Institutional Profile

Site Name: Albany Medical Center

Last modified date: 10/22/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Albany Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00001314</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-01-04</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000159</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>n/a</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- NY

List other names by which your institution is known.

Albany Medical College Albany Medical Center Hospital

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.

Consent for research remains 18 regardless of life situation. i.e. emancipated minor

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?

Yes, I will insert language in text box

Please insert the language required to be used around mandatory reporting to health authorities.

only if applicable to subject matter

Does your site require a site-specific logo appear on consent forms and/or recruitment documents?

No

Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?

No

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

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?

HIPAA language is included in the body of the consent

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

Option 1 (Sponsor agrees in contract to cover research related injury) If you are injured as a result of taking part in this research study, medical services needed to treat such injury will be made available to you at (Insert name of entity to provide care). AMC will not accept financial responsibility for the cost of such services. However, since the sponsor, (Insert name of company), has agreed to pay for medical treatment for any research related injury, there will be no direct charge to you or your medical insurance. This paragraph relates only to billing and payment for services provided, and is not intended to release AMC from responsibility for its negligence or intentional
wrongdoing, if any. By signing this consent form, you have not given up any of your legal rights. Option 2 (Sponsor agrees in contract to cover research related injury after the subject's insurance has been billed) If you are injured as a result of taking part in this research study, medical services needed to treat such injury will be made available to you at [Insert name of entity to provide care]. The sponsor, [Insert name of Company] has agreed to pay for medical treatment for any research related injury, after your insurance company has been billed. AMC will not accept financial responsibility for the cost of such services. This paragraph relates only to billing and payment for services provided, and does not release AMC from responsibility for its negligence or intentional wrongdoing, if any. By signing this consent form, you have not given up any of your legal rights. Option 3 (If no Sponsor or Sponsor does not agree in contract to cover research related injury, or the research study is grant funded or unfunded) If you are injured as a result of taking part in this research study, medical services needed to treat such injury will be made available to you at [Insert name of entity to provide care]. No funds have been set aside for the cost of the medical treatment and it will be billed to you or your insurance company. AMC will not accept financial responsibility for the cost of such services. This paragraph relates only to billing and payment for services provided, and does not release AMC from responsibility for its negligence or intentional wrongdoing, if any. By signing this consent form, you have not given up any of your legal rights.

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

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? | Albany Medical Center Hospital
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Please indicate which questions you will answer about this component. Please only include those questions for which this component's answers differ from those for the FWA-holding site. | • None
Do you have another component site on your FWA? | Yes
What is the name of this component site? | Albany Medical College
Please indicate which questions you will answer about this component. Please only include those questions for which this component's answers differ from those for the FWA-holding site. | • None
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)?

investigator should email the Office of Research Affairs at IRBoard@amc.edu and submit a complete protocol submission packet.

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 | New protocol review request form (NPRRF) subject materials drug or device brochure

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

What should be submitted for serious or continuing non-compliance? | all documentation submitted to reviewing IRB and/or sponsor

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?
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