Institutional Profile

Site Name: Children's Hospital of Alabama

Last modified date: 09/03/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Children's of Alabama</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00005810</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-11-07</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Children's of Alabama uses the University of Alabama at Birmingham (UAB) IRB. The UAB IRB has two IRB committees. Both are combined Social and Behavioral and Health Sciences/Biomedical. There is one meeting a week so the committees alternate the weeks they meet. Both can review all vulnerable populations and exception from informed consent. Both serve as central IRB for the Collaborative Antiviral Study Group (CASG), the National Dental Practice-Based Research Network (PBRN), and the Rett Syndrome, MECP2 Duplication, and Rett-Related Disorders Consortium (RTT Consortium).</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institutions subject?  
- AL

List other names by which your institution is known.  
N/A

Age of majority in your state?  
19

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. On May 7, 2015, the Governor signed Act 2015-167, which lowered the age of consent to 18 years old (previously 19 years) for IRB-approved research conducted by an accredited college or university. This means that 18 year olds may now consent for themselves to participate in research conducted at UAB under IRB approval. Additionally, the UAB IRB does not require parental consent if the potential participant is an "emancipated minor" and a minor who is the parent of a child who is a prospective participant in research being performed in Alabama may consent to research involving that child or infant (neonate).

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.  
IRB records are maintained indefinitely; however this policy is currently under review for change.

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.  
As part of this study, you will be tested for [specify disease/condition]. If the results show that you are positive for [specify disease/condition], the study staff will tell you the results. The study staff will be required to give your name to the Alabama Department of Public Health if you test positive because this is 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

**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?**

There are three options. If using the UAB HIPAA form, the document must be incorporated into the consent form as the last page of the document. The UAB HIPAA form may be a stand alone document, separate from the consent form. The UAB HIPAA language may be embedded into the consent form document.

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

UAB and Children’s of Alabama have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

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

N/A

**Please upload your template HIPAA Authorization language.**

**Do you have any additional HIPAA Authorization language template documents?**

Yes

**Please upload additional template HIPAA Authorization language documents.**

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**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

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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

An Institution Review Form and required documents must be submitted by the Children’s of Alabama investigator via the IRAP system.
submit the request via your local IRB system (as outlined in the questions below)?

| 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)

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)
• Continuing review
• Serious or continuing non-compliance
• Unanticipated problems
• Final report
• Other |

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?

Local amendments should include personnel changes and changes in funding.

What should be submitted at continuing review?

The continuing review approval document from the outside IRB and (if applicable) the newly stamped IRB approved consent form(s) should be submitted at continuing review.

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

Details of the serious or continuing non-compliance findings from the Board review.

What should be submitted for unanticipated problems?

Details of the unanticipated problems from the Board review.

What should be submitted for final reports?

Documentation from the outside IRB of the study closure (or site closure) should be submitted.

What else should be submitted to your HRPP when ceding review?

IRB approved study documents for use by the Children’s of Alabama study team.

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 | Lauren Tarpley, Regulatory Compliance Manager |
| Email | ltarpley@uab.edu |
| Phone Number | (205) 934-3789 |

**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.

<table>
<thead>
<tr>
<th>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.</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD OPERATING PROCEDURES (&quot;SOPs&quot;)</td>
<td>Using SMART IRB SOPs (recommended)</td>
</tr>
<tr>
<td>HIPAA DETERMINATIONS AND ACTIONS</td>
<td>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).</td>
</tr>
<tr>
<td>HIPAA DETERMINATIONS AND ACTIONS: REVIEWING IRB ACTIONS</td>
<td>The Reviewing IRB will make determinations as required by and in compliance with the HIPAA Privacy Rule for use and disclosure of PHI for the Research, including waivers of, or alternations of authorizations. If an authorization is required, the Reviewing IRB will determine the form of the authorization in collaboration with the Relying Institution(s). If the Relying Institution requires a separate authorization form, the Relying Institution shall be responsible for ensuring the authorization complies with the HIPAA Privacy Rule.</td>
</tr>
<tr>
<td>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</td>
<td>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.</td>
</tr>
<tr>
<td>CONFLICTS OF INTEREST</td>
<td>Relying Institution(s) will perform conflict of interest analyses under their policies</td>
</tr>
<tr>
<td>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</td>
<td>Reviewing IRB will provide notifications through another party</td>
</tr>
<tr>
<td>NAME OF NOTIFYING PARTY</td>
<td>Notifications may be made directly from the UAB IRB to a relying site IRB or notifications will be made from the UAB IRB to the Children’s of Alabama PI/study team for dissemination to relying sites.</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IRB-INITIATED AUDITS/INVESTIGATIONS</td>
<td>Relying Institution(s) will conduct any IRB-initiated audits or investigations</td>
</tr>
<tr>
<td>IRB-INITIATED EXTERNAL REPORTING</td>
<td>Relying Institution(s) will draft and submit reports to external recipients</td>
</tr>
<tr>
<td>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</td>
<td>Another party will review congruence</td>
</tr>
<tr>
<td>NAME OF PARTY THAT WILL BE RESPONSIBLE FOR REVIEW</td>
<td>IRB Staff will review Congruence.</td>
</tr>
<tr>
<td>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</td>
<td>Reviewing IRB/Institution will charge the Relying Institution(s) for costs of review: The Reviewing IRB and the Relying Institution(s) will enter a separate agreement or agreements under which the Relying Institution(s) will provide financial support to the Reviewing IRB for the costs of review of the identified study(ies)</td>
</tr>
<tr>
<td>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</td>
<td>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.</td>
</tr>
<tr>
<td>INSURANCE</td>
<td>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).</td>
</tr>
<tr>
<td>INDEMNIFICATION</td>
<td>Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).</td>
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