Institutional Profile

Site Name: Eastern Virginia Medical School

Last modified date: 08/29/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Eastern Virginia Medical School</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00003956</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-04-02</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000460 IRB00001345</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>Medical Oncology Cardiology Pediatrics/Neonatology Pharmacy Microbiology Physiological Sciences Pathology</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
</tr>
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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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- VA

List other names by which your institution is known.

Eastern Virginia Med Sch EVMS

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.

Code of Virginia § 54.1-2969.E A minor shall be deemed an adult for the purpose of consenting to: 1. Medical or health services needed to determine the presence of or to treat venereal disease or any infectious or contagious disease that the State Board of Health requires to be reported; 2. Medical or health services required in case of birth control, pregnancy or family planning except for the purposes of sexual sterilization; 3. Medical or health services needed in the case of outpatient care, treatment or rehabilitation for substance abuse as defined in § 37.2-100; or 4. Medical or health services needed in the case of outpatient care, treatment or rehabilitation for mental illness or emotional disturbance.

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.

The text below is also found in the attached EVMS Subject Consent Form. Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus: • The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases; and, • Those test results will be released to the person who was exposed and to the health department as required by Virginia law.

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?

Yes
| Does the site have a posted policy for the following? | • Consent Process for those with Impaired Decision-Making Capacity  
• Translation of consent forms for non-English speaking individuals |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</td>
<td></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>
<tr>
<td>Please enter any special formatting your IRB requires for HIPAA authorization forms?</td>
<td>Table format indicating the following: Description of PHI to Be Disclosed Organization and Person (or their title) Disclosing PHI Organization and Person (or their title) Receiving PHI Purpose of Disclosure Bullet Format indicating other specifics (expiration, etc.)</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by [indicate who will be providing emergency medical treatment] and paid for by [indicate who will be paying for emergency treatment]. Further medical care and/or hospitalization resulting from this injury or illness will be charged to [indicate who will be paying]. Eastern Virginia Medical School and [indicate institutions where you will be conducting your study] will not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form.</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding costs to participants to participate.</td>
<td>There are no additional costs to you associated with taking part in this study. OR Taking part in this study may result in extra costs due to special tests or procedures that need to be performed. Your health care insurance company policy may or may not cover these. Predicted costs above and beyond those for standard medical care will be: [] ____________ [] ____________ These extra costs will be paid by _____________. [If appropriate, omit this sentence] If, during the study, the [study drug] becomes commercially available (FDA has approved as safe and effective), you may have to pay for the amount of drug needed to complete the study. You will receive _____________ for taking part in this study to help cover your expenses and inconvenience. [If appropriate, this sentence may be deleted.] If any new products, tests, or discoveries resulting from the research have potential commercial value, you will not be compensated or benefit financially.</td>
</tr>
</tbody>
</table>
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? CONRAD

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)?

Currently, contact the Director or Assistant Director by email with study details. In the future, there will be a submission process through our IRB database.

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.

- Local amendments (personnel modifications)
- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events

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

Approval letter from the lead IRB plus revised documents
| What should be submitted for serious or continuing non-compliance? | Complete copy of the compliance matter and any determinations made by the lead IRB or other parties. |
| What should be submitted for unanticipated problems? | Complete copy of the unanticipated problem(s) and the outcome of the lead IRB review. |
| What should be submitted for serious adverse events? | Complete copy of the SAE; reports made to FDA, OHRP, or other entities; and the outcome of the lead IRB review. |

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: Betsy C. Conner
Email: ConnerBC@evms.edu
Phone Number: (757) 446-8423

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