Institutional Profile

Site Name: University of Colorado, Denver

Last modified date: 12/16/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Colorado Denver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00005070</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2018-11-25</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000650, IRB00000651, IRB00002760, IRB00006846, IRB00010162</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>Pediatric (Panel C); High risk (Panel D), Social/Behavioral (Panel S)</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?  
- CO

List other names by which your institution is known.  
NA

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 and for birth control

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

What happens if I am injured or hurt during the study?  
Plans for injury and compensation must be included for research involving more than minimal risk, do not include if the study is minimal risk. PLEASE NOTE: The wording that is submitted in the consent form should remain AS IS if accompanied by an approval email from University of Colorado Denver. Add the following text as the first paragraph of the section: If you have an injury while you are in this study, you should call [insert name] immediately. [His/her] phone number is [insert phone number]. Option 1: We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care. OR Option 2: If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a
research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

Please enter your specific consent form language regarding costs to participants to participate.  see upload also applies to HIPAA

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)?

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.

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.

- Study-wide amendments (protocol or consent form modifications)
- Local amendments (personnel modifications)
- Continuing review
Serious or continuing non-compliance

Unanticipated problems

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?

When they impact the local conduct of the study

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?

When they impact the local conduct of the study This does not include changes to study staff beyond the PI, co-Is and primary contact

What should be submitted at continuing review?

A copy of what was reviewed and approved by your IRB as well as the ongoing approval letter

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

A copy of what was reviewed by your IRB and the outcome of that review

What should be submitted for unanticipated problems?

A copy of what was reviewed by your IRB and the outcome of that review

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?

Deborah Barnard
deborah.barnard@ucdenver.edu
(303) 724-7628

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

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).

<table>
<thead>
<tr>
<th>CONFLICTS OF INTEREST</th>
<th>Relying Institution(s) will perform conflict of interest analyses under their policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</td>
<td>Reviewing IRB will provide notifications directly</td>
</tr>
<tr>
<td>IRB-INITIATED AUDITS/INVESTIGATIONS</td>
<td>Relying Institution(s) will conduct any IRB-initiated audits or investigations</td>
</tr>
<tr>
<td>IRB-INITIATED EXTERNAL REPORTING</td>
<td>Reviewing IRB will draft and submit reports to external recipients</td>
</tr>
<tr>
<td>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</td>
<td>Reviewing IRB will review congruence</td>
</tr>
<tr>
<td>FINANCIAL AGREEMENTS [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>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</td>
<td>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.</td>
</tr>
<tr>
<td>INSURANCE</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>
</tbody>
</table>
Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).