Institutional Profile

Site Name: University of Louisville

Last modified date: 04/04/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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.

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>University of Louisville</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00002211</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2019-08-07</td>
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<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
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<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000251 &amp; IRB00000252</td>
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<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>Yes</td>
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<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>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
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</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 However, any information provided in the IP will be superseded by information provided by the relying site.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?  
- KY

Age of majority in your state?  
18

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.  
If the study is testing for any diseases that require mandatory reporting, we ask that a statement is added to the ICF such as "This study involves testing for _______. If you have a positive test, we are required by Kentucky law to report the results to the local Health Department nearest where you live or to the Kentucky Department for Public Health."

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

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

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

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
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.

- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
- Final report

### 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 changes, Data Safety Monitoring Reports that indicate safety concerns (e.g. suspending treatment, placing enrollment on hold)

### What should be submitted at continuing review?

The continuing review application indicating local enrollment numbers, the reviewing IRBs continuation approval letter

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

The deviations/violations/misc form in iRIS

### What should be submitted for unanticipated problems?

The UPIRTSO form in iRIS

### What should be submitted for final reports?

Notification of study closure amendment form with local enrollment #

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**: Christy LaDuke  
**Email**: clpepp01@louisville.edu  
**Phone Number**: (502) 852-2541

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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.

**Yes**