Institutional Profile

Site Name: University of Illinois at Urbana-Champaign

Last modified date: 10/21/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Illinois at Urbana-Champaign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00008584</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-10-18</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB #1 - 00000018; IRB #2 - 00007613</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>The UIUC IRBs review human subjects research protocols in accordance with applicable federal regulations, state and local laws, and university policies.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- IL

<table>
<thead>
<tr>
<th>Age of majority in your state?</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>What circumstances affect age of consent in your state?</td>
<td>Legal emancipation Minor who is the parent of a child may consent to the medical procedures on the child.</td>
</tr>
<tr>
<td>For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment</td>
<td></td>
</tr>
</tbody>
</table>

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.

- Abuse/Neglect Language: If you disclose actual or suspected abuse, neglect, or exploitation of a child or a disabled or elderly adult, the researcher or members of the study staff will report the information to Child Protective Services, Adult Protective Services, and/or a law enforcement agency.

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?

- 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.

- The University of Illinois does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois provide compensation for any injury sustained as a result of participation in this research study, except as required by law.

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 should submit the 'Single IRB Request form' to UIUC's reliance account irb-reliance@illinois.edu.

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)
- Study contract

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
- Serious adverse events
- Final report

What should be submitted for serious or continuing non-compliance? Serious or continuing non-compliance, unanticipated problems, significant participant complaints. Research teams may contact the IRB for guidance when non-compliance, unanticipated problems, or complaints occur.

What should be submitted for unanticipated problems? Serious or continuing non-compliance, unanticipated problems, significant participant complaints. Research teams may contact the IRB for guidance when non-compliance, unanticipated problems, or complaints occur.
What should be submitted for serious adverse events?

| What should be submitted for serious adverse events? | Serious or continuing non-compliance, unanticipated problems, significant participant complaints. Research teams may contact the IRB for guidance when non-compliance, unanticipated problems, or complaints occur. |

What should be submitted for final reports?

<table>
<thead>
<tr>
<th>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?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Email</td>
</tr>
<tr>
<td>Phone Number</td>
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**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.

<table>
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<th>Is your institution willing to serve as the IRB of Record for other institutions?</th>
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<td>No</td>
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</table>