



# OHSU/PVAMC Joint IRB

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# *The Backstory:*

- Research done at both OHSU and PVAMC have, for the last twelve years, required review by the IRBs at both institutions.
- This involves two IRB submissions, and differing submission requirements.
- In July 2009, OCTRI decided to hire someone to spearhead the initiative to establish a mechanism for single review of joint studies.

## ***2 ½ Years Later:***

- A Memorandum of Understanding has been signed by OHSU and PVAMC (and blessed by lawyers and others far and wide...)
- Forms have been created
- Procedures have been developed
- A study has been piloted through the review process

## *Which studies are eligible?*

- Studies that will be (or are) conducted at both institutions.
  - VA research is research conducted at the VA, using VA resources, or on VA time.
  - Recruiting at the VA is VA research
  - Incidentally enrolling a veteran through a study at OHSU (without going through the VA at all) is not VA research.

## *When Do I Submit?*

- New studies – submit for both institutions at the time of initial submissions (indicate “VA” in eIRB, and submit VA supplemental forms at the same time as the rest of the submission).
- Ongoing Studies
  - Studies currently open at both VA & OHSU – submit modification to OHSU to “add” VA, obtain jIRB approval, “close” study through VA IRB
  - Studies open at OHSU, adding VA as a site (not currently open at VA) – submit a modification to add VA.

## *What you can expect*

- A single eIRB submission (but with some additional forms)
- Review by a single IRB (IRB-3), and correspondence from only that IRB
- A quicker turnaround to getting started at both institutions (hopefully)

## *How it's Different from a "Normal" OHSU Submission:*

- Additional VA forms (currently in Word format) that get uploaded into eIRB
- Submission of a VA Consent
- Submission of a VA Authorization
- Requirements to meet VA policies for the VA portion of the research

## *Some Things to Keep in Mind*

- VA regulations require that the protocol differentiate VA Research from non-VA Research – may be in a protocol addendum.
- Need to differentiate what's done on VA time vs. non-VA time.
- Follow VA Consent Template – do not simply paste in OHSU consent language.
- You will need to meet VA policies for the VA research – guidance and pointers are in VA forms.



## ***VA Policies***

- Enrolling non-veterans in the VA portion of the research (at the VA, using VA resources, on VA time) must be justified and approved by the IRB.
- No cold calls/letters to potential VA participants.
- Banking of VA specimens must be at the VA, or obtain VA Central Office permission.
- VA is protective of its data – follow VA forms for guidance.
- Must retain research data indefinitely (until we hear otherwise).

## *So What's Really Needed?*

- Submit (or have) study in eIRB
- Go to the VA Research Office website:  
<http://www.portland.va.gov/research/>
- Under Committees/IRB or HRPP, select the joint IRB tab
- READ the guidance(psssst! – this is important!)

## ***Submit these in addition to eIRB forms***

- OHSU PPQ (if new)
  - VA Proposed Project Questionnaire (PPQ)
  - VA abstract with headings prompted in the VA PPQ
  - VA Supplemental Questionnaire (VASQ)
  - VA Scope of Work Forms for each individual working on the VA research
  - VA IRQ Appendices, as prompted
  - VA Consent & VA Authorization (separately)
- 
- Follow the guidance on the “Preparing a Combined VA-OHSU Submission”



# Portland VA Medical Center

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## Research and Development Service - Human Research Protection Program (HRPP)

PVAMC IRB Committees

PVAMC and OHSU Joint IRB

HRPP

### PVAMC and OHSU Joint IRB

PVAMC now utilizes an OHSU IRB for studies conducted on both sides of the bridge!

Investigators proposing human subjects studies that will be conducted at **both** OHSU **and** PVAMC, aka joint studies, should submit their study to OHSU IRB-3. This is accomplished by logging in to the [OHSU eIRB system](#) and creating a new study submission.

When completing the eIRQ in the system, question 2.6.13 should be answered to indicate the VA components that will be included in the VA portion of the proposed research. This page contains guidance on how to submit a "joint study" to OHSU. The guidance is also captured in this standalone document: [Preparing a Combined VA-OHSU IRB Submission](#) (92KB, MSWord).

#### I. GATHER TOGETHER ALL THE REQUIRED DOCUMENTS In addition to the eIRB submission, **all studies must have:**

- A. [OHSU PPQ](#) (Proposed Project Questionnaire) – submitted as appropriate according to OHSU requirements
- B. [VA PPQ](#) – completed Word version uploaded into eIRB
  1. If #4 is answered "YES", complete the [VA Financial Administrative Review](#)
- C. Abstract (per item 1 on the VA PPQ) - sent to [research.grants@va.gov](mailto:research.grants@va.gov)
- D. [Lay Language Protocol Summary](#) (*Note: In some cases, such a retrospective chart review only, the Lay Language Protocol Summary may serve as the protocol and may be longer than 1 page.*)
- E. [VA Supplemental Questionnaire \(VASQ\)](#) (263KB, MSWord) - with signed assurances page uploaded into eIRB
- F. [Scope of Work forms \(VA IRO Appendix L\)](#) – signed copy uploaded into eIRB for each individual listed on the VASQ

Note that each of these individuals must have some type of VA appointment and meet the PVAMC Research appointment requirements, including verification of education and credentialing. The requirements are outlined at: [Appointment Requirements](#).

