Institutional Review Board (IRB) Membership	Effective	10.2.2014
	Revised	2.5.2019

1.0 Purpose: This standard operating practice (SOP) establishes guidelines for:

- **1.1** Membership requirements for duly constituted IRBs
- **1.2** Appointment of IRB Members (Full, Alternate and Ex-officio)
- **1.3** Length of Service of IRB Members
- **1.4** Evaluation of the number of IRBs ECU will maintain
- **1.5** Evaluation of the abilities and effectiveness of IRB Members
- **1.6** Responsibilities and Duties of IRB Members
- **1.7** Compensation for serving on the IRB
- **1.8** Liability coverage for IRB Members

2.0 Persons Affected:

- **2.1** Institutional Official (IO)
- **2.2** University and Medical Center Institutional Review Board (UMCIRB) Members (Full, Alternate and Ex-officio)

3.0 SOP: This SOP is to ensure that ECU has duly constituted IRBs that support its Federal-wide Assurance; that those IRBs maintain membership with a broad spectrum of scientific, scholarly, and ethical expertise to appropriately review biomedical and behavioral and social science human research activities submitted by ECU or ECU Affiliate employees, students, or agents.

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 IRB will be composed as follows:

4.1.1.1 Each IRB will have a minimum of at least five members;

4.1.1.2 IRB members will possess varying backgrounds to promote complete and adequate review of human research activities commonly conducted at ECU and institutions for which ECU IRB is the designated IRB of record;

4.1.1.3 IRB members will be sufficiently diverse relative to race, gender, cultural group and sensitivity to community attitudes so as to promote respect for the IRB's advice and counsel and in safeguarding the rights and welfare of those who volunteer to take part in the research;

4.1.1.4 IRB members will include persons able to ascertain the acceptability of proposed human research activities in terms of institutional

commitments, regulations, applicable law, and standards of professional conduct and practice;

4.1.1.5 Each IRB will consist of members from a variety of professions;

4.1.1.6 Each IRB will have at least one member whose primary expertise is in a scientific area; and at least one member whose primary expertise is in a non-scientific area;

4.1.1.7 Each IRB will have at least one member who is not otherwise affiliated with ECU or another institution for which ECU IRB is the designated IRB of record;

4.1.1.8 Each IRB will have sufficient expertise to review the broad range of human research in which ECU and its Affiliates become involved or will seek consultation from external sources;

4.1.1.9 The composition of each IRB will contain at least one member who is knowledgeable about or is experienced in working with vulnerable populations when research involving participants vulnerable to coercion or undue influence is being reviewed.

4.1.2 Each IRB has the authority to:

4.1.2.1 Determine when activities meet the definition of human research;

4.1.2.2 Approve research;

4.1.2.3 Require modifications of the research (including deferring review until major modifications are made); or

4.1.2.4 Disapprove human research activities conducted at ECU or ECU Affiliates.

4.1.3 Each IRB has been established to review human research activities proposed by the faculty, staff, students, or agents acting for ECU and from individuals originating human research activities within any of the affiliate institutions with which ECU has an agreement to provide IRB review and oversight of human research.

4.2 **IRB Member:** Individual appointed by the IO from a variety of sources including employees, students, and agents of ECU, ECU Affiliates, and the community. These individuals will be appointed from a diversity of disciplines that provide the appropriate experience and expertise that represents the types of human research submitted to the IRB for review.

4.3 **IRB Alternate Member:** Individuals appointed by the IO to serve as alternates for specific voting members in the regular member's absence. Alternate members should have the same designation as the member for whom they serve as alternate (e.g., scientist, non-scientist, community member, prisoner advocate, etc.). IRB Alternate Members have the same authority, responsibilities, and duties as a regular member. Alternate members may be qualified to replace more than one regular member; however, only one such member may be represented by the alternate at any convened meeting.

4.4 **Ex-Officio Member:** Individuals appointed to the UMCIRB committee to provide administrative or regulatory guidance to the IRB. Ex-Officio Members are appointed from each of ECU's Affiliates to provide administrative consultation to the IRB regarding research being conducted in that facility. Ex-Officio Members may not vote on IRB determinations and will not be included in establishing quorum at a convened meeting. However, recommendations from Ex-Officio Members should be considered by the IRB during its review process.

4.5 **Ad Hoc Consultant:** An individual who is a scientist or non-scientist possessing special knowledge or expertise recruited to assist the IRB in its deliberations on a specific proposal. Their special expertise shall qualify them to serve as ad hoc reviewers for specific projects or protocols identified by the IRB.

4.5.1 Ad Hoc Consultants may:

4.5.1.1 Be recruited from within ECU or its affiliate institutions or when necessary from an external source;

4.5.1.2 Receive all documents submitted to the IRB that are relevant to the specific project under review;

4.5.1.3 Make recommendations to the IRB for the specified project;

4.5.1.4 Provide a written report and, if available, participate in that portion of the IRB meeting in which the specific protocol is discussed.

