Institutional Profile

Site Name: Children's Hospital Orange County (CHOC)

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Children's Hospital Orange County (CHOC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000255</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-02-21</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00001166 IRB00004296</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>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 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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- CA

List other names by which your institution is known.

CHOC Children's CHOC Children's Mission Hospital

Age of majority in your state?

18

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.

In California, minors may consent to participation in research without parental or guardian permission if legally emancipated and in certain treatment circumstances. An "emancipated minor" may consent to participation in any type of research. In addition, for research involving treatment certain un-emancipated minors may consent to research involving specific types of medical treatment, including: • Outpatient mental health treatment for a minor 12 years or older when certain criteria are met, • Hospital, medical or surgical care related to prevention or treatment of pregnancy for minors (any age), • Medical care related to diagnosis/treatment of a communicable reportable disease or condition, • Hospital, medical or surgical care related to rape for a minor 12 years or older, • Hospital, medical or surgical care related to sexual assault but must attempt to contact parent/guardian unless reasonably believe involved, • Care for alcohol or drug abuse.

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?

No

Does your site require a site-specific logo appear on consent forms and/or recruitment documents?

Yes

Please upload the logo

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
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<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>California law requires HIPAA to be a separate document and in 14pt. font, preferably Arial Narrow.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>If your child is injured as a result of being in this study, CHOC will provide necessary medical treatment. The costs of the treatment may be covered by CHOC or billed to you or your insurer just like other medical costs, depending on a number of factors. CHOC and the study sponsor do not normally provide any other form of compensation for injury, such as loss wages, disability, or discomfort. For more information about this, you may call the Office of Research Compliance at (714) 509-8869 or by email at <a href="mailto:ORC@choc.org">ORC@choc.org</a>.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding costs to participants to participate.</td>
<td>Cost section of the consent needs to accurately reflect what costs will be covered by the study and what costs subjects are responsible for at both the reviewing site and at CHOC Children’s. Recommended language: WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY? [Option 1: If all costs will be the responsibility of the research subject, use the following language:] You or your insurance company will be responsible for all costs related to participation in this study. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, talk to your study team or contact your insurance company. [When the costs to a subject for an experimental procedure are expected to be high, an estimate of those costs should be given and insurance pre-authorization is highly recommended.] [Option 2: When some costs are part of regular treatment (standard of care) and will be billed to the research subject and some are for research purposes only and will be billed to the research study, use the following language:] Some of the services or items in this study are part of the regular treatment for your condition. These would be performed or used even if you were not in this study. The costs for these services or items will be billed to your insurance. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company. If you are uninsured, you will be responsible for these costs. You will not be billed for the costs of any services or procedures that are required by the study but are not considered part of your regular treatment. [Option 3:</td>
</tr>
</tbody>
</table>
If there are no costs to the subject to participate in the study, use the following language: There will be no cost to you or your insurance company to participate in this study. [Use this statement if applicable; elaborate if any resources are available to assist with these costs and any related process.] There may be out-of-pocket expenses such as parking and transportation fees.

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? 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. The investigator seeks approval from the CHOC Children’s Office of Research Compliance (ORC) to use an external IRB to serve as the IRB of Record and provide justification for reliance on the external IRB.
2. The ORC assesses whether an external IRB is qualified to serve as the IRB of Record for the CHOC Children’s human subject research project. 3. The ORC verifies that an appropriate reliance agreement is in place. If a reliance agreement is not in place, but is appropriate, the ORC will execute the proper reliance agreement.

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:
local context form/worksheet, all IRB approved materials including protocol, consent(s) and recruitment tools that will be utilized at CHOC Children'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

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 amendment including approval letter from the Lead IRB and applicable revised documents must be submitted to CHOC Children's Office of Research Compliance.

What should be submitted at continuing review?
Approval letter with expiration date and risk/benefit determination as applicable, from the Lead IRB and revised documents.

What should be submitted for serious or continuing non-compliance?
Report of serious or continuing non-compliance, determination from Lead IRB and any related correspondence.

What should be submitted for unanticipated problems?
Report of unanticipated problem, determination from Lead IRB and any related correspondence.

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?
Megan Bailey
mebailey@choc.org
(714) 509-7674

---

**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
No
reliance preferences/requirements will be collected below.