Institutional Profile

Site Name: St. Jude Children's Research Hospital

Last modified date: 01/30/2020

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>St. Jude Children's Research Hospital, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00004775</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-07-24</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB#00000029 IRB#00000030</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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Pediatrics Oncology Hematology Infectious Diseases</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- TN

Age of majority in your state? 18

What circumstances affect age of consent in your state? Only adults 18 years and older and emancipated minors can consent.

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. Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

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
- 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 your specific consent form language regarding payment for research-related injury. If you have any questions about this study or if you are injured because of this study, contact Dr. [__________________], at 901-595-3300 immediately. If you are injured from being in this research study, St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate. It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or
discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

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

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future. At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care not covered by your health insurer. This includes research-only costs. Research-only tests and procedures (such as optional biopsy or blood samples for biomarker testing) will not be billed to you or your health care insurer.

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?**

Email Office of Human Subjects Protection and request to cede to an external 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

- Protocol
- Other
<table>
<thead>
<tr>
<th>Please specify what other documents must be submitted</th>
<th>Completed &quot;Request to Cede IRB Review to an External IRB Intake Form&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>Yes</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
- 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? | The IRB amendment application, the IRB approval letter, informed consent document(s) with updated IRB approval and expiration dates, and all associated documents under that amendment. |
| What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review? | The local amendment application, summary of changes memo, and any other revised documents. |
| What should be submitted at continuing review? | The continuing review application, the IRB approval letter, informed consent document(s) with updated IRB approval and expiration dates and any other revised documents. |
| What should be submitted for serious or continuing non-compliance? | The IRB application and all pertinent documents for the serious or continuing non-compliance issue. |
| What should be submitted for unanticipated problems? | The IRB application, and all pertinent documents for the unanticipated problem. |
| What should be submitted for serious adverse events? | The IRB application, and all pertinent documents for the serious adverse event. |
| What should be submitted for adverse events? | The IRB application, and all pertinent documents for the adverse event. |
| What should be submitted for final reports? | The IRB application, and all pertinent documents for the final report. |
| 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? | |
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.

| 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 SMART IRB SOPs (recommended)

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

Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis

CONGRUENCE OF FEDERAL GRANT

Reviewing IRB will review congruence
### APPLICATIONS/CONTRACT PROPOSALS

#### 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.