

THE UNIVERSITY OF NORTH CAROLINA AT ASHEVILLE
FACULTY SENATE

Senate Document Number 1517F
Date of Senate Approval 12/07/17

Statement of Faculty Senate Action:

FWDC 5:

Institutional Review Board Policy
Faculty Handbook Sections [10.4.20](#) and [4.3.6.2](#)

Effective date: January 15, 2018

Summary: This document details the changes needed within the UNC-Asheville IRB to maintain compliance with the federal regulations of the Department of Health and Human Services Protection of Human Subjects which will allow UNC-Asheville faculty to continue to conduct research studies examining human subject interventions with one or more health-related biomedical or behavioral outcomes that are now deemed, by definition, clinical trials.

Rationale:

- a. Recently, the Department of Health and Human Services Protection of Human Subjects updated the definition of a clinical trial to now include human subject interventions with one or more health-related biomedical or behavioral outcomes. These types of research studies must be reviewed by a Biomedical IRB. Faculty in several departments regularly conduct research that would now be deemed a clinical trial. Thus, IRB procedures and policy will be updated as necessary in order to remain compliant with the Department of Health and Human Services Protection of Human Subjects (**45 CFR §46**), and any applicable state or local laws so as to allow these types of research studies (now, clinical trials) to continue at UNC-Asheville. These changes will enable the UNC Asheville IRB to review biomedical protocols in addition to behavioral research projects.
- b. To facilitate this transition, all IRB documents will be updated as necessary in order to remain compliant with the Department of Health and Human Services Protection of Human Subjects (**[45 CFR §46](#)**).
- c. In addition, based on the requirements for a biomedical IRB to include at least one member who has a medical background, the number of IRB committee members will be increased from six to seven.
- d. A detailed description of the pool of IRB alternates has also been added to the document below to ensure that there are available members to step in as needed that will maintain compliance with federal guidelines for IRB membership.
- e. Finally, in order to provide the IRB Chair will additional assistance and to facilitate a smoother transition of Chair responsibilities, a new position, IRB Vice Chair, is proposed. This member will be a current IRB committee member and be appointed by the IRB Chair. In addition to assisting the IRB Chair as needed, the IRB Vice Chair, in accepting their role, agrees to serve as the IRB Chair upon the conclusion of the current Chair's period of service or if the IRB Chair takes a leave of absence.

Revise 4.3.6.2 as follows:

4.3.6.2 Institutional Review Board (formerly Human Subjects) Policy (SD8913S) (SD3110S) (SD0393F)

4.3.6.2.1 Purpose

The UNC Asheville Institutional Review Board (IRB) is charged by the University under its [Federal Wide Assurance \(FWA\)](#) with reviewing all University activities involving human research subjects, according to the ~~Department of Health and Human Service's~~ Code of Federal Regulations (CFR) for the Protection of Human Subjects ([45 CFR 46](#)), in order to safeguard the welfare and rights of research participants, including research related to class assignments. The UNC Asheville policy on human subjects applies to all faculty, student, and staff research involving human subjects, regardless of funding source. The UNC Asheville IRB reviews [biomedical and](#) behavioral research protocols; ~~investigators wishing to conduct invasive biomedical research activities should seek approval from an external IRB certified for such review.~~

4.3.6.2.2 Policies and Procedures

IRB procedures and policy will be updated as necessary in order to remain compliant with [45 CFR 46](#), and any applicable state or local laws. UNC Asheville IRB policies as well as links to [45 CFR 46](#) are available at <http://irb.unca.edu>. ~~UNC Asheville faculty, staff and students are~~ [Faculty members are](#) encouraged to consult this site for updated procedures and documents.

~~These regulations apply to all University faculty, staff, and students.~~

Policies on Research Activities

- Except as provided under Exempt Activities ([45 CFR 46.101b](#)), all research activities involving human subjects conducted by UNC Asheville faculty, students, and staff must receive IRB Review before such activities begin. Student projects involving human subjects must be reviewed and approved by the IRB before research activities begin. This includes course-related work.
- The “IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy” ([CFR 46.109](#)). Officials of the institution may disapprove research approved by the IRB, but those officials may not approve any research that has not been approved by an IRB. ([CFR 46.112](#)).
- The IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects ([CFR 46.113](#)).
- IRB approval is limited to one calendar year ([CFR 46.109e](#)), after which continuing review should be sought.
- No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative ([46.116](#)).
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards may be required to protect the rights

and welfare of these subjects (46.111b). Additional regulations may be required for pregnant women and fetuses (46.204), neonates (46.205), children (46.401), and prisoners (46.301).

4.3.6.2.3 Membership

Membership of the IRB conforms to federal guidelines (45 CFR 46.107).

~~6-Seven (7)~~ voting members and ~~3-three (3)~~ alternates, approved by the Provost, in consultation with existing IRB members and FWDC. Faculty members serve staggered three-year terms which may be renewed, while the community representative serves a one-year term which may be renewed.

