Institutional Profile

Site Name: Women & Infants Hospital of Rhode Island

Last modified date: 02/13/2020

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Women &amp; Infants Hospital of Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00000056</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-05-13</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000746</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>OBGYN OB Medicine Pediatrics &amp; Neonatology Behavioral Health Urogynecology Pharmacy Maternal Fetal Medicine</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>We generally do not cede HIPAA review.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?  
- RI

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  
None

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.  
Investigators are to maintain records regarding a subject in conformance with the written study protocol. Subject records, either original or accurate reproductions, shall be maintained for at least 5 years, or longer, if required by the sponsor. In some cases, records are required to be held for a period of 23 years. HIPAA requires maintaining identifiable records for 6 years. (Note: Investigators are required to follow the strictest institutional policy that pertains to the study population.)

Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?  
Yes, I will upload language in file

Does your site require a site-specific logo appear on consent forms and/or recruitment documents?  
Yes

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

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.  
(INSTRUCTIONS: This section can be deleted if there is no more than minimal risk to subjects, unless there are medical procedures being performed (such as blood draws or imaging). 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 become ill or injured as a result of your participation in the study, you should seek medical treatment from your doctor or treatment center of choice. Doctors at the clinic or hospital can arrange for emergency medical care. You should promptly tell the researcher about any illness or injury. If you think you have been injured from taking part in this study, call [PI Name] at [(xxx)-xxx-xxxx]. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do. The Hospital does not offer financial compensation or payment for illness or injuries due to participation in this research. You and your insurance company will be billed for the costs of any care or injuries. In case of illness or injuries resulting from this study, you will not lose any legal rights by signing this form. (INSTRUCTIONS: If research sites in addition to WIH are described in this consent form, the IRB may modify the references to WIH to include reference to such other site(s).)

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

If subject will be receiving standard medical care/therapy while taking part in the study: While you are in this research study, the cost of your routine clinical care will be billed to you/your insurance company in the usual way. If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance. If you do not have insurance, you will be responsible for the costs of taking part in this study. WIH has programs to help uninsured and underinsured families see if financial assistance is available. If you need financial assistance, you can talk with a financial coordinator. Will there be any additional costs? If no additional costs: There are no study-related costs to you for taking part in this research study. Additional costs: Additional costs may include: [explain study-related costs. This information should match the costs and responsible parties outlined in the any other applicable documents.]

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>Women &amp; Infants Health Care Alliance, LLC</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:

The investigator will contact IRB Administration directly as soon as they are aware of a possible request for a reliance agreement. The study contact person will meet with the designated IRB Admin staff, via phone or in person, to facilitate the reliance process and determine the preferred system to be used to execute a reliance agreement between the involved parties. The investigator will submit a New Project package in IRBNet with documents noted in section below and the IRB Reliance Application Request. and the sIRB Local Procedures

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

The Women & Infants Hospital (WIH) investigator will submit a New Project package through IRBNet. The package will contain all documents approved by the Reviewing or single IRB (proposing WIH as relying), the ICF with local content and WIH HIPAA language, CNE Research Application, Reviewing IRB Approval
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.

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<tbody>
<tr>
<td>After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site’s sIRB approved documents before your site is activated/enrollment can begin?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 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? | Investigators will submit Amendment packages through IRBNet which include all revised documents impacted by the amendment (with revised version dates) and a WIH amendment form explaining the changes. The Reviewing IRBs approval letter, reflecting date of approval and noting any change in risk or requirement to notify participants of revisions. The package will be reviewed and acknowledged in accordance with the regulatory requirements of 45 CFR 46.114 for cooperative research. |
| What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review? | changes to KSP and Protocol Violations |
| What should be submitted at continuing review?                           | Reviewing IRB approval of continuation noting approval and expiration dates; approved ICF reflecting Reviewing IRB approval date and version date; copy of CR documents submitted to Reviewing IRB for review; WIH sRIB Study Status Report completed to reflect local site numbers; any other relevant documentation from the Reviewing IRB. The package will be reviewed and acknowledged in accordance with the regulatory requirements of 45 CFR 46.114 for cooperative research. |
| What should be submitted for serious or continuing non-compliance?       | WIH investigators are expected to follow institutional policy for reporting serious or continuing non- |

Letter which documents approval date, expiration date, risk level determination, and approval of subparts B, C, or D as applicable. The package will also include a completed Local Site Procedures form and IRB Reliance Application Request form.
compliance to the WIH IRB. The submission should include all correspondence between WIH investigator and Reviewing IRB regarding the issue(s).

What should be submitted for unanticipated problems?
WIH investigators are expected to follow institutional policy for reporting unanticipated to the WIH IRB. The submission should include all correspondence between WIH investigator and Reviewing IRB regarding the issue(s).

What should be submitted for serious adverse events?
WIH investigators are expected to follow institutional policy for reporting serious adverse to the WIH IRB. This includes events reported from other sites within the study. The submission should include all correspondence between WIH investigator and Reviewing IRB regarding the issue(s).

What should be submitted for adverse events?
WIH investigators are expected to follow institutional policy for reporting adverse to the WIH IRB. This includes events reported from other sites within the study. The submission should include all correspondence between WIH investigator and Reviewing IRB regarding the issue(s).

What should be submitted for final reports?
The WIH Investigator will submit a WIH Closure Report package in IRBNet which will include documentation from the Reviewing IRB regarding closure of the study across all sites or acknowledgment of study closure at WIH site. The package will be reviewed and acknowledged in accordance with the regulatory requirements of 45 CFR 46.114 for cooperative research.

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
Amber Latronica

Email
alatronica@wihri.org

Phone Number
(401) 274-1122 x42266

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. No