Institutional Profile

Site Name: Rhode Island Hospital

Last modified date: 10/31/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Rhode Island Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00001230</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-05-20</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>0000396, 00004624</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>Pediatric, oncology</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
provoked in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?
- RI

List other names by which your institution is known.
Lifespan, Rhode Island Hospital, Hasbro Children’s Hospital, EP Bradley Hospital, The Miriam Hospital, Newport Hospital, Gateway Healthcare

<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
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?
Yes

Please describe how long you are required to keep your records.
6 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?
Yes

Please upload the logo

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?
No

Please enter your specific consent form language regarding payment for research-related injury.
For studies that are greater than minimal risk - where a device/drug/treatment or intervention is part of the research. The following two paragraphs are required template language that cannot be edited. A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added
medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below. For externally sponsored clinical trials: • Insert description of how and to what extent Sponsor has agreed to cover research-related injuries, if applicable. During the contracting process, every effort should be made to get the Sponsor to agree to cover all research injuries, especially in cases where an investigational drug or device is involved. • Investigators should feel free to contact their representative from the Office of Research Administration - Grants and Contracts, or Clinical Trial Office for support in negotiating this point with the Sponsor. Lifespan prefers that Sponsors state upfront what they will cover in the case of subject injury; it is unacceptable for the Sponsor to say it will cover whatever expenses are not covered by insurance. To avoid delays in activating the study, the consent Language must be consistent with subject injury language in the clinical trial agreement. If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

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? Yes

What is the name of this component site? Hasbro Children's Hospital

Do you have another 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)?

Download and complete the Lifespan Reliance Request form from the IRBNet Forms & Templates Library. Send completed form to Alexandra Boutros, aboutros@lifespan.org. As a relying institution, an IRBNet package is not required until the approved study documents from the single IRB are available.

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

Any other study documents that will be used at Lifespan.

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? See Lifespan sIRB Investigator Checklist

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review? See Lifespan sIRB Investigator Checklist

What should be submitted at continuing review? See Lifespan sIRB Investigator Checklist

What should be submitted for serious or continuing non-compliance? See Lifespan sIRB Investigator Checklist

What should be submitted for unanticipated problems? See Lifespan sIRB Investigator Checklist
What should be submitted for serious adverse events? See Lifespan sIRB Investigator Checklist

What should be submitted for adverse events? See Lifespan sIRB Investigator Checklist

What should be submitted for final reports? See Lifespan sIRB Investigator Checklist

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: Alexandra Boutros
Email: aboutros@lifespan.org
Phone Number: (401) 444-6646

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 other SOPs (not otherwise mandated)

NAME OR DESCRIPTION OF ALTERNATIVE SOPs

Lifespan HRPP Manual

WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs

I will upload the SOPs

UPLOAD SOPs

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 the informed consent documents, unless the Relying Institution obtains agreement from the Reviewing IRB to use a separate authorization form (e.g., separate form is required by State law or institutional policy). If the Relying Institution requires a separate authorization 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
<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</strong></td>
<td>Reviewing IRB will provide notifications through another party</td>
</tr>
<tr>
<td><strong>NAME OF NOTIFYING PARTY</strong></td>
<td>Overall PI at Lifespan is responsible for communicating IRB outcomes to relying sites and relying IRBs</td>
</tr>
<tr>
<td><strong>IRB-INITIATED AUDITS/INVESTIGATIONS</strong></td>
<td>Reviewing IRB and Relying Institution(s) will jointly conduct any IRB-initiated audits or investigations</td>
</tr>
<tr>
<td><strong>IRB-INITIATED EXTERNAL REPORTING</strong></td>
<td>Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties</td>
</tr>
<tr>
<td><strong>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</strong></td>
<td>Another party will review congruence</td>
</tr>
<tr>
<td><strong>NAME OF PARTY THAT WILL BE RESPONSIBLE FOR REVIEW</strong></td>
<td>Lifespan Grants and Contracts</td>
</tr>
<tr>
<td><strong>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</strong></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><strong>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</strong></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><strong>INSURANCE</strong></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>
</tbody>
</table>
| **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.