Institutional Profile

Site Name: Louisiana State University Health Science Center at New Orleans

Last modified date: 10/15/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Louisiana State University Health Science Center at New Orleans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00002762</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-02-21</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000177</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>LSUHSC-NO IRB members represent a variety of professions and disciplines to assure appropriate expertise is available to evaluate applications.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- LA

<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. | Louisiana does not have any statue related to consent and research. Because of this, minors cannot provide consent for themselves in a research context. Louisiana law, however, does allow minors to consent for their own medical treatment including the treatment of sexually transmitted diseases and drug abuse. |

| 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. | Records involving research with human subjects must be retained for 10 calendar years following the end of the calendar year in which the research projects is closed. |

| 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? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy. | - 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 any special formatting your IRB requires for HIPAA authorization forms? | For local enrolled subjects, the study team must use the LSU system approved HIPAA authorization. |

| Please enter your specific consent form language regarding payment for research-related injury. | The LSUHSC-NO consent form template includes the standard language below regarding RRI but the IRB will also accept any RRI language noted in the clinical |
trial agreement: The principal investigator will arrange for medical care for any emergency medical problem that you may experience as a direct result of your participation in this research. This will be provided on a fee-for-service basis. There {are/ are not} funds available to pay for any disability that results or for damages such as lost wages, etc.

Please enter your specific consent form language regarding costs to participants to participate.

The costs of all drugs, visits, procedures and study-related and unforeseen complications {(will be covered by the sponsor) / (must be met by the subject. The treatments required are felt to be a part of good medical care and are for the most part covered by most insurance companies.)} [If additional costs are to be incurred by participation in the study, the subject must be informed. If not, state the following.] Participation in this study will not result in any extra charges above and beyond those routinely incurred by patients with similar conditions.

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

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? Yes

What is the name of this component site? School of Graduate Studies

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.

- None

Do you have another component site on your FWA? Yes

What is the name of this component site? School of Allied Health Professions
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Site Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
<td>School of Dentistry</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
<td>School of Medicine</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
<td>School of Nursing</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td></td>
<td></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)?

The investigator should submit an External IRB Reliance application for IRB review and consideration.

**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

- A completed LSUHSC-NO HIPAA authorization form or Lead IRB waiver of HIPAA authorization
- Local recruitment documents
- Lead IRB letter of approval for the study (if available)

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.

<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study-wide amendments (protocol or consent form modifications)</td>
</tr>
<tr>
<td>• Local amendments (personnel modifications)</td>
</tr>
<tr>
<td>• Continuing review</td>
</tr>
<tr>
<td>• Serious or continuing non-compliance</td>
</tr>
<tr>
<td>• Unanticipated problems</td>
</tr>
<tr>
<td>• Final report</td>
</tr>
</tbody>
</table>

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

- Approval letter from the Lead IRB
- Any revised documents

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
- Title change
- Sponsor change
- Funding change
- Any modification to the protocol which would trigger a local ancillary review at LSUHSC-NO
- Approval letter from the Lead IRB

What should be submitted at continuing review?

For studies that require continuing review, the investigator should submit the renewal approval letter from the Lead IRB. For these studies and also studies that do not require continuing review, LSUHSC-NO will still conduct an annual administrative review to manage institutional requirements such as human subject protection and other training and COI disclosure.

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

After the Lead IRB has determined that the event at LSUHSC-NO meets the criteria for serious or continuing non-compliance, the LSUHSC-NO study team should submit a Reportable New Information (RNI) form and the Lead IRB’s determination letter.

What should be submitted for unanticipated problems?

After the Lead IRB has determined that the event at LSUHSC-NO meets the criteria for an unanticipated problem, the LSUHSC-NO study team should submit a Reportable New Information (RNI) form and the Lead IRB’s determination letter.

What should be submitted for final reports?

- A closure submission in IRBManager
- Closure notification from the Lead IRB
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  
Dr. Jawed Alam

Email  
jalam@lsuhsc.edu

Phone Number  
(504) 568-4970

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, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as specified below, if applicable).

HIPAA DETERMINATIONS AND ACTIONS: REVIEWING IRB ACTIONS  
When applicable, the Reviewing IRB will make determinations regarding partial and full waivers of HIPAA, as well as alterations. When LSUHSC-NO is the Reviewing IRB and the relying site typically uses a separate HIPAA authorization, the relying site retains oversight of the HIPAA authorization language.

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 directly

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

Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis

CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS

Reviewing IRB will review congruence

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

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)

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

One or more Participating Institutions require an indemnification agreement: The Reviewing IRB and Relying Institution will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): The executed separate indemnification agreement(s) will be maintained on file with the Reviewing IRB.