IRB MEMBERSHIP COMPOSITION, ROLES AND RESPONSIBILITIES

OBJECTIVE

This Standard Operating Procedure describes the administrative structure of the Institutional Review Board (IRB) at the University of North Carolina at Asheville (UNC Asheville) and the appointment process for IRB chair, vice chair, and members.

DESCRIPTION

The IRB must be appropriately constituted for the volume and types of human subject research to be reviewed, in accordance with federal regulations. The IRB will include members with diverse experience and expertise to assure the professional competence necessary to review the university’s research, as well as knowledge of community attitudes and training in protecting the rights and welfare of human subjects.

IRB COMPOSITION

In appointing IRB members, the Chancellor or their designee will ensure that the following conditions are met for the University IRB:

1. IRB members will have varying backgrounds, expertise, and professional competence as necessary to promote complete and adequate review of research activities commonly conducted at UNC Asheville.
2. The IRB will be sufficiently qualified through the experiences, expertise and diversity of its members, including considerations of race, gender, cultural backgrounds, and sensitivity such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. The IRB will include persons knowledgeable about institutional commitments and regulations, applicable laws, and standards of professional conduct and practices.
4. If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, or handicapped or mentally disabled persons, the Chancellor or their designee will appoint one or more individuals who are knowledgeable about and experienced in working with these participants.
5. No IRB will consist entirely of men or entirely of women, and no appointment to the IRB is made solely on the basis of gender.
6. The IRB will consist of seven members and three alternates.
7. The IRB membership should include:
a. One member whose primary concern are in scientific areas;
b. One member whose primary concern are in nonscientific areas;
c. One member who has a medical background (e.g., medical doctor, nurse, physical therapist, psychiatrist, etc.)
d. One member whose primary perspective represents the perspective of the research participants; and
e. One member who is not affiliated with UNC Asheville.

Note: In many cases, the same member will satisfy several roles. The IRB may, on occasion, meet without representation of the unaffiliated member; however, this should be the exception. Attendance of the unaffiliated member and the member representing the perspective of subjects at convened meetings will be monitored and assessed through documentation in the minutes (e.g., minutes indicate attendance at greater than 50% of meetings).

The IRB may invite individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available on the IRB. These individuals (consultants) may not vote with the IRB.

All IRB members, alternates and OSSP staff receive human subjects protection education related to federal regulations and guidance, University policies and procedures, and IRB procedures. Minimally, initial training in human subjects protection with continuing education every three years is required (e.g., completion of Collaborative Institutional Training Initiative modules). IRB members and OSSP staff also receive additional education/new information via newsletters, email announcements, website postings, and in-person training sessions.

**ROLES AND RESPONSIBILITIES**

A. **IRB Chair**

The Chair of the IRB is appointed by the Chancellor or their designee and selected based on experience and expertise from among current and former IRB members. IRB Chairs serve a three-year term of service (with renewable terms on one to three years). The IRB Chair has primary responsibility for the following:

1. Providing leadership to the IRB to help ensure the rights and welfare of human subjects participating in research reviewed by the IRB
2. Conducting convened meetings and reviewing and approving the minutes documenting IRB discussions and findings
3. Leading discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct.
4. Annually completing the Financial Conflict of Interest form and disclosing any potential conflicts prior to IRB review of research for which a conflict may exist.
5. Managing conflicts of interest by ensuring that the IRB members with conflicts are not present for review of research for which a conflict may exist.
6. Maintaining confidentiality of IRB-related information in accordance with the terms and conditions of the university’s IRB Member Confidentiality Agreement
7. Administering Board decisions and maintaining the independence of the IRB
8. Signing correspondence communicating and documenting IRB decisions
9. Participating in the development of meeting agendas, policies, procedures, and educational efforts to support the human subject protection program.
10. Regularly consulting with the Chancellor or their designee regarding IRB issues.
11. Assisting with investigations and review of alleged noncompliance with human subjects’ protections requirements as specified in policy.

B. IRB Vice Chair

The IRB Vice Chair is appointed by the Chair of the IRB and selected based on experience and expertise from among current and former IRB members. A Vice Chair serves a three-year term of service (with renewable terms of one to three years). They support the roles and responsibilities of the IRB Chair. Vice Chair’s will attend IRB meetings and chair convened meetings when required. The Vice Chair assumes duties as delegated by the Chair.

C. IRB Members

Each IRB member is appointed by the Chancellor or their designee and serves a three year term of service (with renewable terms of one to three years). IRB member responsibilities include all the following:

1. Attending IRB meetings and actively participating in the review of research, unless arrangements have been made for the alternate’s attendance.
2. Completing initial training in human subjects protection for IRB members prior to voting on research, with continuing education every three years and as provided.
3. Understanding and applying the principles of the Belmont Report and the federal regulations related to the protection of human subjects.
4. Providing timely written comments on research undergoing IRB review, when required.
5. Annually completing the Financial Conflict of Interest Form and disclosing any potential conflicts prior to the IRB review of the research for which a conflict may exist.
6. Maintain confidentiality of IRB-related information in accordance with the terms and conditions of the university’s IRB Member Confidentiality Agreement.
7. Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects.
8. Working with investigators to resolve matters relating to research approval and participation in educational efforts for investigators, research staff, and new IRB members.
9. Participating in the discussion of issues affecting the human research protection program and contributing to policy development, as appropriate.
10. Reviewing and approving research by expedited procedures, when designated by the IRB Chair to perform this review.
D. Alternates

Federal regulations allow organizations to appoint an alternate(s) to substitute for an IRB member(s) who is unable to attend so that IRB business may move forward in a timely manner. Alternates will consist of one non-science, one science and one medical alternate. Alternates are appointed by the same process and for the same length as IRB members.

