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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Georgetown University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00001080</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-06-06</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>Committee A IRB00000313 Committee B IRB00002117 Committee C IRB00002118 GHUCCTS IRB00008869 MedStar/GU Oncology IRB00002119</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>Committee A - Pediatric Oncology and Biomedical Committee B - Biomedical Committee C - Social and Behavioral GHUCCTS [Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS)] IRB - Primarily Biomedical/Occasional Social and Behavioral MedStar/GU Oncology IRB - Oncology</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>Since GU is ethically and religiously bound by the</td>
</tr>
</tbody>
</table>
conventions of Catholic moral theology, the Ethical and Religious Directives for Catholic Healthcare Services have the force of policy at Georgetown. Specifically applicable to research are Directives 4, 32, 52, and 67. Directive 4 directs Catholic health care institutions to promote medical research in a manner consistent with its mission of providing health care with concern for the responsible stewardship of resources and in accordance with Catholic moral principles. Directive 32 concerns informed consent procedures. Directives 52 and 67, respectively, pertain to research on living embryos or fetuses and the use of fetal tissue for research purposes. There can be no mention of contraception in the ICF. ICP template language regarding avoidance of pregnancy: Avoidance of Pregnancy: The medicines and procedures used in this study may be unsafe for an unborn baby, an infant, sperm, and eggs. If you, as a subject of study, are a woman of child bearing potential, you must agree to avoid pregnancy during your participation in this study and for three months after the completion of the study (include when appropriate); if you, as a subject, are a man, you must agree to not conceive a child during your participation in this study and for three months after the completion of the study (include when appropriate). If you do become pregnant during the study or if you father a child during the study, you should immediately notify Dr. ______________ at 202-_________. In addition, if you are already pregnant or are breast feeding, you cannot participate in this study.

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?

- DC

Age of majority in your state? 18

What circumstances affect age of consent in your state? A minor of any age may consent to health services For example, in Pennsylvania a minor age 14 or above
can consent to their own mental health treatment which he or she requests for the prevention, diagnosis or treatment of the following medical situations: 1. Pregnancy or it’s lawful termination; 2. Substance abuse, including drug and alcohol abuse; and 3. A mental or emotional condition and sexually transmitted disease.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</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>No</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>• We do not have a posted policy for any of these</td>
</tr>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>No</td>
</tr>
</tbody>
</table>

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

**POLICY/PROCEDURES FOR RESEARCH RELATED INJURY** The Policy and Procedure of [name of the sponsor] are as follows: [Include the Sponsor's statement here---the sponsor will or will not pay for care necessitated by a research related injury] The Policy and Procedure of [institution name] is as follows: Include policy and procedure language for each participating institution. For example (Georgetown University): We 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. The costs of this care will be charged to you or your third party payer (e.g., your health insurer) in the usual manner and consistent with applicable laws. No funds have been set aside by Georgetown University, Georgetown University Hospital, or their affiliates, to repay you or compensate you for a study related injury or illness.

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

**WHAT ARE THE COSTS?** Study subjects will/will not have to pay for the study drug/treatment. You or your insurance company will have to pay for _______________________. Taking part in this study may lead to added costs for you or your
insurance company. Please ask about any expected added costs or insurance problems. [Note to Researchers: Be as specific as possible about additional costs.] You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study. You may find a National Cancer Institute guide: "Clinical Trials and Insurance Coverage - a Resource Guide" helpful. You may ask your doctor for a copy, or it is available on the world wide web at http://cancer.gov/clinicaltrials/insurance. [Include the following paragraph if applicable with site-specific information] Please contact the (Institution’s name) Clinical Trials Office at ______ with any questions or concerns about expected costs, bills you have received from the hospital or your study physician that you feel may be related to your participation in this research 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? 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)?

Contact the IRB Office either by email (IRBoard@georgetown.edu) or by phone (202-687-1506).

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.

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

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

Personnel modifications, new potential conflicts of interest, changes that require review by other committees (e.g., biosafety), changes that may need Catholic Ethic and Religious Directives consideration.

What should be submitted at continuing review?

Completion of our short continuing review questionnaire, copy of report submitted to the IRB of record, IRB approval letter, current ICF(s) and HIPAA authorization.

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

Report sent to IRB of record, documentation of IRB review and outcome.

What should be submitted for unanticipated problems?

Report sent to IRB of record, documentation of IRB review and outcome.

What should be submitted for final reports?

Report sent to IRB of record, documentation of IRB approval.

What else should be submitted to your HRPP when ceding review?

DSMB/DSMC Reports Audit Reports Monitor Reports

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: Kristen Katopol

Email: krk63@georgetown.edu

Phone Number: (202) 687-0328

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