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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Creighton University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00001078</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-06-05</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000155 Creighton U IRB #1 - Biomedical IRB00007137 Creighton U IRB #2 - Social Behavioral</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>We have Board members with representative capacities of women, children, psychology, economically disadvantaged populations, men, minorities, dentistry, nutrition, community perspectives, ethical considerations, Jesuit perspective, patient care, physicians, pharmaceuticals, geriatrics, osteoporosis, endocrinology and patient safety.</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>Creighton University is not a covered entity but does</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 institutions subject?

- NE

Age of majority in your state?

19

What circumstances affect age of consent in your state? Persons who are 18 may consent to mental health services. Minors of any age may consent to receive tests and treatment for sexually transmitted diseases.

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?

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?

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? 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?

Yes

Please enter your specific consent form language regarding payment for research-related injury. The investigator(s) will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care at the usual
charge. The costs of this care (that are not covered by the sponsor) will be charged to you or to your health insurer. No funds are available from Creighton University (or) CHI-Health to repay you or compensate you for a study-related injury or illness. There is also no compensation available for payment of your lost wages or other losses. By signing this consent form, you will not be waiving any of your legal rights that you otherwise would have as a participant in a research study.

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

Additional Costs to the participant • Explain any additional expenses that participants (or their third-party payers) may incur from any source (including health care providers who are not researchers) as a result of participating in the study. • When necessary, indicate that some care might not be covered by insurance.

Please upload your template HIPAA Authorization language.

Do you have any additional HIPAA Authorization language template documents? Yes

Please upload additional template HIPAA Authorization language documents.

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)?

The PI should communicate with the IRB staff and submit the request via our local IRB system (InfoEd).

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)
- Other

Please specify what other documents must be submitted

Reviewing IRB approval documentation.

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.

- Final report

What should be submitted for final reports?

The Creighton University IRB Termination application should be submitted in the electronic system as well as a final study report summarizing results, findings, AEs/SAEs, etc.

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: Brooke Fitzpatrick
Email: bfitzpatrick@creighton.edu
Phone Number: (402) 850-5092

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 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. |
| 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 | Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties |
| CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS | Reviewing IRB will review congruence |
| 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.