**\*\*For all VA documents (such as the VA consent form, VA scope of work, etc.), please title the documents with the prefix "VA" when uploading them into eIRB.**

#### Most studies must have:

##### A. Protocol

1. Describe the study purpose/aims, procedures, data collection, statistical analysis, sample size, measures to protect subjects' safety, etc.

## Preparing a combined VA-OHSU IRB Submission



OREGON  
HEALTH & SCIENCE  
UNIVERSITY

Research Integrity Office

Mail code L106-RI  
3181 S.W. Sam Jackson Park Road  
Portland, Oregon 97239-3098  
tel: 503 494-7887 | fax: 503 346-6808

**Would you like your eIRB submission, for a study involving both PVAMC and OHSU, to move through the IRB review process as efficiently as possible? If so, consider the following steps as a guide to creating a clear and consistent submission:**

### 1. GATHER TOGETHER ALL THE REQUIRED DOCUMENTS (forms are hyperlinked)

In addition to the eIRB submission, **all studies must have:**

- > [OHSU PPQ](#) (Proposed Project Questionnaire) – submitted as appropriate according to OHSU requirements
- > [VA PPQ](#) – completed Word version uploaded into eIRB
  - ✓ If #4 is answered “YES,” complete the [VA Financial Administrative Review](#)
- > **Abstract (per item 1 on the VA PPQ)** - sent to [research.grants@va.gov](mailto:research.grants@va.gov)
- > [Lay Language Protocol Summary](#) (*Note: In some cases, such a retrospective chart review only, the Lay Language Protocol Summary may serve as the protocol and may be longer than 1 page.*)
- > **VA Supplemental Questionnaire (VASQ)** - with signed assurances page uploaded into eIRB
- > [Scope of Work forms \(VA IRQ Appendix L\)](#) – signed copy uploaded into eIRB for each individual listed on the VASQ  
Note that each of these individuals must have some type of VA appointment and meet the PVAMC Research Appointment requirements, including verification of education and credentialing. The requirements are outlined at:  
<http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp>

3181 SW Sam Jackson Park Road , L106-RI  
Portland, OR 97239  
P: 503.494.7887  
[www.ohsu.edu/researchintegrity](http://www.ohsu.edu/researchintegrity)

**Portland VA  
Supplemental Questionnaire (VASQ)**

PVAMC Research Service Office  
tel: 503 273-5125 | fax: 503 273-5351



OHSU Research Integrity Office  
tel: 503 494-7887 | fax: 503 346-6808

Please complete & upload this form for all submissions which will be conducted at both OHSU and the VA. (Note: OHSU and/or VA IRB analysts may ask for additional clarifications beyond what is specified here.)  
❖ All hyperlinks in this document can be activated by pressing "CTRL" + mouse-click.

OHSU eIRB #:  Full Title of Study:

Principal Investigator:

1. Is the Principal Investigator licensed, credentialed and privileged at the Portland VAMC to perform all interventions (such as physical/mental exams, lab test interpretation, adverse outcome diagnosis, medication prescribing/renewal, or invasive procedures) proposed in this research project?

YES  NO  N/A (no interventions)

1.a If **NO**, a PVAMC licensed, credentialed and privileged clinician must be identified here as the "VA Responsible Clinician" for this study. That person must also sign the last page of this supplemental questionnaire, and the scanned signature page must be uploaded into eIRB with this completed questionnaire.

Indicate name of VA Responsible Clinician:

*Note: Any entry into CPRS recording a physical/mental examination, laboratory test interpretation, adverse outcome diagnosis, medication prescribing /renewal, or invasive procedure by a member of the study team who is not licensed, credentialed and privileged by the PVAMC to perform those procedures must be cosigned by the PI or the VA responsible clinician.*

2. Does this research proposal involve any units, services or specialties/subspecialties that are **not** under the supervision of the investigator, including pathology or clinical or inpatient areas such as renal dialysis, or any services that are not currently available at the PVAMC?

YES  NO  (skip to question 3)


2.a If **YES**, please name the units, service(s) and/or the specialties/subspecialties which this study involves:

2.b If you identified Pathology service in question 2.a, please have Dr. Michael Nichols sign here to indicate that pathology has agreed to work with the PI on this study:

Dr. Michael Nichols, Chief, Pathology & Laboratory Medicine

Turn in a signed hard copy of this page with signature to the VA research office, where it will be scanned and attached to your submission.

