Institutional Profile

Site Name: Maricopa County Special Health Care District (Valleywise Health)

Last modified date: 06/20/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Maricopa Integrated Health System IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00003087</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-09-22</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00002620 IRB00000128 IRB00005065</td>
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<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>Burn, Surgery and Trauma Emergency Medicine Ob/Gyn Pediatrics Internal Medicine Behavioral Health</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?  
- AZ

List other names by which your institution is known.  
Maricopa County Special Health Care District dba Maricopa Integrated Health System

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. Arizona law permits minors to get medical treatment for STDs, contraception, and drug abuse treatment without a parental 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?  
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?  
No

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
- 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 any special formatting your IRB requires for HIPAA authorization forms?  
Our IRB requires below 9th grade readability on HIPAA and ICF as measured by Flesch-Kincaid.

Please enter your specific consent form language regarding payment for research-related injury.  
There is not specific wording required, but the IRB mandates that the form specifies that the patient does not pay for treatment of research related injuries and that the sponsor is not the party that makes the decision about whether or not an injury is research related.

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)?

Requests need to be submitted through our local IRB System. Correspondence or questions can be sent to the email address: irb@mihs.org.

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?  
No

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.

- Study-wide amendments (protocol or consent form modifications)
- Serious or continuing non-compliance
- Unanticipated problems
- Serious 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 amended document and a tracked changes copy or an explanation of what was amended.

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

Deviation form in our electronic system should be completed.

What should be submitted for unanticipated problems?

Administrative review form in our electronic system.

What should be submitted for serious adverse events?

Adverse Event form in our electronic system should be completed.

What should be submitted for final reports?

Final Report should be completed in our electronic system.
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>Carla Pauley, IRB Administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:carla.pauley@mihs.org">carla.pauley@mihs.org</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(602) 344-2751</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.

<p>| <strong>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.</strong> | Yes |
| <strong>STANDARD OPERATING PROCEDURES (“SOPs”)</strong> | Using SMART IRB SOPs (recommended) |
| <strong>HIPAA DETERMINATIONS AND ACTIONS</strong> | If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions. |
| <strong>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</strong> | 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). |
| <strong>CONFLICTS OF INTEREST</strong> | Relying Institution(s) will perform conflict of interest analyses under their policies |
| <strong>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</strong> | Reviewing IRB will provide notifications directly |
| <strong>IRB-INITIATED AUDITS/INVESTIGATIONS</strong> | Relying Institution(s) will conduct any IRB-initiated audits or investigations |
| <strong>IRB-INITIATED EXTERNAL REPORTING</strong> | Reviewing IRB will draft and submit reports to external recipients |
| <strong>CONGRUENCE OF FEDERAL GRANT</strong> | Reviewing IRB will review congruence |</p>
<table>
<thead>
<tr>
<th>APPLICATIONS/CONTRACT PROPOSALS</th>
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<tbody>
<tr>
<td><strong>FINANCIAL AGREEMENTS</strong> [For review costs - indemnification agreements are addressed separately below]</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 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><strong>INDEMNIFICATION</strong></td>
<td>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.</td>
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