

<b>Institutional Review Board (IRB) Reliance Agreements</b>	Effective:	10.21.2015
	Revised:	11.29.2023

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to describe:
- 1.1** East Carolina University’s (ECU) process for relying on another IRB, and
  - 1.2** The process required for other, unaffiliated institutions with a Federalwide Assurance (FWA) to rely on the University and Medical Center Institutional Review Board (UMCIRB).
- 2.0 Persons Affected:**
- 2.1** ECU faculty, staff and students.
  - 2.2** Faculty, staff, and students from other, unaffiliated institutions that request to rely on the UMCIRB’s review of a human research study.
  - 2.3** UMCIRB Chairpersons and members.
  - 2.4** UMCIRB office staff members.
- 3.0 SOP:** Institutions engaged in human research can rely on other IRBs for review and approval of human research. An agreement must be negotiated and documented between 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 with documentation for that decision.

Other 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 procedures are described below.

A formal agreement is not required to document ECU’s reliance on another IRB for Exempt categories of human research unless the research study is federally funded/sponsored and requires a “limited review” as part of the Exemption criteria. While ECU will permit investigators to rely on external IRBs for non-limited review exempt research, no documentation will be provided to those sites regarding reliance. If additional documentation is required by the reviewing IRB, the UMCIRB will not permit the reliance and instead will act as the IRB of record for the study. “Exempt Categories” refers strictly to those defined in §46.104 of the Code of Federal Regulations.

Because ECU applies the Common Rule to all human subject research regardless of funding source (with limited exceptions, see Application of Final Rule SOP), ECU will not enter reliance agreements with external institutions for research reviewed and approved under flex policies. Formal reliance agreements will only be completed for research undergoing limited (with federal funding/sponsorship), expedited or full board review as defined in the Common Rule. ECU affiliated investigators seeking to participate in collaborative studies that received initial approval via flex policies will need to submit research for review

by the UMCIRB. The UMCIRB will then serve as the IRB of record for any ECU affiliated investigators engaging in the research.

If a PI is aware that an external IRB is available for a human research study, but submits the protocol to the UMCIRB for approval, and the UMCIRB identifies issues that must be addressed before approval can be granted, the PI may not submit that protocol to an external IRB for approval with the intent of circumventing the UMCIRB. However, if after submission to the UMCIRB, a PI learns there is a mandatory external single IRB review, the review by the UMCIRB may be cancelled in lieu of relying on the required external IRB.

Please note that collaborating independent investigators (not associated ECU, its affiliates, or any other institution) or collaborating institutional investigators (employee/agent of an unaffiliated institution that does not hold an FWA) engaged in human research with ECU or its affiliated institutions have a different process. They are required to complete an Individual Investigator Agreement (IIA). Please refer to the “Individual Investigator Agreement” SOP on the UMCIRB website regarding this process.

#### 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 subject research conducted or supported by the U.S. Department of Health and Human Services (HHS).

**4.7 Limited IRB Review** ensures there are adequate provisions for protecting privacy and maintaining confidentiality and provides privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm.

**4.8 Flexibility Policies (often shortened to “Flex Policies”)** refer to alternative methods of IRB review to the Common Rule for non-federally funded and non-FDA regulated research. Some institutions have exercised the ability to create their own categories and processes for review of human subject research that while they are designed to grant equivalent protections to, do not strictly align with the Common Rule for research that

Institutional Review Board (IRB) Reliance Agreements	East Carolina University University & Medical Center Institutional Review Board	Page 2 of 6
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is not federally funded or FDA regulated. While allowed, ECU does not exercise this flexibility and will not rely on institutions in situations where they have approved research via such policies.

**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 or another institution requests to rely on the UMCIRB.
  - 5.1.2** Complete the appropriate electronic IRB application at ECU to satisfy institutional requirements.
  - 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 notification from the UMCIRB office acknowledging the reliance arrangement.
  - 5.1.5** Immediately notify the UMCIRB of any unanticipated problems, major deviations, suspension or termination of a study where ECU is relying on another IRB.
  - 5.1.6** For studies that will be reviewed and approved by the UMCIRB, ensure any study team members (outside of ECU or affiliate facilities) are appropriately trained, qualified, and assessed for any conflict of interest related to their role on the study, included on the IRB application, and have up-to-date human subject protection training.
- 5.2** Human Research Protections Director (or designee) is responsible for:
  - 5.2.1** Determining whether ECU will rely on another IRB’s approval by reviewing information such as:
    - 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 reliance requests 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 not rely on another IRB.
- 5.3** UMCIRB office staff are responsible for
  - 5.3.1** Maintaining copies of all executed IAAs at ECU.
  - 5.3.2** Verifying the content of the electronic ECU application related to reliance arrangements and requesting any necessary clarifications and/or modifications.
  - 5.3.3** Generating notification to the study team verifying authority has been granted to another IRB.
  - 5.3.4** Verifying whether study team members added to human research studies approved by the UMCIRB need an IAA.
- 5.4** UMCIRB/UMCIRB Chairperson (or designee) will
  - 5.4.1** Continue to review any unanticipated problems, major deviations, and any serious or ongoing noncompliance that occurs according to existing SOPs for studies where ECU relies on another IRB.
  - 5.4.2** Review New Studies or Amendments where unaffiliated study team members are added to ensure these team members are qualified to be part of the study team.

