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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

Institution: Drexel University

Federalwide Assurance (FWA) #: FWA#00005917

FWA Expiration Date: 2022-01-24

Does your institution have an internal IRB? Yes

IRB Registry Number(s): IRB00000696 IRB00002796 IRB00000698

Is the IRB AAHRPP accredited? Yes

Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)? It depends

Describe any board specialties of your IRB: Experience with prisoners, pregnant women, children, people with disabilities, people who are economically disadvantaged, people who are cognitively impaired

Is your institution a covered entity? Hybrid

Additional Comments: If an investigator requests a reliance with an institution that is not AAHRPP accredited, an External IRB Qualifications Form is requested from the proposed reviewing IRB. A determination is then made whether the Drexel IRB is willing rely on the proposed reviewing IRB.
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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?
- PA

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

71 P.S. § 1690.112.112 Notwithstanding any other provisions of law, a minor who suffers from the use of a controlled or harmful substance may give consent to furnishing of medical care or counseling related to diagnosis or treatment. The consent of the parents or legal guardian of the minor shall not be necessary to authorize medical care or counseling related to such diagnosis or treatment.

35 P.S. § 10101 Any minor who is eighteen years of age or older, or has graduated from high school, or has married, or has been pregnant, may give effective consent to medical, dental and health services for himself or herself, and the consent of no other person shall be necessary.

35 P.S. § 10101.1 Any minor who is fourteen years of age or older may consent on his or her own behalf to outpatient mental health examination and treatment, and the minor's parent's or legal guardian's consent shall not be necessary.

35 P.S. § 10102 Any minor who has been married or has borne a child may give effective consent to medical and health services for his or her child.

35 P.S. § 10103 Any minor may give effective consent for medical and health services to determine the presence of or to treat pregnancy, and venereal disease and other diseases reportable under the act of April 23, 1956 (P.L. 1510), known as the "Disease Prevention and Control Law of 1955," and the consent of no other person shall be necessary.

35 P.S. § 10104 Medical, dental and health services may be rendered to minors of any age without the consent of a parent or legal guardian when, in the physician's judgment, an attempt to secure consent would result in delay of treatment which would increase the risk to the minor's life or health.
Pa.C.S.A. § 3206 Except in the case of a medical emergency, or except as provided in this section, if a pregnant woman is less than 18 years of age and not emancipated, or if she has been adjudged an incapacitated person under 20 Pa.C.S. § 5511 (relating to petition and hearing; independent evaluation), a physician shall not perform an abortion upon her unless, in the case of a woman who is less than 18 years of age, he first obtains the informed consent both of the pregnant woman and of one of her parents; or, in the case of a woman who is an incapacitated person, he first obtains the informed consent of her guardian.

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.

Seven years for HIPAA-related information (Adults)
Seven years after the youngest subject has turned 18 (Pediatric) Three years for other human subjects research records

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?

• We do not have a posted policy for any of these

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? None

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

If you become ill during this study, please contact Dr. [name] at telephone no. (XXX) XXX-XXXX. If you require immediate medical attention, you should go to the nearest emergency room or call 9-1-1. It is important that you inform all emergency medical staff that you are participating in this study. If a "research-related injury" results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A "research-related injury" means injury caused by the
product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition. The university and hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital. It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced. There are no plans to pay you for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this research study. If you are injured or have an adverse reaction, you should also contact the Human Research Protection Program at 215-762-3944.

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

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered "standard of care" and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges. Your health insurance company may not pay for these "standard of care" charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay. Select the most appropriate language if either is involved: You [will or will not] be charged for the study [drug or device]. So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the 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? Yes
What is the name of this component site? Drexel U College of Medicine
Do you have another 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 request should be submitted via the local IRB system.

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
- Reliance Request Form
- Conflict of Interest Disclosure Forms
- Study documents which will be used by Drexel investigators, e.g., recruitment materials, surveys, etc.
- If the study itself has been approved by the reviewing IRB, the Drexel investigator should submit the reviewing IRB's initial approval letter or most recent continuing review approval
- When it becomes available, the reviewing IRB's amendment approval letter which adds Drexel as an approved site

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)
- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events
- Adverse events
- Final report

<table>
<thead>
<tr>
<th>What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?</th>
<th>- The amendment approval letter - Any documents reviewed and approved as a part of the amendment, those that have been updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?</td>
<td>Drexel IRB should be reviewing and approving personnel modifications prior to submission to the reviewing IRB.</td>
</tr>
<tr>
<td>What should be submitted at continuing review?</td>
<td>- The continuing review approval letter - The most recently approved consent form - Any documents which have been updated as a part of the continuing review - The HRP-212 Continuing Review/Final Report Form (this is a questionnaire embedded in our local IRB system)</td>
</tr>
<tr>
<td>What should be submitted for serious or continuing non-compliance?</td>
<td>- The report to the IRB - The IRB determination letter - Additional documents depending on the situation</td>
</tr>
<tr>
<td>What should be submitted for unanticipated problems?</td>
<td>- The report to the IRB - The IRB determination letter - Additional documents depending on the situation</td>
</tr>
<tr>
<td>What should be submitted for serious adverse events?</td>
<td>- The report to the IRB - The IRB determination letter - Additional documents depending on the situation</td>
</tr>
<tr>
<td>What should be submitted for adverse events?</td>
<td>- The report to the IRB - The IRB determination letter - Additional documents depending on the situation</td>
</tr>
<tr>
<td>What should be submitted for final reports?</td>
<td>- The closure letter from the reviewing IRB - The HRP-212 Continuing Review/Final Report Form (this is a questionnaire embedded in our local IRB system)</td>
</tr>
</tbody>
</table>

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: Gabrielle Rebillard
Email: gmr59@drexel.edu
Phone Number: (215) 762-2916

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.

No