Institutional Profile

Site Name: Saint Louis University

Last modified date: 04/02/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Saint Louis University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00005304</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-12-07</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000158, IRB00003984, IRB00005627</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>No</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>Boards constituted to review any research.</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?
- MO

<table>
<thead>
<tr>
<th>Age of majority in your state?</th>
<th>18</th>
</tr>
</thead>
</table>

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

In Missouri, a Minor may consent to medical treatment if married or in the case of pregnancy (excluding abortion), sexually transmitted infections, or substance abuse.

<table>
<thead>
<tr>
<th>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?</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Please upload the logo</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</th>
<th>No</th>
</tr>
</thead>
</table>

| 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 |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</th>
<th>Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Please enter your specific consent form language regarding payment for research-related injury.</th>
<th>You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor’s instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have questions, please call the Saint Louis University General Counsel’s office at 314-977-5767.</th>
</tr>
</thead>
</table>
Please enter your specific consent form language regarding costs to participants to participate.

To receive payment for participation in this study, you will be asked to provide your home address and social security number. If you receive $600 or more from Saint Louis University for participation in this research study (or a combination of studies) in one tax year, you will be sent an IRS Form 1099 for tax purposes. [Add if study involves university payment via ClinCard] Payments for taking part in this research study will be put onto a "ClinCard". ClinCard is managed by a company named Greenphire. Your personal information, such as your name, date of birth and social security number will be shared with Greenphire in order to put study payments onto the ClinCard. While the ClinCard is not a credit card, Greenphire may use your information like a credit card company would. You should review the terms and conditions of ClinCard when deciding whether to take part in this study.

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)?

For minimal risk studies: complete the IRB Reliance Agreement Determination Form and submit to the IRB at irb@slu.edu to initiate reliance on an external IRB. For more than minimal risk studies: contact IRB Director/Proxy at irb@slu.edu to ensure reliance will be accepted prior to completing IRB paperwork. If reliance is allowed, the SLU Submission Authorization Form and full central IRB reliance process will likely be required.
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)
- Other

Please specify what other documents must be submitted

HIPAA Authorization, which is separate from the consent form and should follow SLU template unless an exception was granted. IB or Device Manual is also requested for drug/device trials, and other materials as requested in the SLU Submission Authorization Form or IRB Reliance Determination Form.

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.

- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events
- 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?

Submit personnel modifications, changes to HIPAA Authorization, or changes to locally required language in the consent form to the local HRPP.

What should be submitted at continuing review?

Copy of the continuing review form submitted to Reviewing IRB.

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

All related materials that were submitted to the Reviewing IRB, and any related correspondence/determinations from the Reviewing IRB.

What should be submitted for unanticipated problems?

If it occurred at our site, all related materials that were submitted to the Reviewing IRB, and any related correspondence/determinations from the Reviewing IRB.

What should be submitted for serious adverse events?

If it occurred at our site, all related materials that were submitted to the Reviewing IRB, and any related correspondence/determinations from the Reviewing IRB.

What should be submitted for final reports?

Email that the study is closing/copy of central IRB final report.

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
Maureen Bresnahan

Email
irb@slu.edu

Phone Number
(314) 977-7744

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, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.

HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS
Reviewing IRB requires HIPAA authorization language to be incorporated into an authorization form separate from a consent form.: The Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule.

CONFLICTS OF INTEREST
Relying Institution(s) will perform conflict of interest analyses under their policies

IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)
Reviewing IRB will provide notifications through another party

NAME OF NOTIFYING PARTY
PI or delegate on the research team

IRB-INITIATED AUDITS/INVESTIGATIONS
Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis

IRB-INITIATED EXTERNAL REPORTING
Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties

CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS
Reviewing IRB will review congruence

FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately]
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.

### QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM("QA/QI")

| 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. |

### INSURANCE

| 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 from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage). |

### INDEMNIFICATION

| Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies). |