Institutional Profile

Site Name: East Carolina University

Last modified date: 02/10/2020

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>East Carolina University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000658</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2024-01-21</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>Biomedical IRB# 00000705 Behavioral/Social Science IRB# 00003781</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>Biomedical and Social/Behavioral</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>There is an abbreviated pathway in our electronic system to manage those studies where ECU relies on another IRB. Institutional approvals (&quot;ancillary review&quot;) are documented within this electronic system as well. For example, when local patient data is used for research purposes, review is required by HIPAA ancillary reviewers. This review is built in to our electronic submission system.</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?
- NC

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
(a) Any minor may give effective consent to a physician licensed to practice medicine in North Carolina for medical health services for the prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under G.S. 130A-135, (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional disturbance. This section does not authorize the inducing of an abortion, performance of a sterilization operation, or admission to a 24-hour facility licensed under Article 2 of Chapter 122C of the General Statutes except as provided in G.S. 122C-223. This section does not prohibit the admission of a minor to a treatment facility upon his own written application in an emergency situation as authorized by G.S. 122C-223.
(b) Any minor who is emancipated may consent to any medical treatment, dental and health services for himself or for his child.

https://www.ncga.state.nc.us/EnactedLegislation/Statutes/PDF/ByArticle/Chapter_90/Article_1A.pdf Any juvenile who is 16 years of age or older and who has resided in the same county in North Carolina or on federal territory within the boundaries of North Carolina for six months next preceding the filing of the petition may petition the court in that county for a judicial decree of emancipation.
http://www.ncga.state.nc.us/EnactedLegislation/Statutes/HTML/ByArticle/Chapter_7B/Article_35.html

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?

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
- 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 any special formatting your IRB requires for HIPAA authorization forms?

ECU has HIPAA templates available for investigators if this language is not already included in consents provided by the sponsor of a research study.

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

(3) Research Injury Language The consent document must address the issue of possible injury as a result of taking part in the research. For sponsored studies, it is the PI's responsibility, when drafting the informed consent, to ensure the following information matches the language agreed upon in the approved contract document. You may cut and paste the required language from the block below. For industry-sponsored studies include the following statement: If you believe you have been hurt or if you get sick because of something that is done during the study, you should call [Principal Investigator or medical supervisor's name] at [insert telephone number] immediately. There are procedures in place to help attend to your injuries or provide care for you. The sponsor of this study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that your injury is a result of taking part in this research and you think that you may be eligible for getting paid back for some of the costs associated with the care for injuries, let the Principal Investigator know right away. (If the sponsor has indicated they will pay for research related injury, the following paragraph should be added to the consent) If you are injured as a result of taking part in this study, the sponsor will pay for the costs associated with your care. However, because the sponsor is required by federal law to report that
payment to the Center for Medicare and Medicaid Services, ECU will be asked to release your identifiable information (including your social security number) to the study sponsor. The sponsor will only use your information to meet federal reporting obligations and to make any payments to you. ECU will request your authorization before it releases information to the sponsor. You have the right to decline this authorization. If you decline, you will not be able to receive payment to cover the costs of medical treatment of your research related injuries and therefore you will be responsible for those costs.

OR For unfunded, federal, state, or foundation/non-profit studies, include the following statement: If you believe you have been hurt or if you get sick because of something that is done during the study, you should call [Principal Investigator or medical supervisor’s name] at [insert telephone number] immediately. There are procedures in place to help attend to your injuries or provide care for you. Costs associated with this care will be billed in the ordinary manner, to you or your insurance company. However, some insurance companies will not pay bills that are related to research costs. You should check with your insurance about this. Medical costs that result from research-related harm may also not qualify for payments through Medicare, or Medicaid. You should talk to the Principal Investigator about this, if you have concerns.

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

What will it cost me to take part in this research? [Use only the following statements that apply to your research] [If all costs of the research are being paid by the sponsor (including co-payments) the following statement is required:] It will not cost you any money to be part of the research. The sponsor of this research will pay the costs of: [Explain exactly the costs for which the sponsor will pay.] [If the costs of the research are being paid by the sponsor but the individual will be responsible for the co-payments include these statements]. Sometimes, as part of a research study, services/procedures/clinic visits [add the correct term, as appropriate] are needed that are not part of your routine care. The sponsor of the research study has agreed to pay for these services/procedures/clinic visits. You nor your insurance company, Medicare, or Medicaid will be billed for these services. It will not cost you additional money to take part in this research study. The following are the services/procedures/clinic visits that the sponsor will pay: XXXXXX (the specific procedures would need to be listed here). [If the costs are
associated with standard of care procedures and, therefore, passed on to the participant the following statement is required:] You or your insurance company, Medicare, or Medicaid will be billed for the costs of routine services that are performed during this research study. These costs are considered reasonable and necessary. These services/procedures/clinic visits would be performed as part of your care, whether or not you take part in the research. Therefore, you will be responsible for any deductible, co-payment, or co-insurance payments for these routine services/procedures/clinic visits. However, you may want to verify with your insurer that these costs will be covered. [If the costs of the research procedures are going to be passed on to the participant, the following statement is required:] You will be expected to pay for the following costs which result directly from the following research procedures:

Please upload your template HIPAA Authorization language.

Do you have any additional HIPAA Authorization language template documents? Yes

Please upload additional template HIPAA Authorization language documents

**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? Leo Jenkins Cancer Center

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)?

The investigator should call or email the University and Medical Center Institutional Review Board (UMCIRB) office to first verify whether there is an existing "umbrella" agreement with the reviewing IRB. If not, an IAA would be initiated and an abbreviated application in ePIRATE (our electronic submission system) would also be required.

<table>
<thead>
<tr>
<th>Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?</th>
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<tbody>
<tr>
<td>No</td>
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</table>

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.

<table>
<thead>
<tr>
<th>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?</th>
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<tr>
<td>Yes</td>
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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
- Final report
- Other

<table>
<thead>
<tr>
<th>What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study team required to update the approved documents (consents, protocol, IB, surveys/questionnaires, advertisements, etc.) as they become available from the reviewing IRB. These are loaded in ePIRATE.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?</th>
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</thead>
<tbody>
<tr>
<td>Study team required to update personnel and any changes that would affect institutional approvals as they become available within ePIRATE.</td>
</tr>
</tbody>
</table>

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<tr>
<th>What should be submitted at continuing review?</th>
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<tr>
<td>Study team required to upload the updated IRB renewal letter from the reviewing IRB.</td>
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</table>

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<tr>
<th>What should be submitted for serious or continuing non-compliance?</th>
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<tr>
<td>In this case, the study team should report as usual with a &quot;Reportable Event&quot; in ePIRATE. The following is our SOP: https:// rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/2349/2020/02/Noncompliance-SOP_Revised-1-15-20-Clean.pdf</td>
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What should be submitted for final reports?
Study team should upload any correspondence from the reviewing IRB indicating the study has been completed.

What else should be submitted to your HRPP when ceding review?
Suspensions/Terminations should also be reported to the UMCIRB as "Reportable Events" in ePIRATE. SOP is as follows: https://rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/2349/2019/05/SOP-Suspension-or-Termination-of-IRB-Approval_revised-5-2018_Final.pdf

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
Suzanne Sparrow

Email
sparrows@ecu.edu

Phone Number
(252) 744-1785

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.

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