Institutional Profile

Site Name: Cincinnati Children's Hospital Medical Center

Last modified date: 04/11/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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.

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Cincinnati Children's Hospital Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00002988</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2019-12-08</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IORG0000136</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>Pediatrics. We have one committee that contains members with expertise in many specialties, pediatrics, and adults.</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>We have only one board that meets weekly.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- OH

Age of majority in your state?

18 years

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

Ohio's age of consent is 18 years and older. Ohio does not have emancipated minor laws.

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.

It would need to be disclosed in the consent form if reportable disease testing is done for research purposes. The consent would need to state, "if you test positive for XXXX, it will be reported to the health department", or similar language.

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.

- 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?

none

Please enter your specific consent form language regarding payment for research-related injury.

If you believe that your child has been injured as a result of this research you should contact the Principal Investigator as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If your child goes to the Emergency Room or
to another hospital or doctor it is important that you tell them that your child is in a research study. If possible, you should give them a copy of this parental permission form. CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

Do you have any additional HIPAA Authorization language template documents?

Yes

Please upload additional template HIPAA Authorization language documents

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)?

Usually the site is invited to rely for a particular first from the lead site liaison to the research and IRB to 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

- Local consent form(s)
- Study contract
- Other

Please specify what other documents must be submitted

protocol specific application to rely site information sheet Smart IRB flexibility determination form staff log

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.

<table>
<thead>
<tr>
<th>What should be submitted for serious or continuing non-compliance?</th>
<th>In addition to the above, staff changes. The file will be updated annually at the time of continuing review approval in an amendment in the ePAS system to update all documents so that we have a fairly current file.</th>
</tr>
</thead>
<tbody>
<tr>
<td>What should be submitted for unanticipated problems?</td>
<td>If an event is unexpected and at least possibly related to the research, it must be reported to the IRB promptly.</td>
</tr>
<tr>
<td>What else should be submitted to your HRPP when ceding review?</td>
<td>any amendments that the site wishes to make on a local level (i.e. recruitment material, etc.)</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>Jeremy Corsmo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:jeremy.corsmo@cchmc.org">jeremy.corsmo@cchmc.org</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(513) 636-5449</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.

- **Yes**

**STANDARD OPERATING PROCEDURES (“SOPs”)**

- Using other SOPs (not otherwise mandated)

**NAME OR DESCRIPTION OF ALTERNATIVE SOPs**

- CCHMC SOPs

**WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs**

- I will upload the SOPs

**HIPAA DETERMINATIONS AND ACTIONS**

- If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as specified below, if applicable).
### 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 analyses under their policies.

### IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)
Reviewing IRB will provide notifications directly.

### IRB-INITIATED AUDITS/INVESTIGATIONS
Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis.

### IRB-INITIATED EXTERNAL REPORTING
Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties.

### CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS
Reviewing IRB will review congruence.

### FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]
Reviewing IRB/Institution will not charge Relying Institution(s) for costs of review: The Relying Institution(s) will not be responsible for financial support of the costs of review of the identified study(ies). The Reviewing IRB may charge the sponsor or other third parties for those costs.

### QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM("QA/QI")
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.

### INSURANCE
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).

**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.