Institutional Profile

Site Name: Louisiana State University Health Science Center at Shreveport

Last modified date: 11/22/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Louisiana State University Health Science Center at Shreveport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000653</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-03-27</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000178 IRB</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>Yes</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>All</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- LA

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. 17

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 upload language in file

Please upload the language required to be used around mandatory reporting to health authorities.

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? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

- 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. Medical treatment for an injury or illness related to your participation in this study will be made available to you by LSU Health-Shreveport and Academic Medical Center at Ochsner LSU Health Shreveport and/or Monroe Medical Center at Ochsner LSU Health Shreveport. Generally, this care will be billed to you, your insurance, or other third party. We have no program to pay for medical care for research-related injury.

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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>Louisiana State U Hlth Sciences Ctr-Shreveport</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component. Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td>None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>No</td>
</tr>
</tbody>
</table>

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)?

Submit an application for IRB approval in the SHIELD5 system.

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
- Unanticipated problems
- Serious adverse events
- Adverse events
- Final report

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?

Approval letter from lead IRB and the revised documents. Tracked version, clean version and a
summary of changes. Consent form changes if applicable with tracked changes.

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 Modification - updated Delegation Logs, etc.

What should be submitted at continuing review? Approval letter from lead IRB and summary of study activities at the local site.

What should be submitted for serious or continuing non-compliance? Summary of events, resolution and corrective action plan.

What should be submitted for unanticipated problems? Summary of events and if related to the study.

What should be submitted for serious adverse events? Summary of the event

What should be submitted for adverse events? Summary of the event

What should be submitted for final reports? Summary of study activities.

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? Shweta Davalbhakta

Name
Email skhedl@lsuhsc.edu
Phone Number (318) 617-0736

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.

<table>
<thead>
<tr>
<th>CONFLICTS OF INTEREST</th>
<th>Relying Institution(s) will perform conflict of interest analyses under their policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</td>
<td>Reviewing IRB will provide notifications directly</td>
</tr>
<tr>
<td>IRB-INITIATED AUDITS/INVESTIGATIONS</td>
<td>Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis</td>
</tr>
<tr>
<td>IRB-INITIATED EXTERNAL REPORTING</td>
<td>Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis</td>
</tr>
<tr>
<td>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</td>
<td>Reviewing IRB will review congruence</td>
</tr>
<tr>
<td>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</td>
<td>Reviewing IRB/Institution will charge the Relying Institution(s) for costs of review: The Reviewing IRB and the Relying Institution(s) will enter a separate agreement or agreements under which the Relying Institution(s) will provide financial support to the Reviewing IRB for the costs of review of the identified study(ies)</td>
</tr>
<tr>
<td>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(“QA/QI”)</td>
<td>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.</td>
</tr>
<tr>
<td>INSURANCE</td>
<td>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).</td>
</tr>
<tr>
<td>INDEMNIFICATION</td>
<td>Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not</td>
</tr>
</tbody>
</table>
required with respect to the identified study(ies).