

Chairperson and Vice Chairperson Service on the Institutional Review Board (IRB)	Effective:	09.30.2015
	Revised:	2.5.2019

- 1.0 Purpose:** This standard operating practice (SOP) establishes guidelines for:
- 1.1 Appointment of IRB Chairpersons and Vice Chairpersons (or designee)
 - 1.2 Length of Service of IRB Chairpersons and Vice Chairpersons
 - 1.3 Evaluation of the abilities and effectiveness of IRB Chairpersons and Vice Chairpersons
 - 1.4 Responsibilities and Duties of IRB Chairpersons and Vice Chairpersons
 - 1.5 Compensation for serving on the IRB
 - 1.6 Liability coverage for IRB Chairpersons and Vice Chairpersons
- 2.0 Persons Affected:**
- 2.1 Institutional Official (IO)
 - 2.2 University and Medical Center Institutional Review Board (UMCIRB) Chairpersons and Vice Chairpersons
- 3.0 SOP:** This SOP is to ensure that ECU has Chairpersons and Vice Chairpersons (or designee) that appropriately represent the Institutional Review Boards and who are experienced faculty that are viewed by their colleagues as individuals concerned with the ethical use of humans in research activities.
- 4.0 Definitions:**
- 4.1 Institutional Review Boards (IRB)** are appropriately constituted committees that have been formally designated to review and monitor human research. In accordance with federal regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this purpose, IRBs review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of humans participating in research.
- 4.1.1** The Chairperson and Vice Chairperson (or designee) serve as the Primary Reviewers for all expedited and exempt studies and have the authority to:
 - 4.1.1.1** Determine when activities meet the definition of human research;
 - 4.1.1.2** Approve research;
 - 4.1.1.3** Require modifications of the research (including deferring review until major modifications are made); or
 - 4.1.1.4** Forwarding any human research activities that he/she believes does not meet the criteria for approval, as set forth in 45 CFR 46, for review and deliberations.
- 4.2 IRB Chairperson:** Individual appointed by the IO who:
- 4.2.1** Is a respected, active member of the IRB for at least one year;
 - 4.2.2** Is qualified, e.g., understands research and/or has conducted human research;
 - 4.2.3** Is concerned about human rights and ethical issues; and
 - 4.2.4** Is well-informed in regulations relevant to human research protections.

- 4.2.5 Upon reaching the appropriate time interval, the Chairperson will be expected to become a Certified IRB Professional.
- 4.3 **IRB Vice Chairperson:** Individual appointed by the IO who:
- 4.3.1 Is a respected, active member of the IRB;
- 4.3.2 Has served on the IRB for a minimum of one year;
- 4.3.3 Is concerned about human rights and ethical issues; and
- 4.3.4 Will be expected, upon appointment, to become well-versed in regulations relevant to human research protections.
- 4.3.5 Upon reaching the appropriate time interval, the Vice Chairperson will be expected to become a Certified IRB Professional.
- 4.4 **Designee:** IRB Vice Chairperson or, if the Vice Chairperson is unavailable or has a conflict:
- 4.4.1 An experienced IRB member (e.g., with at least one year of experience serving on the IRB)
- 4.4.2 Designated by the IRB Chairperson to serve on behalf of the Chairperson or Vice Chairperson;
- 4.4.3 An IRB member that will be responsible for conducting IRB meetings, reviewing IRB correspondence and submissions, and
- 4.4.4 Willing to serve as the reviewer for expedited and exempt research.
- 4.5 **Length of Term:** The Chairperson and Vice Chairperson will be appointed to serve on the IRB for a period of four years. Should that person not be able to complete the term, a letter of resignation must be submitted to the IO through the Human Research Protections (HRP) Director, UMCIRB.
- 4.6 **Compensation:** The Chairperson, upon request from his/her Departmental Chair or Division Head, may be compensated for their time in service to the IRB.
- 4.6.1 A letter of request must be submitted to the HRP Director, UMCIRB, who will forward it to the appropriate administrative body for consideration.
- 4.7 **Liability Coverage:** Each person who performs a service on behalf of the ECU Institutional Review Board, including persons not otherwise affiliated with ECU, is an “agent” of ECU. No officer, employee, or agent of the state or any of its subdivisions shall be held personally liable in tort or named as a party defendant in any action for any injury or damage suffered as a result of an act, event, or omission of action in the scope of his/her employment or function, unless such officer, employee or agent acted in a manner exhibiting wanton and willful disregard of human rights, welfare or property. The exclusive remedy for injury or damage suffered as a result of an act, event, or omission of an officer, employee, or agent of the state or any of its subdivisions or constitutional officers shall be against the governmental entity.
- 4.8 **Confidentiality:** IRB Chairpersons and Vice Chairpersons (or designee) agree to hold private any proprietary information disclosed during the course of an IRB meeting or during the review of proposed human research.
- 4.9 **Conflict of Interest (COI):** An IRB Chairperson or Vice Chairperson (or designee) is considered to have a conflicting interest when the person or person’s spouse, domestic partner, parents, siblings and their spouses, or children, has any of the following:
- 4.9.1 Involvement in the design, conduct, or reporting of the research;
- 4.9.2 Supervisory role over the PI of the research;

- 4.9.3 Ownership interest, stock options, or other financial interest in an entity, product or service involved with the research when the value of the interest would be affected by the outcome of the research;
- 4.9.4 Compensation related to the research;
- 4.9.5 Proprietary interest related to the research including, but not limited to a patent, trademark, copyright or licensing agreement;
- 4.9.6 Board or executive relationship related to the research, regardless of compensation;
- 4.9.7 Any other reason for which the IRB Chairperson or Vice Chairperson (or designee) believes that he or she cannot provide an independent review.