**6.0 Procedures:**

**6.1** For human research studies where an investigator at ECU is requesting to rely on an outside IRB:

**6.1.1** Study team will query the UMCIRB office to determine if an existing IAA is in place for the study in which they wish to take part by relying on another IRB.

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

**6.1.1.2** If no such agreement exists, the study team will be responsible for inquiring with the reviewing IRB regarding whether they would allow outside investigators to rely on them for IRB approval.

**6.1.2** Secondary to the oversight and monitoring requirements that remain with the local institution when relying on another IRB, the study team will complete an abbreviated electronic IRB application which includes review by any applicable institutional ancillary approvers.

**6.1.2.1** Study team will incorporate locally required language into the consent document template they receive from the reviewing IRB for the research study, if applicable.

**6.1.2.2** Ancillary review will continue to take place within the electronic ECU application as usual.

**6.1.2.3** 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.

**6.1.2.4** Study team changes should also be updated in the electronic application as soon as possible.

**6.1.3** The abbreviated electronic IRB application process is also required for studies that meet an Exempt category of research with a limited review requirement and federal funding/sponsorship.

**6.1.4** To rely on another IRB for a study that meets an Exempt criteria of research with a limited review requirement that is not federal funded/sponsored or an Exempt criteria with no limited review requirement, the study team will need to provide a protocol and/or IRB application defining the study methods and procedures, any consent forms as approved by the reviewing IRB, the IRB approval letter, and any other material that may have been approved.

**6.1.4.1** The investigator may submit this information by email to the UMCIRB office staff.

**6.1.4.2** As it is not required by the federal regulations on human subject research, no formal documentation will be provided to the reviewing IRB by the UMCIRB.

**6.1.5** Human subjects research granted an approval by an external institution via a flex policy will not be considered for reliance at ECU. Investigators will need to submit a study in ePIRATE to be reviewed as research under the oversight of the UMCIRB.

**6.1.6** Study team will await email acknowledgement from the UMCIRB office regarding the reliance on another IRB before initiating the study.

**6.2** For human research studies review and approved by the UMCIRB where an unaffiliated investigator at another institution will be added:

Institutional Review Board (IRB) Reliance Agreements	East Carolina University University & Medical Center Institutional Review Board	Page 4 of 6
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**6.2.1** The PI should ensure any study team members (outside of ECU or affiliate facilities) are added to the IRB application and have verified what their responsibilities are with their home institution.

**6.2.1.1** The UMCIRB office will reach out to the PI and outside study team member(s) to determine IRB reliance requirements.

**Revision History:**

<b>Date</b>	<b>Change</b>	<b>Reference Section(s)</b>
5.19.2017	Clarification of when studies should be added to ePIRATE to document External IRB review.	5.1, 6.2, 6.3
1.21.2019	Updated to reflect revised regulations.	Sections 2.0-6.0
2.27.2020	Updated to add procedure for unaffiliated institutions to rely on UMCIRB; added requirement for all studies (except Exempt studies with no limited review) to be added to the electronic IRB system for tracking and monitoring; clarified responsibilities and procedures for including studies in the electronic system and procedures for including team members from unaffiliated institutions on UMCIRB approved studies.	Section 1.0-3.0, 5.0-6.0
3.29.2023	Updated language on reliance procedures for situations where ECU would be relying on external IRBs for exempt non-limited review research.	Section 3, 6.1
10.26.2023	Updated language regarding the UMCIRB policy on reliance for research approved via flexibility policies.	Section 3, 4.8, 6.15
11.29.2023	Updated language about requirement for IAA for Exempt research with a limited review only when federally funded/sponsored.	Section 3.0, 6.1.3, 6.1.4

**References:**

OHRP, Guidance on Engagement of Institutions in Human Subjects Research.

<http://www.hhs.gov/ohrp/policy/engage08.html>

OHRP, Federalwide Assurance Instructions.

<http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html>

<p><b>Institutional Review Board (IRB) Reliance Agreements</b></p>	<p><b>East Carolina University University &amp; Medical Center Institutional Review Board</b></p>	<p><b>Page 6 of 6</b></p>
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