# VA Consent

 Department of Veterans Affairs	<b>VA Informed Consent Form</b> Page 1 of 31
Subject Name: _____ Date: _____	
Title of Study: _____	
Principal Investigator: _____	VAMC: 648 – Portland, OR

## **WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

1. About the research, call <name> at <phone number>. *If you give the name and number of the PI, be sure someone will always be available to answer at that number. Consider whether a research coordinator would be a better contact, or give more than one contact.*
2. If you become sick or injured (*if there is risk of physical, mental or emotional injury*) or if you feel your privacy or confidentiality may have been violated) e.g., someone without authorization has received personal information about you), call <name of PI or responsible clinician> at <phone number>.
3. *You may either include the following statement:*  
Other research team members include <name(s)\* or study position title(s) of study staff with whom the patient is likely to have contact (e.g., study coordinator or co-investigator who will obtain consent, administer a questionnaire or procedure or perform an intervention)>.  
*OR*  
*You may create a separate page that can be used to provide research personnel contact information. The page should include the study title, study role(s), names, degrees as appropriate, and phone numbers. A sample contact information page is available at <http://www.portland.va.gov/research/documents/irb/icf-sample-contact-info.doc>. This page may be updated each time someone is deleted from or added to the study, via the Research Personnel Change Form, without revising the informed consent form as well.*
4. To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the Portland VA Medical Center Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

## **WHAT IS THE PURPOSE OF THIS STUDY?**

1. *Describe in simple language the purpose of the study, using language such as the following:* This is a research study. The purpose(s) of this study is to learn about a new drug called <name of drug> that may help in treating <health issue>.

# Appendix L – Scope of Work

1 of 2

Portland VA Medical Center Institutional Review Board  
**IRQ Appendix L – Scope of Work**

For Office Use Only

MIRB No: \_\_\_\_\_

Project Title: [REDACTED]

Name of Individual/Employee: [REDACTED]

Position on Study: [REDACTED]

(e.g., co-investigator, responsible clinician, research nurse, research coordinator or assistant, etc.)

- Is the individual a student or trainee (e.g., resident or fellow) working on the research to fulfill educational requirements? Yes  No

If Yes, name of educational institution: [REDACTED]

Name of Principal Investigator: [REDACTED]

**This form should be completed by the principal investigator for each individual (including the PI) working on the PVAMC portion of a study. If the study includes another research site in addition to the PVAMC, the answers below should only apply to those procedures conducted on VA time.**

**PROCEDURES:**

	Yes	No
1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.	<input type="checkbox"/>	<input type="checkbox"/>
2. Is knowledgeable of the informed consent process and is authorized to obtain informed consent from research subjects.	<input type="checkbox"/>	<input type="checkbox"/>
3. Administers questionnaires or conducts mental status or psychosocial exams.	<input type="checkbox"/>	<input type="checkbox"/>
4. Interacts with subjects by performing physical examinations or procedures.	<input type="checkbox"/>	<input type="checkbox"/>
If yes, describe the exam to be performed and list all procedures or attach pages from protocol that describe exams and/or procedures: [REDACTED]		
5. Provides education and instruction to subjects or relatives regarding details of study and, if applicable, study medication, including use, administration, storage, side effects and reporting adverse drug reactions to study site.	<input type="checkbox"/>	<input type="checkbox"/>
6. Prescribes and renews study medication.	<input type="checkbox"/>	<input type="checkbox"/>
If yes, complete the Prescription Authorization Form for this individual and submit it with this form. The form can be found at <a href="http://www.portland.va.gov/research/documents/irb/prescription-authorization.doc">http://www.portland.va.gov/research/documents/irb/prescription-authorization.doc</a>		
7. Has final responsibility for reviewing laboratory data and other entries in the	<input type="checkbox"/>	<input type="checkbox"/>



# *What's the Process?*

- Submit materials in eIRB
- Study gets a full pre-review by IRB Analysts at both institutions – expect communications with them requesting changes, corrections, etc.
- When the material is ready AND there's room on an IRB-3 agenda, it will be reviewed by the IRB.
- Single set of correspondence which includes changes requested for either institution will go to Research Team

## *Process, cont'd*

- Can receive approval from the institutions at different times – read correspondence carefully
- Review by additional VA Committees (such as the PO/ISO/R&DC) will take place automatically
- Once approval by all required bodies in place, final approval will be generated and sent out via eIRB
  - VA consent will be made available, etc.

# *Closing Thoughts*

- We're still working out the kinks
- Ask questions up front
  
- Who to contact:
  - Questions about completing VA forms:
    - Shari Maier, 503-220-8262, x54503, [Shari.Maier@va.gov](mailto:Shari.Maier@va.gov)
  - Questions about Agenda Availability/IRB Process:
    - Trish Lindstrom, 503-494-1021, [Lindstrp@ohsu.edu](mailto:Lindstrp@ohsu.edu)
  - Feedback/Questions on VA Forms, Policies:
    - Sola Whitehead, 503-402-2885, [Sola.Whitehead@va.gov](mailto:Sola.Whitehead@va.gov)



# Mark your calendars!

Next Brown Bag Session is  
**Consent Form Writing** with  
Wendy Doggett  
June 28<sup>th</sup> in MacDonald  
Auditorium

“A well-written consent form  
significantly increases the  
efficiency of IRB review.”

Visit our website for more  
information:  
[www.ohsu.edu/researchintegrity](http://www.ohsu.edu/researchintegrity)

