Individual Investigator Agreement (IIA) (Collaborating Investigators from Outside East Carolina University (ECU) and its Affiliates)	Effective Date	11/2/11
	Revisions Date	01.21.2019

1.0 Purpose: This rule establishes guidelines and mechanisms for when the use of an Individual Investigator Agreement (IIA) is appropriate to submit for a collaborating investigator, from an institution other than ECU and its Affiliates, "engaged" in human research activities. ECU and its Affiliates are assured institutions that may extend, for one or more protocols, their Federalwide Assurance (FWA) to cover collaborating independent or institutional investigators. This rule will describe who meets to the criteria to complete and submit an Individual Investigator Agreement.

2.0 Research Protocols Affected:

2.1 Human research reviewed and approved by the UMCIRB (may include some Exempt categories of research).

2.2 Human research in which the principal investigator is affiliated with ECU or its Affiliates and includes a collaborating investigator from outside those institutions.

3.0 Rule: This rule is to ensure that collaborating investigators outside of ECU and its Affiliates are appropriately acknowledged under the ECU FWA and that the Individual Investigator Agreement is utilized accordingly. All collaborating investigators outside the jurisdiction of ECU or its Affiliates, that qualify as an "independent" or "institutional" investigator should submit an Individual Investigator Agreement for review with each applicable protocol submission.

4.0 Definitions:

4.1 Affiliate: An institution which relies upon East Carolina University, through a formal, signed agreement, for Institutional Review Board review and oversight of human research activities.

4.2 Assured institution: an institution holding an approved FWA from the Office for Human Research Protections (OHRP).

4.3 Engaged: an institution is *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project: (1) obtain information about or biospecimens from the subjects of the research through intervention or interaction with the subjects and uses, studies, or analyzes the information or biospecimens; (2) obtain, use, study, analyze, or generate identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) obtain the informed consent of human subjects for the research.

4.4 Federalwide Assurance (FWA): assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subject research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

4.5 Independent investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

4.6 Institutional investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; acting as an employee or agent of an institution that does not hold an OHRP-approved FWA.

4.7 Individual Investigator Agreement (IIA): a written agreement to extend an assured institution's FWA to cover a collaborating individual investigator.

5.0 Responsibilities:

5.1 Principal Investigator (PI) will direct and appropriately supervise all of the research activities performed by the collaborating investigator outside the assured institution.

5.1.1 Ensure that collaborating institutional investigators provide written approval from their non-assured institution allowing the conduct of the research at their institution.

5.1.2 Ensure an IIA is submitted for each collaborating investigator per applicable study.

5.1.3 Submit any changes to study personnel in a timely fashion.

5.2 Collaborating Investigator will adhere to the terms in the IIA and complete the required educational training through the CITI program (this educational requirement is good for 3 years and a link to the CITI site is provided on the ORIC website).

5.3 University and Medical Center Institutional Review Board (UMCIRB) office will provide assistance and guidance in making determinations on which collaborating investigators may be eligible to submit an IIA.

5.4 UMCIRB Administrative Director or designee will ensure compliance with this policy.

5.4.1 The Administrative Director or designee will coordinate obtaining the signature of the appropriate Institutional Official on the IIA and will return a fully executed copy of the agreement to the PI.

6.0 Procedures:

6.1 The collaborating independent or institutional investigator should obtain and complete the appropriate IIA from the ORIC website: www.ecu.edu/irb, under Forms, Docs & Templates > General Forms and Worksheets (choose the ECU or VMC IIA as applicable).

6.2 The PI should submit this completed IIA at the time of submission to the IRB.

6.3 The appropriate Institutional Official's signature will be obtained on the IIA by the UMCIRB office.

6.4 A copy of the fully executed IIA will be forward to the PI.

6.5 The PI should notify the UMCIRB of any changes to the IIA or removal of the collaborating investigator from the study through the submission of an Amendment (to revise research team members) in the IRB electronic submission system.

6.6 If a collaborating institutional investigator does not meet the criteria to be included on a study with the IIA, there are other means of collaborating such as obtaining IRB approval from the collaborating investigator's institution in addition to UMCIRB approval or executing an IRB Authorization Agreement between the two institutions where one institution relies on the other for IRB review and approval. The UMCIRB is available to assist in determining the appropriate regulatory documents necessary for collaboration.

Revision History:

Date	Change	Reference Section(s)
01.21.2019	Common Rule revisions and updating ORIC name	

References

DHHS, OHRP. Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement.
http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html

DHHS, OHRP. Guidance on Engagement of Institutions in Human Subjects Research.
http://www.hhs.gov/ohrp/policy/engage08.html