Faculty Supervisor Responsibilities in Human Research	Effective Date	07.19.2016
	Revisions Date	01.21.2019

1.0 Purpose: This standard operating practice (SOP) outlines the primary responsibilities of faculty members who serve as supervisors for students, residents, fellows (medical and post-doctoral) and visiting faculty serving as Principal Investigator (PI) of human research projects.

2.0 Persons Affected:

2.1 Any faculty member who serves as a faculty supervisor for another individual who conducts human research.

2.2 Any student, resident, fellow or visiting faculty serving as the PI for a human research project.

3.0 SOP: The Faculty Supervisor overseeing human research activities conducted by students, residents, fellows and visiting faculty is responsible for the overall management of an approved research project in conjunction with the student, resident, fellow or visiting faculty PI. Management of the research encompasses the ethical, administrative, fiscal and applied elements of a project.

4.0 Definitions:

4.1 Faculty Supervisor: a faculty member who accepts responsibility for actively overseeing the conduct of approved human research where the PI is either a student, resident, fellow or visiting faculty. Faculty Supervisor responsibilities may only be carried out by a member of East Carolina University faculty, or others designated as such by ECU's affiliates, that meet the qualifications to be a PI. The Faculty Supervisor is considered the responsible party for assisting student, resident, fellow or visiting faculty PIs in making ethical decisions throughout the life of the research project.

4.2 Human Research: a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge where the researcher obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

4.3 Non-compliance: Failure (intentional or unintentional) to comply with federal regulations, state or local laws, institution or UMCIRB policies, rules or UMCIRB determinations regarding research involving humans or ethical principles of the Belmont Report. Noncompliance can result from action or omission and may be non-serious (minor), serious and/or continuing

5.0 Responsibilities:

5.1 Faculty Supervisor:

5.1.1 Accept and acknowledge their responsibility for protecting the rights and welfare of human research participants, by being listed as the Faculty Supervisor on the research project and electronically signing the study submission;

5.1.2 Ensure students, residents, fellows and visiting faculty have sufficient training and experience to conduct the research in accord with the protocol;

5.1.3 Satisfy the human subject research training requirement (CITI) and understand the ethical standards and regulatory requirements governing research activities with

human participants;

5.1.4 Collaborate with student, resident, fellow or visiting faculty PIs during the preparation of the IRB proposal and ensure the proposed research complies with the ethical principles outlined in the Belmont Report, human subject research regulations, institutional policies, and other applicable federal or state laws;

5.1.4.1 Reviews proposal and advises student, resident, fellow or visiting faculty on the development of a relevant research question;

5.1.4.2 Assist the student, resident, fellow or visiting faculty in determining the appropriate procedures necessary to answer the research question;

5.1.4.3 Provides guidance and information regarding IRB review and approval;

5.1.4.4 Assist the student, resident, fellow or visiting faculty in obtaining consultation with ORIC staff; and

5.1.4.5 Reviews the final proposal, IRB application and applicable documents for consistency, accuracy and validity.

5.1.5 Ensure the student, resident, fellow or visiting faculty PI is in compliance with the additional responsibilities listed as investigator responsibilities;

5.1.6 Report any real or potential conflicts of interest in compliance with the COI policy of the University;

5.1.7 Make adequate time to consult with the student, resident, fellow or visiting faculty PI on a regular basis to monitor research progress;

5.1.8 Assist and supervise the researcher in problem solving in the event a problem, emergent question or concern were to arise;

5.1.9 Ensure all research activities have IRB approval and other ancillary approval required by the institution before human subjects are involved, and implement the research activity as it was approved by the IRB;

5.1.10 Ensure all research activities are conducted in compliance with internal policies including IRB policy, applicable regulations and state law;

5.1.11 Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained;

5.1.12 Ensure prompt reporting by student, resident, fellow or visiting faculty PIs of unanticipated problems, protocol deviations, and DSMB reports to the UMCIRB;

5.1.13 Ensure the IRB is notified when the research is completed. In the event that the PI is unable or unwilling to do so, the responsible Faculty Supervisor will be required to do so prior to when the PI graduates or otherwise leaves ECU.

6.0 Authority of the IRB:

6.1 The IRB has the authority to:

6.1.1 Request modification to a proposed research activity to better protect the rights and welfare of the participants;

6.1.2 Grant approval for research activities involving humans for 364 days or less, depending upon the:

6.1.2.1 Level of risks associated with the research;

6.1.2.2 Level of expertise or experience of the student, resident, fellow or visiting faculty PI;

6.1.2.3 Previous experience with the Faculty Supervisor.

6.1.3 Investigate any allegations of non-compliance;

6.1.4 Observe or have a third party observe the consent process and the research; and

6.1.5 Suspend or terminate IRB approval with due cause.

Revision History:

Date	Change	Reference Section(s)
07.19.2016	New	All sections
01.21.2019	Common Rule revisions	4.2