

UMCIRB Determination of Investigator and Key Research Personnel Qualifications to Conduct Human Research	Effective Date	12.05.13
	Revision Date	5.16.2024

1.0 Purpose: The UMCIRB is responsible for ensuring proposed human research satisfies the criteria for approval. To fulfill this responsibility, the UMCIRB needs information about the qualifications of the investigator(s) who will be conducting and supervising the proposed research as well as research personnel who will be engaged in the research. This SOP establishes guidelines for use by the UMCIRB in determining whether investigator(s) and key research personnel possess the qualifications to conduct human research activities.

2.0 Persons Affected:

- 2.1 Investigators proposing research activities involving humans
- 2.2 Key research personnel engaged in human subject research
- 2.3 Department Chairs
- 2.4 UMCIRB office staff
- 2.5 UMCIRB members

3.0 SOP: In the effort to protect human research participants the UMCIRB, during the review of proposed human research, will evaluate the qualifications of the investigator(s) and key research personnel to establish whether they possess the appropriate experience or expertise to accurately and effectively implement the procedures proposed in the research submission.

4.0 Definitions:

- 4.1 Investigator: Title indicating the person serving as either the principal investigator or sub-investigator (including faculty, staff, students and/or others) who is responsible for the design, conduct, implementation, evaluation, participant safety, and/or reporting of the proposed or ongoing project. Investigators include individuals employed by ECU, ECU Affiliates ECU Health, and those who fall under a contractual agreement (including IRB Authorization Agreements and Individual Investigator Agreement [IIA]) with the UMCIRB.
- 4.2 Key Research Personnel: individuals who contribute to the scientific development or execution of a project in a substantive, measurable way by obtaining voluntary informed consent of individuals to participate in research, obtaining, studying, interpreting, or analyzing identifiable private information or data for research purposes, or obtaining information about living individuals by intervening or interacting with them for research purposes.
 - 4.2.1 An individual who will be interacting with research subjects during the course of a research study, but only in his/her regular non-research employment capacity, such as a clinic receptionist, nurse or phlebotomist, or a radiologist or radiology technician, should not be included as key research personnel for the study if the person will perform only genuinely non-collaborative services meriting neither professional recognition nor publication privileges and not associated with individual financial gain, and will not contribute to the design, governance and/or analysis of the study.

5.0 Responsibilities:

5.1 Investigators are responsible for:

- 5.1.1 Completing the mandatory, web-based, training on human research protections as required by ECU UMCIRB standard operating practice.
 - 5.1.1.1 Equivalent training may be acceptable for investigators who are not affiliated with the Institution and who are relying on either a contractual agreement, an IRB Authorization Agreement, or an Individual Investigator Agreement (IIA) with the UMCIRB.
- 5.1.2 Adding their training completion date in the electronic IRB system.
- 5.1.3 For research that involves greater than minimal risk, providing the IRB with a copy of their CV or resume outlining evidence of their qualifications to conduct human research. The CV or resume should outline the education, training, and experience of the investigator. The investigator’s CV or resume should be provided to the IRB within the electronic IRB system.
- 5.1.4 Submitting research for prospective IRB review and complying with all IRB conditions of approval, institutional policy and federal and state regulations and laws.
- 5.1.5 Identifying the roles and responsibilities of key research personnel within the IRB application.
 - 5.1.5.1 Principal Investigators (PI) that will be away from the study site for an extended period of time (but less than 90 days) may remain the PI named on a research study as long as the PI has a plan for and can maintain adequate oversight of the study, ensures all procedures are done properly and by the proper research personnel, obtains concurrence from the sponsor or other relevant stakeholders, and ensures there are no work related issues that would prevent contact for work (ECU PIs may need to contact ECU Human Resources for further guidance). The research site should contact the UMCIRB office for anticipated or unexpected absences of 90 days or more, or for further guidance.

5.2 Key Research Personnel are responsible for:

- 5.2.1 Completing the mandatory, web-based, training on human research protections as required by ECU UMCIRB standard operating practice.
- 5.2.2 Equivalent training may be acceptable for research personnel who are not affiliated with the Institution and who are relying on either a contractual agreement, an IRB Authorization Agreement, or an Individual Investigator Agreement (IIA) with the UMCIRB.
- 5.2.3 The training completion date should be logged in the electronic IRB system.
- 5.2.4 For research that involves greater than minimal risk, providing the IRB with a copy of their CV or resume outlining evidence of their qualifications to conduct human research. The CV or resume should outline the education, training, and experience of the research personnel. The CV or resume should be provided to the IRB within the electronic IRB system.