4.5.2 Ad Hoc Consultants may not:

4.5.2.1 Be included in determining or establishing quorum; or

4.5.2.2 Vote on IRB determinations.

4.6 **Continuing Consultant:** An individual who is a scientist or non-scientist possessing specialized knowledge or expertise recruited to provide on-going assistance to the IRB in its deliberations across projects that have a common element or ethical issue.

4.6.1 Continuing Consultants may:

4.6.1.1 Be recruited from ECU faculty or administrative staff as the IRB deems appropriate;

4.6.1.2 Receive all documents submitted to the IRB that are relevant to the specific project on which they are asked to consult;

4.6.1.3 Take part in all meetings of the IRB;

4.6.1.4 Provide a written report and, if available, participate in the deliberations and make recommendations to the IRB for the project for which they hold specialized expertise or knowledge;

4.6.1.5 The continuing consultant's duration of appointment may be unlimited.

4.6.2 Continuing Consultants may not:

4.6.2.1 Be included in determining or establishing quorum; or

4.6.2.2 Vote on IRB determinations.

4.7 **Length of Term:** Each member will be appointed to serve on the IRB for a period of four years. Should the member not be able to complete the term, a letter of resignation must be submitted to the IO through the Human Research Protections Director, UMCIRB.

4.8 **Compensation:** Excluding the Chairpersons there is no compensation made to any member of the IRB by the University or any of its Affiliates. Each member is asked to contribute his or her time in the completion of responsibilities and tasks associated with serving on the IRB. Acknowledgement of that service is provided by the IO in letters of appreciation.

4.9 **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.

4.10 **Confidentiality:** IRB members agree to hold private any proprietary information disclosed during the course of the IRB meetings or during the review of proposed human research.

4.11 **Conflict of Interest (COI):** An IRB member or consultant is considered to have a conflicting interest when the member/consultant or the member or consultant's spouse, domestic partner, parents, siblings and their spouses, or children, has any of the following:

- **4.11.1** Involvement in the design, conduct, or reporting of the research;
- **4.11.2** Supervisory role over the PI of the research;
- **4.11.3** 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;
- **4.11.4** Compensation related to the research;
- **4.11.5** Proprietary interest related to the research including, but not limited to a patent, trademark, copyright or licensing agreement;
- **4.11.6** Board or executive relationship related to the research, regardless of compensation;
- **4.11.7** Any other reason for which the member or consultant 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** Appoint IRB Chairs and Vice Chairs, IRB members and alternates;
- **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 IRB members, including Chairs and Vice Chairs, 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 IRB members 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** Recruit ex-officio members and consultants as needed to conduct the business of the IRB and ensure proper review of human research;
- **5.2.2** Make recommendations to the IO on membership issues;
- **5.2.3** 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;
- **5.2.4** Ensure continuing education is made available to IRB members;
- **5.2.5** Provide recommendations on Committee Business; and

5.2.6 Provide guidance and interpretation of federal regulations, state laws, and institutional policies as is relevant to human research activities being reviewed.

5.3 **IRB Members** have the following responsibilities:

5.3.1 Complete orientation in human research protections and ECU IRB procedures prior to serving as a voting member; including:

5.3.1.1 Attend at least one IRB meeting as a visitor prior to serving as a voting member;

5.3.1.2 Complete the CITI training in compliance with ECU IRB requirements;

5.3.1.3 Submit a current curricula vita (CV) at the time of appointment and an updated CV if term is renewed;

5.3.1.4 Sign a Confidentiality Agreement;

5.3.1.5 Disclose any real or perceived conflicting interests in research being reviewed.

5.3.2 Ensure research involving human participants has met the criteria set forth in the federal regulations, state laws, and institutional policies and procedures before issuing final approval;

5.3.3 Understand that by serving on the IRB they are also serving as a member of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Board;

5.3.4 Attend a minimum of 75% of the annual IRB meetings; if unable to attend the meeting the member should:

5.3.4.1 Except in the case of emergencies; provide at least 72 hour (3 business days) notification to the UMCIRB office staff; and

5.3.4.2 Contact the appropriate alternate in time for that individual to conduct the review in the member's place;

5.3.5 Serve as scientist reviewers, with experience in areas of research commonly submitted to the IRB; or

5.3.6 Serve as non-scientist reviewers, with interest in human rights issues and/or ethical or legal experience or expertise relevant to human research; or

5.3.7 Serve as non-affiliated members

5.3.7.1 Whenever possible, will be a non-scientist; and be familiar with Eastern North Carolina populations;

5.3.7.2 Will have no affiliation with ECU or an ECU Affiliate;

5.3.7.3 Review proposed research for applicability and potential benefit to the individuals in Eastern North Carolina.

5.3.8 Serve as primary reviewers for research, whenever possible, that falls within their areas of specialized knowledge and expertise;

5.3.8.1 Primary reviewers are responsible for comparing information provided in the consent document, the IRB application and the grant, protocol, or proposal for consistency and reasonability;

5.3.8.2 Primary reviewers are responsible for providing comments from their reviews within 24 hours before the convened meeting; and

5.3.8.3 Primary reviewers are responsible for leading the discussion regarding the elements required for approval to be granted.

