Institutional Profile

Site Name: Allina Health HRPP

Last modified date: 05/01/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Allina Health HRPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00002425</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-06-22</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00001381</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>Our board primarily reviews biomedical studies, of neuroscience or cardiovascular nature. All industry sponsored clinical trials go to external IRB's.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- MN

List other names by which your institution is known.

Abbott Northwestern Hospital MINNEAPOLIS MN
Buffalo Hospital BUFFALO MN Cambridge Medical Center CAMBRIDGE MN Mercy Hospital-Mercy Campus COON RAPIDS MN New Ulm Medical Center NEW ULM MN Owatonna Hospital OWATONNA MN Phillips Eye Institute MINNEAPOLIS MN River Falls Area Hospital RIVER FALLS WI United Hospital ST. PAUL MN St. Francis Regional Medical Center SHAKOPEE MN Mercy Hospital - Unity Campus FRIDLEY MN Abbott Northwestern - WestHealth PLYMOUTH MN Regina Hospital Hastings MN District One Hospital Faribault MN Courage Kenny Rehabilitation Institute MINNEAPOLIS MN

Age of majority in your state?

18

What circumstances affect age of consent in your state?

According to Minnesota law, minors are persons under the age of eighteen. However, under Minnesota law, minors may provide consent for their own medical treatment for "Confidential Minor Services". Confidential Medical Services are those services for which a minor can give consent and the consent of a parent or other person is not required, including care related to pregnancy (including birth control), STDs, drug or alcohol dependency, hepatitis B vaccination, and admission of a 16 or 17-year-old for treatment of a mental illness. While no formal system exists in Minnesota for a judge to legally emancipate a minor, a minor living separately from parents or guardians, and managing his/her own financial affairs, may seek any medical treatment without the consent of a parent or guardian. This exception applies to a minor regardless of whether the minor's parents have consented to the minor living apart, or regardless of the extent or source of the minor's income. Minnesota law also allows minors who have been married or have given birth to seek treatment without the consent of parent or guardian for their own medical, mental, dental, or other health services or for services for the minor's child. Minnesota statute 144.343 addresses requirements for parental notification before a minor may undergo an abortion. Because Minnesota law
does not specifically address when minors may provide consent for research, the Allina Health HRPP applies the above standards to research involving medical care of treatment. When research does not involve medical care or treatment, the Allina Health HRPP defines children as persons who are under the age of eighteen and, unless specified otherwise, allows "emancipated" minors and minors who have been married or given birth to provide consent for their own participation, or their child's participation, in research not involving medical treatment. NOTE: For research conducted in jurisdictions other than Minnesota, the research must comply with the laws regarding the legal age of consent in the relevant jurisdictions. No consent may be given for experimental treatment of a child or children who is/are ward(s) unless it is first approved by an order of the court as set forth in Minnesota Statute 524.5-207.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>No</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>No</td>
</tr>
<tr>
<td>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</td>
<td>No</td>
</tr>
<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>Yes</td>
</tr>
<tr>
<td>Does the site have a posted policy for the following?</td>
<td>• 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</td>
</tr>
<tr>
<td>NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</td>
<td></td>
</tr>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please enter any special formatting your IRB requires for HIPAA authorization forms?</td>
<td>We can utilize a combined HIPAA, however exception needs to be made, and it needs to be reviewed by the Allina IRB office as part of its local context review.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>This must be reviewed by Allina's OSP office, the IRB does not have template language.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding costs to participants to participate.</td>
<td>This must be reviewed by Allina's OSP office, the IRB does not have template language.</td>
</tr>
<tr>
<td>Please upload your template HIPAA Authorization</td>
<td></td>
</tr>
</tbody>
</table>
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?

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)?

1) Request to cede via email or phone with IRB Manager or HRPP Director 2) May have a meeting with external IRB if needed or either has concerns. 3) Complete an IRBNet Submission following “External IRB Submission” Process 4) IRB office will review submission, and complete requirements from external/reviewing IRB. 5) Produce an acknowledgement letter and any other documentation in IRBNet and publish to study team when ready.

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
- Final report

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

Protocol and Consent Modifications only, documents submitted to external IRB, the updated material, and approval letter from reviewing IRB.
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 Amendments should be submitted in IRBNet utilizing external personnel submission form. Allina IRB will publish acknowledgement letter once training and COI have been completed.

What should be submitted at continuing review?

CR report submitted to reviewing IRB, reviewing IRB approval/action letter, project specific disclosure for PI (COI Review, and any updated CITI training.

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

The event report form that was submitted to the external/reviewing IRB within 7 working days of the event occurring, along with any documentation or acknowledgement from the reviewing IRB.

What should be submitted for unanticipated problems?

The event report form that was submitted to the external/reviewing IRB within 7 working days of the event occurring, along with any documentation or acknowledgement from the reviewing IRB.

What should be submitted for final reports?

The closure form submitted to the reviewing IRB and the closure letter/acknowledgement from the reviewing 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

Gayle Kusch

Email

gayle.kusch@allina.com

Phone Number

(612) 262-2512

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