Institutional Profile

Site Name: Sharp HealthCare

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Sharp HealthCare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00000084</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-09-16</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IORG0000587</td>
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<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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Clinical trials</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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.

Sharp HealthCare, Sharp Mary Birch Hospital for Women & Newborns

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.

See link for all circumstances: [http://www.publichealth.lacounty.gov/dhsp/Providers/toolkit2.pdf](http://www.publichealth.lacounty.gov/dhsp/Providers/toolkit2.pdf) Please note: Sharp HealthCare may elect to not allow the inclusion of pregnant minors and/or minor mothers if maternal data is collected for the purposes of the research.

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?

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?

- Consent Process for those with Impaired Decision-Making Capacity
- Use of short forms for non-English speaking individuals

NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

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?

HIPAA authorizations must be at the end of the document, as CA Civil Code requires they be separate from any other consent language.

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

This will be completed internally prior to submission of the site-specific consent to UPitt IRB.

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

This will be completed internally prior to submission of the site-specific consent to UPitt IRB.

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

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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 submit the request via your local IRB system (as outlined in the questions below)?
  - The investigator submits an Application for Reliance on Non-SHC IRB to the SHC IRB office. This has already been submitted.

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)
- Budget template
- Study contract

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:

- After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site’s SIRB approved documents before your site is activated/enrollment can begin?  
  - Yes

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
- Serious adverse events
- Adverse events
- Final report
- Other

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP

Research team updates and addition/removal of any
and what should be submitted when ceding review? | SHC research sites.
---|---
What should be submitted at continuing review? | SIRB continuation approval letter.
What should be submitted for serious or continuing non-compliance? | Context dependent
What should be submitted for unanticipated problems? | HRP-214 and supporting documentation
What should be submitted for serious adverse events? | HRP-214 (only for reportable SAEs, per HRP-214).
What should be submitted for adverse events? | HRP-214 (only for reportable AEs, per HRP-214).
What should be submitted for final reports? | SIRB Final Closure Acknowledgement
What else should be submitted to your HRPP when ceding review? | Any issues related to a breach of confidentiality

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 | Rita Taylor, IRB Specialist
Email | research@sharp.com
Phone Number | (858) 939-7161

**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>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>No</td>
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</tbody>
</table>