Institutional Profile

Site Name: Indiana University Health

Last modified date: 03/23/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Indiana University Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00003566</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-04-04</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>N/A - Utilize Indiana University IRB</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institutions subject?
- IN

[Here](#)
### 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. Under Indiana law, a parent or guardian does not have to provide consent for a minor to participate in research in the following special circumstances:
- Minors who are at least 17 years old may donate blood without parental permission
- Minors who have, suspect they have, or have been exposed to a venereal disease may consent to research related to treatment.

### 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.

For studies involving individually identifiable health information (i.e., subject to HIPAA), Indiana state law requires retention of medical records for seven (7) years.

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

No

### 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?

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

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

Yes

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

If a source of funds for payment of treatment costs is NOT available, include the following statement: In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. If you have a government insurer, your insurer will not be billed and you may be responsible for those costs. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If a
source of funds for payment of treatment costs IS available, the source and conditions for payment of those costs should be identified.

| Please enter your specific consent form language regarding costs to participants to participate. | N/A |
| Please upload your template HIPAA Authorization language. | |
| Do you have any additional HIPAA Authorization language template documents? | Yes |
| Please upload additional template HIPAA Authorization language documents | |
| Please upload additional template HIPAA Authorization language documents | |

**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? Should they just submit the request via your local IRB system (as outlined in the questions below)? | Submit a Reliance Request to the IU IRB via KC IRB - see http://researchcompliance.iu.edu/hso/hs_reliancerequests.html |
| 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  
• Other |
| Please specify what other documents must be submitted | Standalone HIPAA authorization form  
Documentation of IRB approval |

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.

- Other

What else should be submitted to your HRPP when ceding review?

- The initial IRB-approved informed consent, assent, and HIPAA authorization documents
- PI and personnel changes
- Changes which require revisions to the HIPAA authorization
- Potential conflicts of interest, including institutional and potential financial interests, which could affect or be affected by the research
- Study closure

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>IU Human Subjects Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:irb@iu.edu">irb@iu.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(317) 274-8289</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