1.0 **Purpose:** The purpose of this standard operating practice (SOP) is to describe East Carolina University’s (ECU) process for relying on another IRB.

2.0 **Persons Affected:**
2.1 ECU faculty, staff and students
2.2 UMCIRB Chairpersons and members
2.3 Office of Research Integrity and Compliance (ORIC) staff members

3.0 **SOP:** Institutions engaged in human research are allowed to rely on other IRBs for review and approval of human research. An IRB Authorization Agreement (IAA) must be negotiated and signed by the institution conducting the human research and the IRB reviewing the research before the research can begin locally. Those research studies that ECU determines cannot rely on another IRB will be submitted for UMCIRB approval as usual.

IRBs can fall under the following categories:
- Commercial (or Independent) IRBs
- Central IRBs
- External IRBs

Depending on which IRB the investigator wishes to rely on will determine the process for reliance to occur. The processes are described below.

An IAA is not required for human research that is certified to fall under an Exempt category of research however the ORIC should be provided with documentation to confirm their agreement with the other IRB that has certified the research as Exempt.

4.0 **Definitions:**
4.1 **IRB Authorization Agreement (IAA)** is a form of agreement executed between institutions conducting human research and the IRB delegated to oversee that human research.

4.2 **Engaged** means an institution is considered involved in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

4.3 **Central IRB** is the recognized IRB for the National Cancer Institute

4.4 **Commercial (or Independent) IRBs** are for-profit companies whose business is to provide IRB review services mostly for industry sponsors.

4.5 **External IRBs** are those IRBs that do not fall into the central or commercial category of IRBs and are usually associated with other academic institutions with an approved Federalwide Assurance (FWA).
4.6 The Federalwide Assurance (FWA) is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the U.S. Department of Health and Human Services (HHS).

5.0 Responsibilities:

5.1 Investigators have the responsibility to

5.1.1 Ensure a fully executed IAA exists prior to moving forward with a study where ECU will need to rely on another IRB. The investigator should contact ORIC if (s)he is uncertain whether there is a fully executed agreement in place

5.1.1.1 A “blanket” agreement may already be in place with some commercial or central IRBs.

5.1.1.2 If no such agreement exists, the investigator will be responsible for inquiring with the other IRB regarding whether they would allow outside investigators to rely on them for IRB approval.

5.1.2 For more than minimal risk human research, research utilizing local patient information, or research involving the local collection and storage of any patient data, the completion of an abbreviated electronic application at ECU will be required to satisfy institutional requirements

5.1.2.1 The abbreviated ECU application will need to be updated when new documents are provided by the IRB that approved the study and when the study is renewed or closed.

5.1.2.2 For these studies, unanticipated problems and major protocol deviations must be submitted as reportable events in the electronic ECU application.

5.1.3 Adding ECU boilerplate language to consent documents (as applicable) that may be utilized locally for the research study.

5.1.4 Initiate the study only after receipt of email from ORIC acknowledging the reliance on another IRB.

5.1.5 Immediately notify the UMCIRB upon suspension or termination of the study.

5.2 ORIC Director (or designee) is responsible for:

5.2.1 Determining whether ECU will rely on another IRBs approval by reviewing

5.2.1.1 Accreditation of the IRB

5.2.1.2 IRB registration information

5.2.1.3 DHHS/FDA Determination letters

5.2.2 Discussing this request with any affiliates outside of ECU that may need to be involved in the local approval process.

5.2.3 Informing the local investigator(s) of the decision to rely on another IRB.

5.3 ORIC staff are responsible for

5.3.1 Maintaining copies of all IAAs executed between ECU and other IRBs.

5.3.2 Verifying the content of the electronic ECU application (if required).

5.3.3 Requesting any necessary clarifications and/or modifications to required documents and sections of the electronic application that pertain to the local policies and SOPs or institutional ancillary reviews required.

5.3.4 Providing notification to the study team verifying authority has been granted to another IRB.

5.4 UMCIRB/UMCIRB Chairperson (or designee) will
5.4.1 Review any unanticipated problems and major deviations according to existing SOPs.
5.4.2 Be notified of and review any serious or ongoing noncompliance that occurs according to existing SOPs.

6.0 Procedures:
6.1 Study team will query the UMCIRB/ORIC to determine if an existing IAA is in place for the study in which they wish to take part.
6.2 Secondary to the oversight and monitoring requirements that remain with the local institution, more than minimal risk human research, research utilizing local patient information, or research involving the local collection and storage of any patient data where the investigator wishes to rely on another IRB will require the study team to complete an abbreviated electronic IRB application process which includes review by any applicable institutional ancillary approvers.
6.2.1 Study team will incorporate locally required language into the consent document template they receive from the reviewing IRB for the research study
6.2.2 Ancillary review will continue to take place within the electronic ECU application as usual.
6.2.3 Study team will provide updated documents, renewal dates (or closure information) and unanticipated problems/major deviations/suspensions via the electronic application as they receive this information.
6.3 Human research that does not fall under the categories described in 6.2 will still need to be reviewed by the ORIC to determine agreement with the reviewing IRBs determinations and execution of an IAA.
6.3.1 The investigator will need to submit a protocol and/or IRB application defining the study methods and procedures, the consent form as approved by the reviewing IRB, the IRB approval letter and any other documents as requested by the ORIC to assist in this determination.
6.3.2 The investigator may submit this information by email to the ORIC staff.
6.4 Study team will await email acknowledgement from the UMCIRB/ORIC regarding the reliance on another IRB before initiating the study.

Revision History:

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<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<tr>
<td>5.19.2017</td>
<td>1.0</td>
<td>Clarification of when studies should be added to ePirate to document External IRB review.</td>
<td>5.1, 6.2, 6.3</td>
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http://www.hhs.gov/ohrp(policy/engage08.html

OHRP, Federalwide Assurance Instructions.
http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html