5.0 Responsibilities:

- 5.1 **Institutional Official (IO)** has the following responsibilities:
 - 5.1.1 Authority to bind the institution by signature on correspondence to federal agencies, sponsors, and external institutions on behalf of the IRB;
 - 5.1.2 Appoints IRB Chairperson and Vice Chairperson;
 - 5.1.3 Ensures sufficient meeting space, staff and budgetary resources to support the IRB's substantial review and record keeping responsibilities;
 - 5.1.4 Remove Chairperson or Vice Chairperson, for scientific misconduct, non-reported conflict of interest, excessive absences, abuses or other actions that make it difficult for the IRB to carry out its responsibilities;
 - 5.1.5 Protect the Chairperson and/or Vice Chairperson from undue influence by investigators or administrative officials;
 - 5.1.6 Complete educational training on human research protections at least once every three years, in accordance with ECU IRB educational requirements.
- 5.2 **UMCIRB Administrative Director or designee** has the following responsibilities:
 - 5.2.1 Make recommendations to the IO for the positions of Chairperson and Vice Chairperson;
 - 5.2.2 Review the IRB SOPs at least annually to ensure current compliance with all Federal, State and local requirements for the protection of humans in research;
 - 5.2.3 Ensure continuing education is made available to the Chairperson and Vice Chairperson;
 - 5.2.4 Provide recommendations on Committee Business; and
 - 5.2.5 Provide guidance and interpretation of federal regulations, state laws, and institutional policies as is relevant to human research activities being reviewed.
- 5.3 **IRB Chairperson** has the following responsibilities:
 - 5.3.1 Complete educational training on human research protections at least once every three years, in accordance with ECU IRB educational requirements;
 - 5.3.2 Attend national conferences on human research protections at least biennially;
 - 5.3.3 Seek professional certifications recognizing their expertise and experience in human research protections;
 - 5.3.4 Submit a curricula vita (CV) at time of appointment and an updated CV if term is renewed;
 - 5.3.5 Conduct IRB meetings in an orderly manner:
 - 5.3.5.1 Lead the IRB meetings and provide structure to the meeting's proceedings;
 - 5.3.5.2 Conduct IRB business to ensure that each proposal is fairly and completely reviewed;

- 5.3.5.3 Ensure the Board reaches a decision on the disposition of each proposal; and
 - 5.3.5.4 Ensure that these decisions are communicated to the investigators in writing.
 - 5.3.6 Review, as needed and as delegated by the IRB, responses from investigators to determine if the IRB's concerns are sufficiently addressed to allow approval, when appropriate, without being returned to the fully convened IRB;
 - 5.3.7 Disclose any real or perceived conflicting interests in research being reviewed;
 - 5.3.8 Sign correspondence on behalf of the IRB;
 - 5.3.9 Attend any policy and program meetings (retreats) and participate in discussions on policy or program revisions and educational initiatives;
 - 5.3.10 Serve as reviewer for IRB submissions requiring expedited review and complete those reviews within a five working day period;
 - 5.3.11 Serve as reviewer for IRB submissions within a five working day period where exempt certification is requested;
 - 5.3.12 Maintain a commitment to uphold federal regulations, state laws, and institutional policies, rules and regulations that pertain to human research protections.
- 5.4 **IRB Vice Chairperson** has the following responsibilities:
- 5.4.1 Serve in the capacity of Chairperson, in the Chairperson's absences and assume all of the same responsibilities listed in 5.3 above;
 - 5.4.2 Serve as reviewer for proposed human research activities;
 - 5.4.2.1 During the Chairperson's absence;
 - 5.4.2.2 If the Chairperson has a real or perceived conflict of interest;
 - 5.4.2.3 When the number of submissions is excessive; or
 - 5.4.2.4 When the Chairperson is unable to review within the five-day review period.

6.0 Procedures:

- 6.1 **IRB Policy and Program Meetings (Retreats):** UMCIRB will hold a Policy & Program meeting during the year and it is the responsibility of all Chairpersons and Vice Chairpersons to attend these meetings.
- 6.2 **Annulment of Membership:** A letter of annulment copied to the IRB Chairperson/Vice Chairperson's Department Chairperson and Dean and/or annulment of the individual's membership on the IRB will be reported to the IO and can be the result of:
 - 6.2.1 Failure to attend 75% of the scheduled UMCIRB meetings,
 - 6.2.2 Missing two consecutive IRB Policy and Program Meetings (retreats);
 - 6.2.3 Failure to properly prepare for meetings:
 - 6.2.3.1 Unprepared to lead discussion of the proposed research when assigned as primary or secondary reviewer;
 - 6.2.3.2 Unprepared to participate in discussion of any and all agenda items as general reviewer;
 - 6.2.4 Failure to notify, in a timely manner, the UMCIRB office staff of scheduled absences three or more times during a calendar year.
- 6.3 **Evaluations:** Chairpersons and Vice Chairpersons will be assessed on the following:
 - 6.3.1 Attendance and notification of absences in a timely fashion;
 - 6.3.2 Insightful, well-prepared reviews;

- 6.3.3 Participation in discussions during meetings, relevant to submissions and address the criteria for approval;
- 6.3.4 Service as a designee, when called upon;
- 6.3.5 Consultation, mentoring to investigators and research staff;
- 6.3.6 Overall performance in the protection of humans in research.

Revision History:

Date	Change	Reference Section(s)
09.30.15	Updated to stand-alone document.	All
2.5.2019	Clarification of office name and titles.	All

References:

Department of Health and Human Services. Protection of Human Subjects. [45CFR46.107](#)

Food and Drug Administration. Institutional Review Boards. [21CFR56.107](#)