Institutional Profile

Site Name: Rush University Medical Center

Last modified date: 07/26/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Rush University Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000482</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-05-21</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000530, IRB00000531</td>
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<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>Yes</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>Yes</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- IL

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

Illinois law and RUMC policy #OP-0029 allows for consent, rather than assent, for legally emancipated minors 16 years or older, minors who are married, and minors who are pregnant or are parents. Minor subjects who are pregnant or are parents can also consent to the participation of their fetus/child in research.

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.

[For studies involving HIV testing or hepatitis testing, include the following language]: "If we discover during the study that you have tested positive for a reportable infectious disease (HIV and/or hepatitis), we will be required to report such findings to the Illinois Department of Public Health, according to applicable Illinois laws. The study doctor will refer you to a doctor for counseling and treatment. The sponsor, [Insert Sponsor Name], will not cover the cost of this treatment or further care. This means that along with the test result, your personal information (name, birth date, phone number and address) will be released to the public health authorities."

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?

- Consent Process for those with Impaired Decision-Making Capacity
- Use of short forms for non-English speaking individuals
- Translation of consent forms for non-English speaking individuals

NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.
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. The contract drives the specific language that should be used on a case by case basis.

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

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)?

The Investigator is required to complete the Master Project in the Rush Research Portal as well as the XIRB application. At the same time, a reliance agreement should be requested via SMART IRB or the equivalent that allows us to review the specific request.

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely? No

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
- Serious adverse events

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent

Amendment approval letter from Lead IRB and all
form modifications) when ceding review?

approved documents associated with the amendment.

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

Personnel modifications pertaining to the local site (not quite sure what this question is asking).

What should be submitted at continuing review?

Continuing Review approval letter from Lead IRB and consent documents pertaining to the re-approval.

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

Would make that determination on a case-by-case basis. The Local PI should contact us first.

What should be submitted for serious adverse events?

We require that the local PI follow the Lead IRB’s policy on reporting SAEs. If the SAE involves a subject of the local PI, the local PI should contact us and allow us to make a determination. We do have an SAE policy in place but not a policy specifically for studies that use an external IRB.

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: John Cobb
Email: John_T_Cobb@rush.edu
Phone Number: (312) 942-6855

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