Institutional Profile

Site Name: Augusta University

Last modified date: 08/14/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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**Section 1: GENERAL HRPP INFORMATION**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Augusta University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00019721</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-01-17</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB A 00000150 IRB B 00009178 IRB C 00009025</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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Behavioral, Biomedical, Cancer</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- GA

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

Augusta University (AU) follows state law governing the conduct of research involving children.

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.

Our university adheres to Board of Regents for the University System of Georgia on Behalf of Augusta University Record retention Policy: http://www.usg.edu/policymanual/section10/C442/

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

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?

- Consent Process for those with Impaired Decision-Making Capacity
- Use of short forms for non-English speaking individuals
- Translation of consent forms for non-English speaking individuals

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

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.

A. If you think that you have suffered a research related injury, seek medical care right away and contact the study team as soon as possible at [insert phone number]. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Augusta University (AU), AU Medical Center, AU Medical Associates, AU Dental Associates, AU Nursing Associates, Inc., AU Health
Professions Associates, Inc. collectively designated AU Affiliates [or any other facility involved with this study]. You do not give up your legal rights by participating in this study. B. If you think that you have suffered a research related injury, seek medical care right away and contact the study team as soon as possible at [insert phone number]. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed, so long as (1) the injury was not caused by negligence or willful misconduct of the institution and (2) it was not due to the natural progression of a pre-existing condition, cost for such care will be paid by [insert sponsor's name]. No reimbursement, compensation, or free medical care is offered by Augusta University (AU), AU Medical Center, AU Medical Associates, AU Dental Associates, AU Nursing Associates, Inc., AU Health Professions Associates, Inc. collectively designated AU affiliates [or any other facility involved with this study]. You do not give up your legal rights by participating in this study.

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

A. It will not cost you anything to take part in the study other than basic expenses like transportation. B. If you agree to participate in this study, you and/or your insurance will not be billed for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. You will be responsible for all co-pays, deductibles, and denied claims. You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you. C. If you agree to participate in this study, you and/or your insurance will be billed for the tests and treatments that are standard clinical care as well as those being done only for research. You are responsible for paying for the usual care you would normally receive for the treatment of your illness. You will be responsible for all co-pays, deductibles and denied claims. You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may
choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you. D. If you agree to participate in this study, you and/or your insurance will not be billed for the following tests and treatments that are being done for clinical care or for research: • A • B • C • Etc. You or your insurance company are still responsible for paying for research care and/or the usual care you would normally receive for the treatment of your illness (including all co-pays, deductibles and denied claims) listed below: • A • B • C • Etc. • Any items not listed above as being covered. You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you.

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)?

a. The investigator must notify the AU IRB Office of the request for a reliance agreement before communicating agreement of reliance to the External IRB or submitting a new application submission to the AU IRB. b. Reliance Request notifications should be submitted via an email to IRBReliance@augusta.edu. The email should contain the completed AU Reliance
Request Form which can be located on the External IRB website. Please be sure the form is completed in entirety and any applicable documents uploaded as an attachment. Incomplete Reliance Request Forms will be returned to submitter c. Requests to enter into a reliance agreement are handled by the AU IRB Office Reliance team; in accordance with decisions from the institutional official and legal counsel, on a case by case basis. Following the Reliance team meeting, communication will be sent to the AU PI regarding determination of reliance or if any additional information may be needed. Please allow 10 business days to receive communication once a reliance request is submitted to our office d. Following the Reliance team meeting and determinations, the IRB Office Associate schedules a conference call with the AU PI, External IRB, and IRB Office Reliance Team to discuss any additional questions and next steps. e. Once communication is sent to the AU PI regarding acceptance of the reliance, it is the responsibility of the AU PI to ensure the site has been added on the AU IRB Application at initial or protocol amendment. The following additional forms, specific to the Reviewing Organization, must be included in the IRBNet package:

1. External Core Data Form
2. Training Linked for all study team members
3. COI attestation form for all study team members
4. Research Data Attestation form
5. IRB-approved protocol
6. IRB-approved consent document to include AU boilerplate language (see checklist for AU Relying on a Non-Commercial IRB under a Reliance Agreement for additional guidance). If the study will recruit at Augusta University, the consent document must contain the required Augusta University boilerplate language. If a waiver of consent and/or waiver of HIPAA Authorization is granted, documentation of the reviewing IRB’s determination must be included in the submission package.
7. IRB approval of reviewing IRB to add AU site

f. The local AU PI is responsible for complying with the policies and procedures of the external IRB and AU Human Research Protection Program (HRPP) and the directives of the Authorization Agreement.

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<table>
<thead>
<tr>
<th>Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?</th>
<th>Yes</th>
</tr>
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</table>

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
- Adverse events

<table>
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<th>What should be submitted for serious or continuing non-compliance?</th>
<th>A Reportable Events Form</th>
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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: Heather Wilson, Regulatory Compliance Manager
Email: hwilson@augusta.edu
Phone Number: (706) 721-1482

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.

<table>
<thead>
<tr>
<th>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.</th>
<th>Yes</th>
</tr>
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<tbody>
<tr>
<td>STANDARD OPERATING PROCEDURES (&quot;SOPs&quot;)</td>
<td>Using SMART IRB SOPs (recommended)</td>
</tr>
<tr>
<td>HIPAA DETERMINATIONS AND ACTIONS</td>
<td>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).</td>
</tr>
<tr>
<td>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</td>
<td>Reviewing IRB requires HIPAA authorization language to be incorporated into the informed consent documents, unless the Relying Institution obtains</td>
</tr>
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</table>
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).

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<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>Reviewing IRB and Relying Institution(s) will jointly 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 charge the Relying Institution(s) for costs of review: The Reviewing IRB and the Relying Institution(s) will enter a separate agreement or agreements under which the Relying Institution(s) will provide financial support to the Reviewing IRB for the costs of review of the identified study(ies)</td>
</tr>
<tr>
<td>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</td>
<td>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.</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>
<tr>
<td>INDEMNIFICATION</td>
<td>Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).</td>
</tr>
</tbody>
</table>