- 5.3 Department Chairs are responsible for:
- 5.3.1 Ensuring the Investigator has the appropriate expertise and/or knowledge to conduct the research as proposed;
 - 5.3.2 Ensuring there are adequate resources including space and support personnel available to the Investigator to conduct this study in the proposed manner; and
 - 5.3.3 Ensuring the proposed research is scientifically sound, contributes to the scope and mission of the Department, and, therefore, to that of the University
- 5.4 UMCIRB staff are responsible for:
- 5.4.1 Ensuring that the investigator’s and key research personnel’s mandatory training has been completed within the time frame required and is documented in the electronic IRB system;
 - 5.4.2 Ensuring a copy of the investigator’s and key research personnel’s CV or resume is available for review in the electronic IRB system, if applicable;
 - 5.4.3 Ensuring that new study submissions have been routed for and received proper Departmental Review and approval;
 - 5.4.4 In the case of an investigator or key research personnel who is not known, the UMCIRB staff may take additional steps to assess their qualifications. In addition, the UMCIRB staff may:
 - 5.4.4.1 Verify professional association and professional licensure,
 - 5.4.4.2 Review FDA’s Inspections, Compliance, Enforcement, and Criminal Investigations website for information related to clinical investigator inspections, Warning Letters, disqualification proceedings, and debarments, and other public websites such as the OIG Exclusion Database,
 - 5.4.4.3 Review relevant publications generated by the investigator,
 - 5.4.4.4 Seek counsel from outside sources; and/or
 - 5.4.4.5 Recommend to the UMCIRB that the investigator(s) be required to complete training in good clinical practice.
- 5.5 UMCIRB members are responsible for:
- 5.5.1 Ensuring that all new studies submitted for review and approval meet all federal, state and institutional guidelines;
 - 5.5.1.1 inclusive of an assessment of the investigator’s and key research personnel’s qualifications to conduct the described research.
 - 5.5.1.2 this assessment should be made based on the information provided by the investigator and reviewed by the UMCIRB staff as described above.
 - 5.5.2 Assessing the investigator’s and key research personnel’s training and experience specifically related to a proposed study, particularly if the proposed research involves increased risks, vulnerable participants, or novel technologies. In such cases, the IRB’s assessment is particularly important and may include a review of the investigator’s and research personnel’s previous specific experience as demonstrated by recent presentations or publications, and prior clinical experience with investigational agents, test articles or study-related procedures. In particular, the IRB will pay close attention to an investigator’s qualifications to conduct a study if the study involves one or more of the following:

- 5.5.2.1 when the investigator also serves as the sponsor,
 - 5.5.2.2 a study that is outside of the investigator’s area of expertise; or
 - 5.5.2.3 any study design features or other characteristics that may significantly increase potential risks to participants.
- 5.5.3 If, after assessment of an investigator’s and key research personnel’s qualifications, concerns remain, the UMCIRB may elect to request more information, observe, or have a third party observe the consent process and/or any other portion of the research.

Revision History:

Date	Change	Reference Section(s)
12.5.13	New SOP	All sections
02.25.14	Revision	All sections
5.31.2019	Update office name	2.0, 5.4, 5.5
11.1.2019	Updated Key Research Personnel definition; added Investigator responsibility	4.2, 5.1.6
7.15.2021	Added guidance about PI’s who may need to be out for extended leave	5.1.5.1
5.16.2024	Updated site name; clarified when additional resources may be used for determining qualifications	4.1, 5.4.4

References:

ICH E6 Good Clinical Practice: Consolidated Guidance, 3.1.3 and 4.1.1
 Code of Federal Regulations, Title 21 CFR Part 56.102(h)(j)
 Code of Federal Regulations, Title 21 CFR Part 312.53(a)
 Code of Federal Regulations, Title 21 CFR Part 812.43(a)

NIH, Frequently Asked Questions, Senior/Key Personnel:
https://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm#1658

OHRP, Investigator Responsibilities FAQ: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>

US Food and Drug Administration (FDA), Inspections, Compliance, Enforcement, and Criminal Investigations: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations>

Office of Inspector General (OIG), Exclusion Database: <https://exclusions.oig.hhs.gov/>