Institutional Profile

Site Name: Oregon Health & Science University

Last modified date: 08/30/2019

ABOUT THE INSTITUTIONAL PROFILE
The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance. This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website [here](#). This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.

******

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Oregon Health &amp; Science University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000161</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-08-21</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000471</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>No</td>
</tr>
<tr>
<td>Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>All biomedical specialties</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>HIPAA Authorization language is embedded in the uploaded Consent Form. The stand alone HIPAA Authorization form was also uploaded just to provide specific HIPAA language. But, at OHSU we use a combined Consent/HIPAA Authorization form.</td>
</tr>
</tbody>
</table>

Section 2: SITE-SPECIFIC LOCAL CONTEXT
This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization. Additional, study-specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements). However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).

To what state laws is your institution subject?

• OR

<table>
<thead>
<tr>
<th>Age of majority in your state?</th>
<th>18 except in circumstances detailed below</th>
</tr>
</thead>
<tbody>
<tr>
<td>What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment.</td>
<td>Laws Concerning Children or Minors A. Age of Majority (ORS 109.510, 109.520, 419B.550-558) i. The age of majority is 18 years in the State of Oregon. ii. All persons shall be deemed to have arrived at the age of majority upon their being married according to law or legally emancipated. B. Relation of Adopted Child to Adoptive Parents (ORS 109.050) i. Same relation in every respect pertaining to the relation of birth parent and child. ii. Treated as if the adopted child was the natural child of such parents. C. Medical or Dental Treatment (ORS 109.640) i. A minor 15 years of age or older may give consent to hospital care, medical or surgical diagnosis or treatment. ii. A hospital or any physician, nurse practitioner or dentist may advise the parent or legal guardian of any minor of the care, diagnosis or treatment or the need for any treatment, without the consent of the patient with regard to ORS 109.640 above. D. Treatment for Sexually Transmitted Infections (ORS 109.610) i. A minor who may have come in contact with any venereal disease may give consent to the furnishing of hospital, medical or surgical care related to the diagnosis or treatment of such disease, if the disease or condition is one that is required by law or regulation to be reported to the local or state health officer or board. E. Diagnosis or Treatment for Mental or Emotional Disorder or Chemical Dependency (ORS 109.675) i. A minor 14 years of age or older may obtain, without parental knowledge or consent, outpatient diagnosis or treatment of a mental or emotional disorder or a chemical dependency, excluding methadone maintenance. However, the parents of the minor must be involved by the end of treatment unless the parents refuse or unless there are clear clinical indications to the contrary. ii. The healthcare provider above may advise the parent or legal guardian of any minor</td>
</tr>
</tbody>
</table>
described in ORS 109.675 of the diagnosis or treatment if clinically appropriate and in the best interests of the minor's treatment (ORS 109.680). F. Educational/School Records (ORS 336.187) i. A public school or school district shall disclose personally identifiable information from an education record of a student in connection with a health or safety emergency if knowledge of the information is necessary to protect the health and safety of the student or other individuals. G. Wards of the Court i. If a judge finds that the child has been abused or neglected, or the child's behavior is beyond the parents' control, the child may be left in the parents' home under the supervision of CAF, removed to protective foster care, or become a ward of the court. ii. If a child becomes a ward of the court, this means that the parents have lost the right to discipline the child or control the child's education. Those responsibilities then go to the people with whom the child is placed.

Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule?

Yes

Please describe how long you are required to keep your records.

Our Policy (HRP-023) Section 2.3.21. indicates that IRB Records are retained indefinitely.

Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?

Yes, I will insert language in text box

Please insert the language required to be used around mandatory reporting to health authorities.

"OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments."

Does your site require a site-specific logo appear on consent forms and/or recruitment documents?

Yes

Please upload the logo

Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?

Yes

Does the site have a posted policy for the following?

• We do not have a posted policy for any of these

Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?

No

Please enter your specific consent form language regarding payment for research-related injury.

