OHSU/VAPORHCS Joint IRB
By Trish Lindstrom and Anna Spece
The Backstory:

• Research done at both OHSU and VAPORHCS 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 was signed by OHSU and VAPORHCS (and blessed by lawyers and others far and wide...)
• Forms were created
• Procedures were developed and redeveloped
• Studies were 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 submission (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 the VA & OHSU – please submit a modification to OHSU to “add” the VA, once approved “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) a 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 – this is important – differs greatly on either side of the bridge
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 HIPAA Authorization (separately)

Follow the guidance on the “Preparing a Combined VA-OHSU Submission”
VAPORHCS-OHSU IRB

VA Portland Health Care System (VAPORHCS) now utilizes an OHSU IRB for studies conducted on both sides of the bridge!

For more information and instructions on the process please choose one of the following options:
Initial Submission
Continuing Review Submission

Initial Submission

The VAPORHCS-OHSU IRB (also known as OHSU IRB-3) reviews the following types of studies that are being conducted at both institutions:

1. Brand new submissions that are not yet active at either institution
2. Studies which are active at OHSU, and are adding the VA as a new site
3. Studies which currently have IRB approval at BOTH VAPORHCS and OHSU, and want to transition to a single review at OHSU

Please follow the applicable instructions (specific to the type of study) located in the "Preparing a Combined VA-OHSU IRB Submission" document.

In addition, depending on the type of study submission, one of the forms listed here will be required. Carefully review the instructions for which form should be used for your situation. This page only includes forms that are specific to joint VAPORHCS-OHSU IRB Submissions. Additional forms may be required, and hyperlinks to those forms are provided in the "Preparing a Combined VA-OHSU IRB Submission" document for easier access.

VA Supplemental Questionnaire (VASQ)
Preparing a combined VA-OHSU IRB submission

These instructions include guidance for three different types of submissions. Please be sure you follow the correct set of instructions, as this will affect how smoothly the study goes through the review process.

1. Guidance and Required Materials for brand new submissions that are not yet active at either institution

2. Guidance and Required Materials for studies which are active at OHSU and are adding the VA as a new site (no IRB approval exists at PVAMC)

3. Guidance and Required Materials for studies which are currently active at both OHSU and VA, and which are transitioning to a single IRB review

4. Guidance on adding personnel to a research study

This document also includes the following sections:
Increasing the Chances of a Quick Review Time
Tools and Resources available to you (in the event that these instructions do not provide enough guidance)

Guidance and Required Materials for brand new submissions (not yet active at either institution)

1. GATHER TOGETHER ALL THE REQUIRED DOCUMENTS (forms are hyperlinked)
In addition to the eIRB submission, all studies must have:
   - OHSU PPO (Proposed Project Questionnaire) – submitted as appropriate according to OHSU requirements
   - VA PPO – completed Word version uploaded into eIRB
     - If #4 is answered “YES,” complete the VA Financial Administrative Review
   - Abstract (per item 1 on the VA PPO) - sent to research.grants@va.gov
   - VA Supplemental Questionnaire (VASQ) –
     When complete, please either convert to a pdf document and have the PI sign

12/30/13
PORTLAND VA
Supplemental Questionnaire (VASQ)

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

Please complete & upload a word version of this form for all submissions which will be conducted at both OHSU and the VA. Separately upload the signed signature page. (Note: OHSU and/or VA IRB analysis 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: 

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

YES (skip to 3) NO N/A (no interventions, skip to 3)

2. If NO to 1, is the PI a clinician at the VAMC who can respond to emergencies experienced by participants, even if they do not have all applicable privileges listed above? NO YES

➢ If NO to 1 and NO to 2, a PVAMC licensed, credentialed, and privileged clinician must be identified as the "responsible clinician" for this study. That person should be listed in the table below, and must sign the last page of this application. If the responsible clinician is not the PI, the PI does not have privileges for all necessary components of the study, please also identify an appropriate co-investigator(s) in the table below.

➢ If NO to 1, but YES to 2, list an individual from each unit/specialty in which the PI does not have privileges in the staff table below.

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 assigned by the PI or the VA responsible clinician.
VA Consent

VA Informed Consent Form
Page 1 of 33

Subject Name: ___________________________ Date: ___________________________
Title of Study:

Principal Investigator: ___________________________ VAMC: 648 – Portland, OR

INSTRUCTIONS for this VA Informed Consent Form Template (Form 10-1086)

1. Once complete with preparing the informed consent form for a specific study, delete all instruction text, from “INSTRUCTIONS for this VA Informed Consent Form Template (Form 10-1086),” to the link for the HIPAA Authorization template. The consent form should begin with the heading “WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?”

2. Required items - All items in the template must be included in the Informed Consent Form (ICF) unless the instructions indicate otherwise (e.g. “required only if applicable”). Please do not change the order of the items in the template.

3. Entering text - In the body of the ICF, you may either: (1) type directly, (2) copy and paste text from another document, or (3) insert an existing text file. As new text is entered, new form pages will be created automatically to accommodate the added text. Any blank text within greater/less than symbols (<>) should be replaced with study-specific text and the symbols removed from the final ICF. All text in the final document should be black.

