Institutional Profile

Site Name: Advocate Health Care Network (Downers Grove)

Last modified date: 03/05/2019

**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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Advocate Health Care Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000472</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-11-27</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00001341 IRB00001824 IRB00001825 IRB00001342</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>Yes</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Pediatrics, Cardiology</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- IL

Age of majority in your state? 18

What circumstances affect age of consent in your state? Emancipated minor, Consent to Medical Treatment Consent by minor if married, parent, or victim of sexual assault (410 ILCS 210/1, et seq.

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

Please insert the language required to be used around mandatory reporting to health authorities. We report according to the law.

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.

- 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 any special formatting your IRB requires for HIPAA authorization forms? single space, should start on a new page, all on 1 page if possible

Please enter your specific consent form language regarding payment for research-related injury. No funds have been set aside by Advocate Health Care as compensation for research related injury or associated costs. You do not waive any of your legal rights by signing this form.

Please enter your specific consent form language regarding costs to participants to participate. [Include for research that may result in additional costs to the subjects. Otherwise state explicitly that there are no costs to the subjects or their insurance carrier if they participate.] Taking part in this research study may lead to added costs to you.
[Describe what these costs are.]

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

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)? Through IRBNet, contact Jasmine Taylor, we have Submission Guidelines that outlines the process

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
- 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? Modification form for amendments that revises the consent

What types of local amendments (e.g. personnel) will your investigator submit when ceding review? personnel, change of PI, local enrollment number,
modifications) should be submitted to the local HRPP and what should be submitted when ceding review?

<table>
<thead>
<tr>
<th>What should be submitted at continuing review?</th>
<th>reportable new information (HRP-214), delegation log, consent, IRB of record approval, CR form completed for IRB of Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>What should be submitted for serious or continuing non-compliance?</td>
<td>HRP-214, reportable new information, and any other supporting documents</td>
</tr>
<tr>
<td>What should be submitted for unanticipated problems?</td>
<td>HRP-214, reportable new information, and any other supporting documents</td>
</tr>
<tr>
<td>What should be submitted for serious adverse events?</td>
<td>HRP-214, reportable new information, and any other supporting documents</td>
</tr>
<tr>
<td>What should be submitted for adverse events?</td>
<td>HRP-214, reportable new information, and any other supporting documents</td>
</tr>
<tr>
<td>What should be submitted for final reports?</td>
<td>HRP-214, Closure letter from IRB of Record, and Final Report that was submitted to the IRB of record</td>
</tr>
</tbody>
</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>Jasmine Taylor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:jasmine.taylor2@advocatehealth.com">jasmine.taylor2@advocatehealth.com</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(630) 929-6151</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