Cover Sheet, VA IRB Information Sheet**, and **Study Team Tracking Sheet**. VAIRRS includes a **wizard** for each that is used to complete them within the system.
* To locate and complete the 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 wizard you need to complete.

***NOTE:*** *For additional guidance, consult the* ***000-WIZARDS GENERAL GUIDANCE & UPDATES*** *and/or the specific* ***0-Wizard Guide*** *documents**located in the* ***VA Portland IRB – Documents for Researchers VAIRRS library.***

# 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.**

# Review Process for Exempt Human Subjects Studies:

* + 1. **Pre-Review**

After you submit your project in VAIRRS/IRBNet, an IRB Analyst will review it to confirm that it is complete and satisfies all criteria for approval.

* + 1. **Review by the VAPORHCS Information Systems Security Officer (ISSO) and VAPORHCS Privacy Officer (PO)**
		2. **Review by a designated IRB member**

When this step is complete, you will receive an email notification from VAIRRS/IRBNet stating that the study has been found to be Exempt.

* + 1. **Review by a designated R&D Committee member**

 When this step is complete, you will be notified that you may begin the study.

# Making Required Revisions:

If any of the above reviewers require changes, you will be notified by email that your submission has been "unlocked" for revisions. Once you have made those changes, you will need to **mark revisions complete** to re-lock the package. This will notify the IRB analysts that the project is ready to be sent back to the reviewer who requested the changes.

Additional instructions are available in the **0-HELP GUIDE\_STUDY-TEAMS\_Minor Revisions-Finding Approval-Ltr-Docs** and **0-VAIRRS FAQ-For Study Teams** help guides in the **VA Portland IRB - Documents for Researchers** VAIRRS library.

# Additional Resources and Guidance:

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>

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

**QUESTIONS?**

Email the IRB Inbox at pvamc-irb@va.gov

# Categories of Exempt Research Permitted at VAPORHCS:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
4. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
5. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §16.111(a)(7).
6. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
7. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
8. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
9. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §16.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

1. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
2. The identifiable private information or identifiable biospecimens are publicly available;
3. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
4. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
5. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
6. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
7. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
8. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
9. Taste and food quality evaluation and consumer acceptance studies:
10. If wholesome foods without additives are consumed, or
11. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Dept of Agriculture.