IRB alternates function as regular board members when they are in attendance. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities (i.e., “job-share”) in terms of required education, service and time commitments, and participation.

Each alternate member is paired with one or more regular member with comparable experience and expertise, as possible. The IRB roster identifies the primary member(s) for whom each alternate may substitute. The IRB will identify the member(s) for whom each alternate can substitute.

When an alternate substitutes for a regular IRB member, the alternate receives and reviews the same materials that the regular member would receive (or would have received), and IRB minutes documents that the alternate replaced a primary member.

E. Consultants

For research that requires expertise beyond or in addition to that available on the IRBs (including application of laws outside the state of North Carolina), or involves a vulnerable population where no IRB member is knowledgeable about or experienced in working with these participants will be present at the meeting, one of the following will occur:

- IRB Chair or Vice Chair may identify the need for review by a consultant during the screening of a protocol submission. The IRB Chair or Vice Chair will work with the Chancellor or their designee to invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.
- The primary reviewers or IRB membership may identify the need for a consultant during their review. The primary reviewer(s) will work with the IRB Chair or Vice Chair to invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.

Consultants with potential conflicts of interest may not provide information to the IRB.

The use of a consultant and the result of the consultant’s review will be shared with the IRB by either having the consultant attend and present to the convened IRB or by having the consultant provide a written report to the IRB.

- If the consultant presents at a convened meeting, the IRB minutes will document key information provided by the consultant. The consultant will not vote with the IRB.
- If the consultant provides a written report, the report will be included in the protocol records.

**MEMBERSHIP ROSTERS**
Rosters for each IRB contain the following information for each member and alternate:

- Name
- Earned degree(s)
- Chief anticipated contribution (board certifications, licenses, etc.)
- Special representation
- Scientist status (physician, other, or non-scientist)
- Affiliation (yes or no)
- Employment or other relationship with the University (e.g., paid or unpaid member of the university governing panel or board member (not including the IRBs), consultant, volunteer, etc.)

Information for alternates includes also the member(s) for whom the alternate may substitute. Prisoner representatives are listed as “ad hoc” members on the IRB rosters and will only count toward quorum when he/she is in attendance and reviewing studies involving prisoners.

OSSP staff will promptly update the roster with Office of Human Research Protections when changes in the IRB membership are made. Rosters are posted on the UNC Asheville IRB website.

**QUORUM**

OSSP staff attending IRB meetings are responsible for determining that meeting are appropriately convened before the discussion and vote for each review. For convened IRB review, a quorum is defined as follows:

The necessary number (i.e., more than half) of the IRB members listed on the membership roster are present.

- At least one member is present whose primary concerns are in non-scientific areas
- At least one member is present whose primary concerns are in scientific areas
- For clinical research, a member is present who has a medical background
- For FDA-regulated research a member is present who is a licensed physician
- For research involving vulnerable populations, such as children, prisoners or handicapped or mentally disabled persons, a member is present representing the vulnerable population’s interest

If both an IRB member and his/her respective alternate(s) are present, only one may vote and be counted toward quorum.

Comments from members unable to attend a meeting that have been provided in advance (e.g., by fax or email) may be considered by the attending IRB members, but not be counted as votes toward the quorum for convened meetings.

Any member may participate by teleconference or videoconference, provided he/she has received all materials before the meeting and can actively and equally participate in the discussion.
Assuming all applicable composition requirements are satisfied, the number of IRB members necessary for a quorum is calculated by dividing the number in half and “rounding up” when there is an odd number of members or “adding one” for an even number. For example:

- If an IRB has five members, the quorum is 3.
- If an IRB has ten members, the quorum is 6.

If quorum is not met, then IRB voting cannot take place; and the items on the agenda will be tabled until the next convened IRB meeting.

If quorum is lost during a convened meeting (e.g., due to a member leaving the meeting), then no further voting can take place; and the remaining items on the agenda will be tabled until the next convened IRB meeting.

OSSP staff attending IRB meetings are responsible for recording the attendance of members as they enter and leave the room. If quorum is lost, OSSP staff will notify the IRB Chair or Vice Chair that no further actions can be taken until/unless quorum is restored.

IRB members with potential conflicts of interest must leave the room before discussion of the research, except to provide information requested by the IRB. Members with potential conflicts of interest may not be present for the vote and are not counted toward quorum for review of the research for which the potential conflict exists.

**APPLICABLE REGULATIONS AND GUIDELINES**


**DEFINITIONS**

Affiliated: IRB membership status designated associated with the university. *Note: A member (or alternate) is considered to be affiliated if he/she or a member of his/her immediate family is a current or past (within the last 2 years): employee (full or part-time); clinical, adjunct, or visiting faculty member or instructor; paid or unpaid member of a university’s governing panel or board (not including the IRB); volunteer working at the university (unrelated to IRB service); or university consultant or advisor (paid or unpaid). An emeritus faculty or retired staff member is also considered to be affiliated if he/she has been retired or involved in paid or unpaid university activities within the last 2 years.*

Alternate: An individual appointed to the IRB to serve in the same capacity as the specific IRB member(s) for whom the alternate is named, who substitutes for the member at convened meetings when the member is not in attendance. *Note: IRB members and alternates have equal responsibilities in terms of required education, service, and participation.*
Non-scientist: An individual appointed to the IRB who (due to training, background, and/or occupation) is inclined to view research activities from the standpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves.