Institutional Profile

Site Name: Albert Einstein Healthcare Network

Last modified date: 03/15/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Albert Einstein Healthcare Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000762</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-11-06</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>0000165</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>Yes</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Biomedical</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?
- PA

List other names by which your institution is known.
Einstein Healthcare Network Albert Einstein Medical Center

Age of majority in your state?
18

What circumstances affect age of consent in your state?
Pennsylvania law does not have an emancipation statute. Instead, each county in the Commonwealth of Pennsylvania has its own procedures for emancipation. A minor can be considered emancipated for one purpose (for example, obtaining birth control) but not for others. Unless a minor has been emancipated by court order, which should be confirmed by requesting a copy of the order, a minor should not be considered emancipated for purposes of consenting to participation in research.

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?
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?
- 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

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?
See consent template

Please enter your specific consent form language regarding payment for research-related injury.
None
Please enter your specific consent form language regarding costs to participants to participate. | None.
---|---
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.

<table>
<thead>
<tr>
<th>Do you have a component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>Einstein Medical Center - Philadelphia</td>
</tr>
<tr>
<td>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 .</td>
<td>• None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do you have another component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>MossRehab Hospital</td>
</tr>
<tr>
<td>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 .</td>
<td>• None</td>
</tr>
</tbody>
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<tr>
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<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>Einstein Medical Center-Montgomery</td>
</tr>
<tr>
<td>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 .</td>
<td>• None</td>
</tr>
</tbody>
</table>

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<th>Do you have another component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>Einstein Medical Center-Elkins Park</td>
</tr>
<tr>
<td>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 .</td>
<td>• None</td>
</tr>
</tbody>
</table>

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<tr>
<th>Do you have another component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>Einstein Center One</td>
</tr>
<tr>
<td>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 .</td>
<td>• None</td>
</tr>
</tbody>
</table>
Do you have another component site on your FWA? | Yes
---|---
What is the name of this component site? | Einstein at Germantown
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? | ECHA Practices
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? | Fornance Practices
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)? | Must contact Director, ORTD for more information on how to proceed.

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.

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
- Final report
### What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?

- Approval letter from Lead IRB and revised documents.

### 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 and any other amendments that are site-specific and associated approval letter(s) from Lead IRB. Must also submit the required conflict of interest/financial disclosure forms when applicable.

### What should be submitted at continuing review?

- Continuing review report showing site-specific activity, list of site staff active on the project, conflict of interest screening forms for staff who are not on the PHS system, and approval letter from Lead IRB.

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

- Letter from Lead IRB summarizing results of review and copy of report.

### What should be submitted for unanticipated problems?

- Letter from Lead IRB summarizing results of review and copy of report.

### What should be submitted for serious adverse events?

- Letter from Lead IRB summarizing results of review and copy of report.

### What should be submitted for final reports?

- Final report summarizing site-specific activity, list of staff participating in project, COI forms for any staff not on PHS system, and approval letter from Lead IRB.

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

- Protocol Consent form to be used at site Recruitment materials Any other study-specific materials submitted for IRB review Current approval letter from Lead IRB.

### 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**: Mary Klein, PhD
- **Email**: mklein@einstein.edu
- **Phone Number**: (215) 456-7216

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**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</th>
<th>No</th>
</tr>
</thead>
</table>
reliance preferences/requirements will be collected below.