RESEARCH CONSENT FORM LIABILITY LANGUAGE
Please review the categories below and select the language applicable for your study. (NOTE: You may not modify the language in the liability section without
seeking the permission of the ORIO.) Cut and paste the appropriate language into your consent form. For questions, contact your IRB Specialist at 503-494-7887, Option 1, or the IRB Manager, David Holmgren, MS, at 503-346-3528 or the IRB Chair, Kathryn Schuff, MD, MCR, at 503-494-1685. For more information regarding research injuries, see: Liability Language - Payment for Subject Injuries. 1. Use for studies that are industry funded and meet one or more of the following: • Drug study conducted under IND or new use of marketed drug or Category A Device • Clinical trial with Category B device(s) • Clinical trial using non-research care with research procedures that would not otherwise be required for clinical care (e.g. CT scan or blood draw solely for research purposes) If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact [study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]. If you are injured or harmed by the [study drug(s), study device(s), or study procedures], you will be treated. Your medical treatment will be provided at no cost to you or your insurance company if the injury is directly caused by the [study drug(s), study device(s), or study procedures] and would not have been expected from the standard treatment for your condition, progression of your condition or other reasons. Any medical treatment you need for the standard treatment for your condition, progression of your condition, or other reasons will be billed to you or your insurance. OHSU and the funder do not offer any other financial compensation if you are injured or harmed as a result of participating in this research. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim. If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887. 2. Use for: • Industry funded clinical trial of a marketed drug or device used per labeling • Treatment use of an investigational drug or device, including expanded access use, compassionate use, and Humanitarian Use Devices • Investigator-designed study of a drug or device, regardless of level/type of support provided by industry • All non-industry sponsored research, including federally
funded (NIH and NIH subcontracts, cooperative oncology groups, OCTRI awards [not just services] • Unfunded research involving any physical risk If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact [study team info, if study involves physical risks that may be immediate provide a phone number that is available 24 hours a day]. If you are injured or harmed by the [study drug(s), study device(s) or study procedures], you will be treated. OHSU [and the funder, if applicable] [does/do] not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim. If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887. If federally funded, add the following statement: This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment. 3. Use for data collection only, regardless of funding: If you believe you have been injured or harmed as a result of participating in this data collection, contact [study team info]. OHSU and the funder do not offer any financial compensation or payment for the cost of any injury or harm. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim. If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.
appropriate language into your consent form. For questions, contact your Managing Analyst at 503-494-7887 or Melanie Hawkins at 503-494-8586. 1. If all costs will be the responsibility of the research subject, use the following language: You or your insurance company will be responsible for all costs related to participation in this study. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. When the costs to a subject for an experimental procedure are expected to be high, an estimate of those costs should be given and insurance pre-authorization is highly recommended. If subjects are compensated for participation in the study: Indicate how (i.e. one amount versus pro-rated per visit), the amount, and how the amount will be prorated if the subject withdraws before completing the study. If subjects will receive payment by a ClinCard debit card, include the following: You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. If subjects may receive >$600 within one year, please include the following statement: Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, OHSU is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS. 2. When some costs are part of regular treatment (standard of care) and will be billed to the research subject and some are for research purposes only and will be billed to the research study, use the following language: Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs. You will not be billed for the costs of any services or
procedures that are required by the study but are not considered part of your regular treatment. If subjects are compensated for participation in the study: Indicate how (i.e. one amount versus pro-rated per visit), the amount, and how the amount will be prorated if the subject withdraws before completing the study. If subjects will receive payment by a ClinCard debit card, include the following: You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. If subjects may receive >$600 within one year, please include the following statement: Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, OHSU is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS. 3. If there are no costs to the subject to participate in the study, use the following language: There will be no cost to you or your insurance company to participate in this study. If subjects are compensated for participation in the study: Indicate how (i.e. one amount versus pro-rated per visit), the amount, and how the amount will be prorated if the subject withdraws before completing the study. If subjects will receive payment by a ClinCard debit card, include the following: You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet. If subjects may receive >$600 within one year, please include the following statement: Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, OHSU is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS.

Please upload your template HIPAA Authorization language.
Do you have any additional HIPAA Authorization language template documents?  

