Institutional Profile

Site Name: Hennepin Healthcare Research Institute

Last modified date: 09/18/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Hennepin Healthcare Research Institute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00006047</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-11-01</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000203 00007957</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>Internal Medicine Obstetrics and Gynecology Emergency Medicine Pediatrics</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)
To what state laws is your institution subject?

- MN

List other names by which your institution is known.

Effective August 1, 2018, Minneapolis Medical Research Foundation (MMRF) was renamed Hennepin Healthcare Research Institute (HHRI)

Age of majority in your state?

18

What circumstances affect age of consent in your state?

Under Minnesota law, a minor who has a court appointed guardian may not receive experimental treatment of any kind without a court order. Minnesota law permits emancipated minors to give effective consent for any medical services. Emancipated minors are those living apart from their parents and managing their own affairs, minors who have been married, those who have borne a child, and those declared by a court to be emancipated. Also, minors may give effective consent without parental permission to receive services in connection with: pregnancy, sexually transmitted diseases, drug or alcohol abuse, Hepatitis B vaccination, and inpatient mental health care if the minor is age 16 or older. If a minor receives these services, including pregnancy testing, as part of a research study with parental/guardian consent, the study physician may not inform the parent or legal guardian of the treatment/testing information without the minor’s consent unless failure to do so would seriously jeopardize the health of the minor.

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 insert language in text box

In the event of a positive result for Hepatitis or HIV, reporting of the results to the Department of Health is mandatory. In the event of a positive pregnancy test with a positive screen for some drugs of abuse (not used for approved medicinal purposes), reporting of this information to the Hennepin County Child Protection Agency is mandatory.

Does your site require a site-specific logo appear on

No
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</td>
<td>No</td>
</tr>
<tr>
<td>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.</td>
<td>• We do not have a posted policy for any of these</td>
</tr>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>No</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>COMPENSATION AND MEDICAL TREATMENT FOR ANY STUDY-RELATED INJURY language may be omitted only if the IRB finds that the research involves no more than minimal risk to the subject. Template language: If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study doctor, [name and telephone number], day or night. Medical care for any study-related sickness or injury will be available to you at Hennepin Healthcare. Financial compensation for lost wages, disability, and discomfort is not routinely available. [See below - choose one option]. The cost of this medical care will be billed to you or your insurance company. OR [The Sponsor] will pay all medical costs needed to treat any research-related injury that your insurance does not pay. [The Sponsor] will pay for this only if you have followed the directions of the study doctor. [The Sponsor] does not offer any payment other than for medical costs for the research-related injury. OR [The Sponsor] will pay all medical costs needed to treat any research-related injury. [The Sponsor] will pay for this only if you have followed the directions of the study doctor. [The Sponsor] does not offer any payment other than for medical costs for the research-related injury.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding costs to participants to participate.</td>
<td>COSTS ASSOCIATED WITH THE RESEARCH STUDY [Explain who will pay for the costs of the research study.] Example: Neither you nor your insurance provider will be billed for the costs of any of the medicines (or procedures, or treatments) used just for this research study [i.e., Screening procedures, study drugs/devices/procedures, monitoring/follow-up procedures] explained earlier. You will be billed in the regular way for any medicine/procedures/treatments done as part of your routine medical care. OR You will not be billed for any of the medicines/procedures/treatments connected with this study.</td>
</tr>
</tbody>
</table>

Please upload your template HIPAA Authorization
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?  Hennepin County Medical Center

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?  No

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**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 Request for IRB Reliance form and supporting documentation to Hennepin Healthcare IRB

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

Hennepin Healthcare Resources and Utilization checklist; site-specific protocol supplement Note: localized informed consent form may be submitted separately after initial reliance is approved

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)

<table>
<thead>
<tr>
<th>What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?</th>
<th>any changes (addition/removal) of site personnel any changes to site-specific protocol or consent form</th>
</tr>
</thead>
</table>

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?

<table>
<thead>
<tr>
<th>Name</th>
<th>Jennifer Hart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:jhart@hhrinstitute.org">jhart@hhrinstitute.org</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(612) 873-6883</td>
</tr>
</tbody>
</table>

**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 |