Institutional Profile

Site Name: George Washington University

Last modified date: 01/29/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>The George Washington University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00005945, FWA00022160, FWA00015133</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-05-07</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>0000103</td>
</tr>
<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>Social Behavioral research, Biomedical research</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- DC

List other names by which your institution is known.

George Washington University, George Washington University Hospital, George Washington University Medical Faculty Associates

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.

600 MINOR'S HEALTH CONSENT 600.1 Any person who is eighteen (18) years of age or older may consent to the provision of health services for himself or herself, or for his or her child or spouse. 600.2 Any minor who is seventeen (17) years of age or more may consent to voluntarily donate blood to a nonprofit organization, being regarded as having achieved his or her majority for the purposes of this section. 600.3 A minor parent may consent to the provisions of health services to his or her child. 600.4 Health services may be provided to a minor of any age without parental consent when, in the judgement of the treating physician, surgeon, or dentist, the delay that would result from attempting to obtain parental consent would substantially increase the risk to the minor's life, health, mental health, or welfare, or would unduly prolong suffering. 600.5 A health professional may render or attempt to render emergency service of first aid, medical, surgical, dental, or psychiatric treatment without compensation to any injured person or any person regardless of age who is in need of immediate health care when, in good faith, the professional believes that the giving of aid is the only alternative to probable death or serious physical or mental damage. 600.6 In an emergency where major surgery or any dangerous procedures will be performed, concurrence of another physician shall, if practical, be obtained. 600.7 A minor of any age may consent to health services which he or she requests for the prevention, diagnosis, or treatment of the following medical situations: (a) Pregnancy or its lawful termination; (b) Substance abuse, including drug and alcohol abuse; and (c) A mental or emotional condition and sexually transmitted disease. 600.8 Self-consent of minors shall not apply to sterilization, such as tubal ligation or vasectomy. AUTHORITY: Unless otherwise noted, the authority for this chapter is Commissioners' Orders dated January 7, 1924, April 2, 1943, May 21, 1947,

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>No</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>Yes, I will insert language in text box</td>
</tr>
<tr>
<td>Please insert the language required to be used around mandatory reporting to health authorities.</td>
<td>[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities]. The privilege of confidentiality does not extend to information about sexual or physical abuse of a child. If any member of the research team has or is given such information, he or she is required to report it to the appropriate authority or agency, such as child protective services, a law enforcement agency, or your State's toll-free child abuse reporting hotline. The obligation to report includes past and current alleged or reasonably suspected abuse as well as past or current known abuse. Examples of such abuse include physically harming your child or having inappropriate sexual contact with your child.</td>
</tr>
<tr>
<td>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</td>
<td>No</td>
</tr>
<tr>
<td>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</td>
<td>Yes</td>
</tr>
<tr>
<td>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.</td>
<td>• Translation of consent forms for non-English speaking individuals</td>
</tr>
</tbody>
</table>
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 believe I am injured because I took part in this study? The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study. [Include if compensation for research related injury is not available. Otherwise delete and insert language detailing compensation and medical treatment available.] If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company. You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Please enter your specific consent form language regarding costs to participants to participate.  
Are there any costs for participating in this research?  
[Include any costs that may be incurred due to the research. Indicate whether participants will be financially responsible for any clinic/hospital charges.]

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?  
Submit an IRB request form to our office via email.
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?

Yes

Select all documents that must be submitted along with the reliance request package or reliance application

- Protocol
- Local consent form(s)

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.

- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events

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

A Promptly Reportable Information Form

What should be submitted for unanticipated problems?

A Promptly Reportable Information Form

What should be submitted for serious adverse events?

A Promptly Reportable Information Form

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: Rebecca Eberle
Email: reberle@gwu.edu
Phone Number: (202) 994-5009

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, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.

**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).

**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**

Reviewing IRB will conduct any IRB audits or investigations

**IRB-INITIATED EXTERNAL REPORTING**

Reviewing IRB will draft and submit reports to external recipients

**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 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.

**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.