- Voting Members
 - ~~Two-At least one~~ faculty member who ~~have~~has expertise in research involving human subjects from a behavioral or biomedical research discipline (~~e.g., Psychology, Management~~);
 - At least one faculty member who has expertise in research using the scientific method but not primarily involving human subjects (~~e.g., Environmental Science, Chemistry~~) ~~and one or two faculty members from any discipline to bring total voting faculty membership up to five~~;
 - At least one member who has a medical background (e.g., nursing, physical therapy, pharmacy); and
 - One member unaffiliated with the university who has expertise in scientific study which may or may not involve human subjects (Community Representative);
 - ~~One alternate from each of the above categories~~

- Alternate Members
 - At least one faculty member who has expertise in research involving human subjects from a behavioral or biomedical research discipline (e.g., Education, Health and Wellness, Psychology);
 - At least one faculty member who has expertise in research using the scientific method but not primarily involving human subjects (e.g., Art, Environmental Science, Modern Languages); and
 - The Chancellor will appoint one physician from Student Health Services to serve as an alternate. (Note: The physician will serve as a voting member, replacing the medical background member whenever reviewing FDA sponsored protocols or at the Provost's request.)

- Non-voting Members
 - Representatives from the Office of Sponsored Scholarship and Programs, ex officio ~~and non-voting~~.
 - Liaison from Academic Affairs, ex officio ~~and non-voting~~, as needed, to facilitate the work of the IRB. The Academic Affairs liaison should not participate in IRB deliberations

~~In appointing the members of the IRB, attention should be paid to gender, racial, and professional diversity.~~

Every nondiscriminatory effort will be made to ensure that the IRB will not consist entirely of men or women, including the University's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession (45 CFR 46.107b). In appointing members of the IRB, attention will be paid to gender, racial, and professional diversity.

Committee members are requested to serve a minimum of one full term as specified above, and must maintain IRB Member CITI Training Certification.

The Chair of the IRB must be a tenured member of the faculty. It is best for the Chair to have served ~~two~~ one years as a Vice Chair ~~Committee member~~ prior to assuming the role of Chair, and to serve as Chair for more than one year. ~~At the completion of his or her term, outgoing Chairs are requested to attend IRB meetings for one year after their term, either as a formal member of the committee or as an ex-officio non-voting member, to serve as a mentor for the new Chair and to promote consistency and continuity. In the rare situation where the Vice Chair is unable to move to the Chair role, it is best that the new Chair has at least two years of IRB committee service.~~

A Vice Chair of the IRB will be appointed by the current Chair of the IRB. It is best for the Vice Chair to have served one year as a member prior to assuming the role of the Vice Chair, and to agree to serve as the Chair upon the conclusion of the current Chair's period of service or if the IRB Chair takes a leave of absence.

Alternates substitute for an IRB member(s) who are unable to attend (e.g., administrative/instructional scheduling conflict, conflict of interest, professional/medical leave, etc.) so that IRB may achieve quorum in order that business may move forward. Alternates and IRB members have equal responsibilities (i.e., "job-share") in terms of required education, service and time commitments, and participation.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals do not have a vote.

No IRB member may participate in an initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB. The Chair determines whether a conflict of interest exists.

A quorum shall be achieved prior to the IRB's review of protocols and/or engaging in official business. Behavioral protocol review requires four members, including at least one scientist and one non-scientist. With clinical research, a quorum requires four members of which one scientist (may also be the medical background member), one non-scientist and one person with a medical background is present.

Details regarding IRB responsibilities should refer to <insert web link: https://irb.unca.edu/sites/default/files/SOP_IRB_001_Composition_Member_Roles.pdf at least four of the six members of the IRB, one of whom must have primary concerns in research not involving human subjects.

Recommendations and reports to: Provost

Revise 10.4.20 as follows:

10.4.20 Institutional Review Board ([SD8913S](#)) ([SD0393F](#)) ([SD3110S](#))

Purpose

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Asheville IRB reviews biomedical and behavioral research protocols; ~~investigators wishing to conduct invasive biomedical research activities should seek approval from an external IRB certified for such review.~~

Membership

Membership and procedures (see 4.3.6.2) of the IRB conforms to federal guidelines (45 CFR 46.107).

- ~~6 voting members and 3 alternates, selected by the FWDC in consultation with the Provost and VCAA and the existing IRB chair. Faculty members serve staggered three-year terms which may be renewed, while the community representative serves a one-year term which may be renewed.~~
 - ~~Two faculty members who have expertise in research involving human subjects from a behavioral or biomedical research discipline (e.g., Psychology, Management)~~
 - ~~At least one faculty member who has expertise in research using the scientific method but not primarily involving human subjects (e.g., Environmental Science, Chemistry) and one or two faculty member from any discipline to bring total voting faculty membership up to five~~
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Procedures

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Recommendations and reports to: the Provost