Institutional Profile

Site Name: University of Arizona

Last modified date: 02/27/2020

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

********

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>The University of Arizona</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00004218</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-04-11</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000291</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>Cancer, Medicine and Social Behavioral</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>We are a land-grant university with a comprehensive cancer center and academic medical center.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- AZ

### Age of majority in your state?

18

### What circumstances affect age of consent in your state?

Emancipated minors

For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment

### 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.

6 years

### 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?

- 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

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

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

### 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)?

All ceded reviews require that the local PI submit the Application for Human Research to the local IRB before submitting to the reviewing IRB. Investigators should check the box for "Ceding Review, complete the application, and submit to the UA IRB for verification of local requirements.

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)
- Study contract
- Other

Please specify what other documents must be submitted

Training documents, radiation safety review, research intake form (if using hospital partner), SRC review (if study is a cancer study), COI determination, global travel (if study involves international travel)

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? No

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
- Investigators should submit the 'amendment of human research' form with the 'notify IRB' box checked. Submit supporting documenting submitted to reviewing IRB. Submit promptly.

### Final report
- Copy of final report for our files.

#### What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?
- PI changes and local protocol amendments specific to our site only should be submitted if a project is ceded. Submit copy of approval letter and submission materials from Lead IRB. This is for our documentation only so we can update our records.

#### What should be submitted at continuing review?
- Approval letter and continuing review documentation from Lead IRB

#### What should be submitted for serious or continuing non-compliance?
- Investigators should submit the 'amendment of human research' form with the 'notify IRB' box checked. Submit supporting documenting submitted to reviewing IRB. Submit promptly.

#### What should be submitted for unanticipated problems?
- Investigators should submit the 'amendment of human research' form with the 'notify IRB' box checked. Submit supporting documenting submitted to reviewing IRB. Submit promptly.

#### What should be submitted for serious adverse events?
- Investigators should submit the 'amendment of human research' form with the 'notify IRB' box checked. Submit supporting documenting submitted to reviewing IRB. Submit promptly.

#### What should be submitted for final reports?
- Copy of final report for our files.

### 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>Christine Melton-Lopez</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:melton1@email.arizona.edu">melton1@email.arizona.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(520) 626-8630</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
<table>
<thead>
<tr>
<th><strong>STANDARD OPERATING PROCEDURES (&quot;SOPs&quot;)</strong></th>
<th>Using SMART IRB SOPs (recommended)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIPAA DETERMINATIONS AND ACTIONS</strong></td>
<td>If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.</td>
</tr>
<tr>
<td><strong>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</strong></td>
<td>Reviewing IRB requires HIPAA authorization language to be incorporated into an authorization form separate from a consent 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><strong>CONFLICTS OF INTEREST</strong></td>
<td>Relying Institution(s) will perform conflict of interest analyses under their policies</td>
</tr>
<tr>
<td><strong>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</strong></td>
<td>Reviewing IRB will provide notifications through another party</td>
</tr>
<tr>
<td><strong>NAME OF NOTIFYING PARTY</strong></td>
<td>The Reviewing IRB local PI or designee</td>
</tr>
<tr>
<td><strong>IRB-INITIATED AUDITS/INVESTIGATIONS</strong></td>
<td>Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis</td>
</tr>
<tr>
<td><strong>IRB-INITIATED EXTERNAL REPORTING</strong></td>
<td>Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis</td>
</tr>
<tr>
<td><strong>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</strong></td>
<td>Another party will review congruence</td>
</tr>
<tr>
<td><strong>NAME OF PARTY THAT WILL BE RESPONSIBLE FOR REVIEW</strong></td>
<td>Local Research Administration Office will review grants and contracts as applicable</td>
</tr>
<tr>
<td><strong>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</strong></td>
<td>QA/QI program access not required: Participating Institutions engaged in or conducting the identified study(ies) are not required to have or have access to a human subjects research QA/QI program or service.</td>
</tr>
<tr>
<td><strong>INSURANCE</strong></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</td>
</tr>
</tbody>
</table>
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.