4. Note that, if this is a multi-site study, the consent form should only cover the PVAMC research activities (research conducted while on VA time, utilizing VA resources (e.g. equipment), or on VA property).

5. Remove instructions/Notes in red italics prior to submission to the IRB. Item numbering should also be removed (place the cursor within the numbered item and click on “numbering” on tool bar).

6. Page numbering - Page numbering is automatic.

7. Header and Footer - To complete the header and footer, select “View” in the toolbar at the top of your screen, then “Header and Footer.” Because the footer is different on page 1, a section break was required, which means that the header and footer need to be edited on both pages 1 and 2 for the information to be correct on all following pages. The ICF version date assigned by the PI (not the template version) must be indicated in the right hand side of the footer. Each change to the ICF, whether substantive or

Do NOT Change Anything below this line, including bottom margin. Study ICF Version Date: mm/dd/yyyy
Subject’s Identification (I.D. Plate or complete below)

LAST: __________ FIRST: __________ SSN(last 4 digits): __________

PVAMC Research Template Version Date: 08/28/2014
VA Form 10-1086
APR 1993
Appendix L – Scope of Work

For Office Use Only

Associate Chief of Staff, Research & Development
An electronic signature by the ACOS/R&D in this box indicates approval of the Scope of Work, and will be obtained by Research Administration Staff after submission by the PI.

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

Principal Investigator
Project Title:

Name of Employee:

Position/Role on Study

- Is the individual a student or trainee (e.g., resident or fellow) working on the research to fulfill educational requirements? Yes [ ] No [X]
  If Yes, name of educational institution

- Has the individual earned a new degree or obtained licensure or certification since the time they initially started working on PVAMC research? Yes [ ] No [ ] N/A – first study [ ]
  If Yes, please submit a revised Education Verification Form

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

PROCEDURES:

1. Screens patients to determine study eligibility criteria by reviewing patient medical information or interviewing subjects.

2. Is knowledgeable of the informed consent process and is authorized to obtain informed consent from research subjects for this study.

3. Provides education and instruction to subjects or relatives regarding details of study.

4. Administers questionnaires or conducts mental status or psychosocial exams.

5. Provides education and instruction to subjects or relatives regarding study medication, including use, administration, storage, side effects and reporting adverse drug reactions to study site.

6. Prescribes and renews study medication. (If Yes, this individual should be included on the Investigational Drug Information Record, VA Form 10-9012.)

7. Has responsibility for reviewing laboratory data and other entries in the medical record for the purpose of identifying possible adverse events.

8. Performs venipuncture.

   a. If yes, describe training and steps taken by PI to ensure competency:

10. Collects, organizes and/or analyzes documents/data outlined in the IRB-approved protocol.

11. Uses CPERS to:
   - enter research progress notes,
   - extract data specified by the IRB-approved protocol,
   - schedule return visits, and/or
   - order lab tests, etc. (if non-physician, requires written document from physician)
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 into the OHSU eIRB system and creating a new study submission. In the eIRB system, please begin the Short Title with the phrase “PVAMC/OHSU”.

When completing the eIRB 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 Submission (22KB, 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
C. If #4 is answered “YES”, complete the VA Financial Administrative Review
D. Abstract (per item 1 on the VA PPQ) - sent to research grants@va.gov
E. Lay Language Protocol Summary (Note: in some cases, such as retrospective chart review only, the Lay Language Protocol Summary may serve as the protocol and may be longer than 1 page.)
F. VA Supplemental Questionnaire (VASQ) (253KB, MSWord) – with signed assurances page uploaded into eIRB

II. 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: 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 purposes/aims, procedures, data collection, statistical analysis, sample size, measures to protect subjects' safety, etc.
2. Separate the VA activities/research from the OHSU activities/research – especially critical for studies that will combine VA and OHSU data

   a. “VA data” are data collected:
      i. By a VA investigator
      ii. On VA time
      iii. Under the portion of the protocol approved by PVAMC R&D Committee

   b. “OHSU data” are data collected:
      i. By an OHSU investigator
      ii. On OHSU time
      iii. Under the OHSU portion of the approved protocol

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3181 SW Sam Jackson Park Road L106-R1
Portland, OR 97239

www.ohsu.edu/researchintegrity
**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.
- A single set of correspondence which includes changes requested for either institution will go to Research Team
**Process, cont’d**

- You may potentially receive approval from the institutions at different times – read correspondence carefully
- There will be a review by additional VA Committees (such as the PO/ISAP/R&DC) – these reviews will take place automatically
- Once approval by all required bodies are in place, final approval will be generated and sent out via eIRB – VA consent will be made available, etc.
So what have we learned?

• We’re working on that, too. Survey analysts were hired.

• The survey has gone out – may go out again before final results are released.

• Early findings suggest.......
**Closing Thoughts**

- We’re still working out the kinks
- Ask questions up front

**Who to contact:**

- Questions about VA forms, policies:
  - Anna Spece, 503-220-8262, x53077, anna.spece@va.gov
- Questions about Agenda Availability/IRB Process:
  - Trish Lindstrom, 503-494-1021, Lindstrp@ohsu.edu
Thank you for joining us!

Mark your calendars!

Introduction to IRB 11/20 and again on 12/18.

Brown Bags will begin again next year.....

Visit our website for more information: www.ohsu.edu/researchintegrity