5.3.9 Serve as secondary reviewers for research, whenever possible, that falls within their areas of specialized knowledge or expertise;

5.3.9.1 Secondary reviewers are responsible for comparing information provided in the consent document, the IRB application and the grant or sponsor's protocol for consistency and reasonability,

5.3.9.2 Secondary reviewers are responsible for providing comments from their reviews within 24 hours before the convened meeting; and

5.3.9.3 Providing any additional comments or concerns that may have not been addressed during the primary reviewer's discussion.

5.3.10 Serve as general reviewers for all research submitted for review at a convened meeting;

5.3.10.1 General reviewers are responsible for making themselves familiar with all of the proposed research, whether being submitted for initial or continuing approval in order to be able to participate in the discussion of the required elements necessary for approval; and

5.3.10.2 General reviewers are responsible for reading each of the proposed consent forms to ensure that;

5.3.10.2.1 All of the general, basic and additional elements are present;

5.3.10.2.2 The information is presented in a language that would be understandable to the targeted population;

5.3.10.2.3 The information is consistent with that provided in the IRB application and all other materials.

5.3.11 Disclose any real or perceived conflicting interests in research being reviewed and recuse from discussion and voting by leaving the IRB meeting room;

5.3.12 Experienced members (e.g. those that have served at least one year on an IRB) may serve as designee for the Chair and/or Vice Chair in the absence of or when there is a perceived or real conflict of interest identified by the Chair or Vice Chair.

5.4 **Ad Hoc Consultants** have the following responsibilities:

5.4.1 Provide, upon request from the IRB, certification of experience and/or expertise;

5.4.2 Serve as unbiased advisors to the IRB on specific issues identified by the IRB;

5.4.3 Provide in writing, in a timely fashion, accurate information on specific protocols as requested by the IRB;

5.4.4 Disclose any perceived or real conflict of interest associated with the proposed or ongoing research on which they are asked to consult;

5.4.4.1 If such a conflict is disclosed, the Ad Hoc Consultant will be recused from serving as a reviewer;

5.4.5 Sign and uphold a Confidentiality Agreement for any proprietary information to which they may have access during their review of materials for the IRB.

5.5 **Continuing Consultants** have the following responsibilities:

5.5.1 Submit a current CV at the time of appointment and a revised CV as needed;

5.5.2 Complete the CITI training in compliance with ECU IRB requirements;

5.5.3 Serve as unbiased advisors to the IRB on an as-needed basis for proposed or ongoing research that have a scientific, scholarly or ethical issue which falls within their area of expertise and/or experience;

5.5.4 Provide in writing, in a timely fashion, accurate information on specific protocols as requested by the IRB;

5.5.5 Sign and uphold a Confidentiality Agreement for any proprietary information to which they may have access during their review of materials for the IRB.

6.0 Procedures:

6.1 **IRB Policy and Program Meetings (Retreats):** UMCIRB office will hold at least one IRB Policy & Program meeting during the year and it is the responsibility of all Chairs, Vice Chairs, regular and alternate members to attend these meetings.

6.2 **Annulment of Membership:** A letter of annulment copied to the members' 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:** IRB Members 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 Attendance at IRB Policy and Program Meetings;

6.3.7 Overall performance in the protection of humans in research.

6.4 **Evaluation of the number of IRBs required to review and approve human research**:

6.4.1 The UMCIRB office in collaboration with the IO and the existing IRBs will evaluate the need for the creation of additional IRBs to carry out the review, approval and oversight of human research. The goal being to ensure that the appropriate level of resources exists to meet or exceed federal, state and local regulations in the protection of human research participants.

Revision History:

Date	Change	Reference Section(s)
10.02.2014	Updated to stand-alone document.	All
5.6.2015	Clarify review time frames.	Section 5
9.30.2015	Remove all references to Chairs and Vice Chairs. These sections were deleted or revised.	Section 1.0 (revised) Section 2.0 (revised) Section 4.2-4.4 (Removed) Section 4.6-4.8 (Revised) Section 4.11 (Revised) Section 5.3 (Removed)

		Section 5.4 (Removed) Section 6.3 (revised)
4.22.2016	Clarify those recusing from IRB discussion and vote will leave room.	Section 5.3.11
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