**No**

**LOCAL CONTEXT: Component Sites**  
As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites here, in the Institutional Profile, and for specific studies, as requested by the Reviewing IRB. **If your component sites have information that differs from that provided in the previous section, specify the site and what differs below.**

Do you have a component site on your FWA?  

**No**

**Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.**

These steps occur BEFORE the study is approved by the Reviewing IRB:

How should an investigator request to cede review to an external IRB? For example, should they email the IRB? Is there a specific person at the IRB? Should they just submit the request via your local IRB system (as outlined in the questions below)?  

They submit an application in our eIRB system, and indicate that they want to waive to an external IRB. We require reliance requests in our eIRB application, but we don’t have an actual package to upload in this form.

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?  

**Yes**

Select all documents that must be submitted along with the reliance request package or reliance application

- Protocol
- Local consent form(s)
- Budget template
- Study contract
- Other

Please specify what other documents must be submitted  

Drug/device information Radiation safety form (if applicable) Funding Information (including grant) PPQ form HIPAA forms (if applicable)

These steps occur AFTER the study is approved by the Reviewing IRB: Indicate below what documentation and events are submitted to your local IRB when relying on an external IRB.

Should your investigator submit any of the following to your HRPP when ceding review to another institution? If checked, you will be asked to detail what should be submitted.

- Study-wide amendments (protocol or consent form modifications)
- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
### What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?

A modification application in the eIRB should be submitted and include copies of modified documents and copy of Lead IRB approval. Basically anything the Reviewing IRB reviews and approves that affects our required document set (i.e., protocol, consent forms, etc.), drug information, funding information, or the answers in the OHSU IRQ form, should be uploaded in our eIRB system, along with the external IRB approval letter(s). If the study is transitioned to the Revised Common Rule, this change should be submitted to us as well.

### What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?

A modification in the eIRB should be submitted and include all local amendment documents. Any documents that the study team chooses to upload should also be kept up to date. Local amendments should be made for:
- All personnel modifications
- Any modification that affects the required document set (i.e., protocol, consent forms, etc.), drug information, funding information, or the answers in the OHSU IRQ form.

### What should be submitted at continuing review?

A continuing review should be completed and submitted in the eIRB with a copy of the approval letter from Lead IRB. If the Reviewing IRB does not require Continuing Review (under the Revised Common Rule), a local compliance "check-in" will still be required for the local study team.

### What should be submitted for serious or continuing non-compliance?

All items that the Reviewing IRB has determined to be serious/continuing non-compliance need to be submitted to us.

### What should be submitted for unanticipated problems?

All items that the Reviewing IRB has determined to be unanticipated problems need to be submitted to us.

### What should be submitted for serious adverse events?

Study teams should submit all serious adverse events to the Reviewing IRB. Only submit to OHSU if directed by the Reviewing IRB.

### What should be submitted for adverse events?

Study teams should submit all adverse events to the Reviewing IRB. Only submit to OHSU if directed by the Reviewing IRB.

### What should be submitted for final reports?

Any final reports should be submitted to the Reviewing IRB. Only submit to OHSU if directed by the Reviewing IRB.
What else should be submitted to your HRPP when ceding review?  
Nothing additional to what is stated above.

Who at your institution should be contacted if a Lead IRB wishes to report an unanticipated problem, a determination of serious or continuing non-compliance, or a suspension or termination?

<table>
<thead>
<tr>
<th>Name</th>
<th>Kathryn Schuff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:schuffk@ohsu.edu">schuffk@ohsu.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(503) 494-1685</td>
</tr>
</tbody>
</table>

**Section 4: The Study-Specific Reliance Plan**  
The questions below have been harmonized with the [SMART IRB Agreement Implementation Checklist](#) and serve as your reliance preferences when serving as the IRB of record for other sites.

If you decide to serve as the Reviewing IRB in IREx, when you create the study, these preferences will appear as the basis for your SSRP. You may edit your responses for the study or for one (or more) sites, if requested, at your discretion.

Is your institution willing to serve as the IRB of Record for other institutions? If yes, more information on your reliance preferences/requirements will be collected below.

No