Institutional Profile

Site Name: University of Rochester

Last modified date: 07/18/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Rochester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00009386</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-02-04</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000462 (Board 01) IRB00001226 (Board 01 Prisoner) IRB00000463 (Board 02) IRB00000464 (Board 02 Prisoner) IRB00000465 (Board 03) IRB00000466 (Board 03 Prisoner) IRB00000467 (Board 04) IRB000001227 (Board 04 Prisoner) IRB000007740 (Board 05) IRB000007741 (Board 05 Prisoner)</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>Yes</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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>N/A</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- NY

Age of majority in your state? 18

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

1) The subject has married or is the parent of a child (occurs with the birth of a child). [NYS Law Section 2504]. 2) The subject is a minor participating in research for reproductive health services, such as birth control, emergency contraception, care for sexually transmitted diseases and HIV/AIDS. 3) The subject is a pregnant minor participating in research relating to prenatal care. 4) Parents who are minors may give permission for their own children to participate in research. 5) Minors over the age of 16 may, in some situations, consent to psychiatric treatment (If research is proposed that involves administration of psychotropic medication to minors over 16, or other psychiatric care without parent or guardian permission, the RSRB will consult the Office of Counsel.

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? No

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. The University of Rochester has a specific guideline for HIV testing. http://www.rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/GDL_HIV_Research.pdf

Does your site require a site-specific logo appear on consent forms and/or recruitment documents? No

Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects? No

Does the site have a posted policy for the following? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice

- Consent Process for those with Impaired Decision-Making Capacity
and guidance are not policy.

- Use of short forms for non-English speaking individuals
- Translation of consent forms for non-English speaking individuals

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.

Compensation for Injury (For greater than minimal risk studies only; this section may be omitted if the study involves no more than minimal risk.) If you are directly injured by the [drug(s) / device(s)] being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition. If your research injury is paid for by the University [or Sponsor], we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Please enter your specific consent form language regarding costs to participants to participate.

Costs Choose or modify ONE of the following sentences as appropriate to the specific study: There will be no cost to you to participate in this study. -OR- Some of the tests/procedures/exams [specify what tests/procedures/exams] you will receive are standard care. You and/or your insurance company will be responsible for paying for any tests/procedures/exams that are done as part of your standard care. You are encouraged to discuss your coverage with your insurance provider. If medications, tests and therapies are to be provided free as part of the study, please specify.

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)?

Investigators should contact the IRB, specifically Kristin Dauenhauer, Reliance Specialist.

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)

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.

- Serious or continuing non-compliance
- Unanticipated problems
- Other

What should be submitted for serious or continuing non-compliance? We would want to be very involved in anything that occurred at our local site that could be potentially serious or continuing non-compliance or an unanticipated problem. We would want information about that event, IRB minutes related to the situation, along with all documentation reviewed by the IRB related to the event. If the event is determined to be serious or continuing non-compliance we would want to review and provide comment on the letter BEFORE it is submitted to any regulatory agencies or funding agencies.
What should be submitted for unanticipated problems? We would want to be very involved in anything that occurred at our local site that could be potentially an unanticipated problem. We would want information about that event, IRB minutes related to the situation, along with all documentation reviewed by the IRB related to the event. If the event is determined to be an unanticipated problem we would want to review and provide comment on the letter BEFORE it is submitted to any regulatory agencies or funding agencies.

What else should be submitted to your HRPP when ceding review? We would want to be very involved in anything that occurred at our local site that might lead to a suspension or termination before it occurred. We would want information about that event, IRB minutes related to the situation, along with all documentation reviewed by the IRB related to the event. If the event causes a suspension or a termination we would want to review and provide comment on the letter BEFORE it is submitted to any regulatory agencies or funding agencies.

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?

Name: Kristin C. Dauenhauer
Email: Kristin_Dauenhauer@URMC.Rochester.edu
Phone Number: (585) 273-4577

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. Yes

STANDARD OPERATING PROCEDURES ("SOPs")
Using SMART IRB SOPs (recommended)

HIPAA DETERMINATIONS AND ACTIONS
If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to
use/disclose PHI (as specified below, if applicable).

<table>
<thead>
<tr>
<th>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</th>
<th>Reviewing IRB requires HIPAA authorization language to be incorporated into the informed consent documents, unless the Relying Institution obtains agreement from the Reviewing IRB to use a separate authorization form (e.g., separate form is required by State law or institutional policy). If the Relying Institution requires a separate authorization form, the Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule).</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONFLICTS OF INTEREST</td>
<td>Relying Institution(s) will perform conflict of interest analyses under their policies</td>
</tr>
<tr>
<td>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</td>
<td>Reviewing IRB will provide notifications directly</td>
</tr>
<tr>
<td>IRB-INITIATED AUDITS/INVESTIGATIONS</td>
<td>Reviewing IRB and Relying Institution(s) will jointly conduct any IRB-initiated audits or investigations</td>
</tr>
<tr>
<td>IRB-INITIATED EXTERNAL REPORTING</td>
<td>Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties</td>
</tr>
<tr>
<td>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</td>
<td>Reviewing IRB will review congruence</td>
</tr>
<tr>
<td>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</td>
<td>Reviewing IRB/Institution will not charge Relying Institution(s) for costs of review: The Relying Institution(s) will not be responsible for financial support of the costs of review of the identified study(ies). The Reviewing IRB may charge the sponsor or other third parties for those costs.</td>
</tr>
<tr>
<td>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</td>
<td>QA/QI program access required Each Participating Institution engaged in or conducting the identified study(ies) must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.</td>
</tr>
<tr>
<td>INSURANCE</td>
<td>Insurance required: Each Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified study(ies), including coverage of its IRB/IRB members when acting as a Reviewing IRB. (State/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.) Note: Participating Institutions may request</td>
</tr>
</tbody>
</table>
from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

<table>
<thead>
<tr>
<th>INDEMNIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>One or more Participating Institutions require an indemnification agreement: The Reviewing IRB and Relying Institution will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): The executed separate indemnification agreement(s) will be maintained on file with the Reviewing IRB.</td>
</tr>
</tbody>
</table>