Purpose:

To establish policies and procedures related to IRB membership

Definitions:

None

Policy:

1. Membership

   A. The IRB shall consist of nine voting members, including at least:
      i. One member whose primary concerns are in scientific areas
      ii. One member who primary concerns are in nonscientific areas
      iii. One member who is not otherwise affiliated with Nova Southeastern University (community member)
      iv. Four members representative of the Colleges of Health Professions Divisions (HPD) who are engaged in human subjects research
      v. Four members representative of other Nova Southeastern University (NSU) Colleges who are engaged in human subjects research
      vi. Overall diversity of gender, race, ethnicity, and cultural backgrounds appropriate for NSU’s student body and the human subjects research reviewed by the convened IRB

   B. IRB Members will meet the following requirements:
      i. College Representative or alternate College Representative for their College
      ii. Full-time faculty or full-time professional staff with experience in human subjects research. Full-time administrative staff may be eligible, at Institutional Official (IO)’s discretion
      iii. Competence in reviewing specific research protocols involving human subjects research
      iv. Current CITI training in the following areas: IRB Member, HIPAA, Conflicts of Interest

   C. Alternate Voting Members
      i. Alternate Voting Members have the same requirements as IRB members and will replace voting IRB members who are unable to attend convened meetings, with that IRB member’s full authority
      ii. College Representatives, and their alternates, who are not voting IRB members will be designated as Alternate Voting Members
      iii. Alternate Voting Members may be designated as alternates for more than one voting IRB member
      iv. Alternate voting members are welcome to attend the convened IRB meetings for continuing education purposes
      v. If the voting member and his/her alternate member attend the same convened meeting, only one individual may vote

D. Terms of Membership
   i. All IRB members will be appointed by the IO in collaboration with the IRB
Chair, and IRB Director. IRB Members will be selected from among College Representatives and their alternates based on individual expertise, their college’s overall use of the IRB, and time since that College had its Representative as an IRB member.

ii. Terms as Voting IRB members will be for 2 years, independent of status as a College Representative or alternate. Terms will begin and end on January 1st, except in the case of vacancies.

iii. Voting IRB members may be reappointed at the discretion of the IO, in consultation with the member’s Dean, the IRB Chair, and the IRB Director.

iv. Vacancies shall be filled as required, at the discretion of the IO, in consultation with the IRB Chair, and IRB Director.

v. Terms of IRB members will be staggered so that no more than half of the voting IRB members’ terms will expire at any given time.

vi. IRB Chairs and Vice Chairs will serve until their terms are completed.

E. Removal

i. When a voting member fails to attend at least one-half of the meetings per year, the member’s status is to be reviewed. These expectations do not apply to community members.

ii. The IRB may recommend to the IO that a member, including the Chair, be removed for cause via a two-thirds vote of voting members present at a convened meeting. Deans, in consultation with the IO, may recommend changes in membership. The IO, at his or her discretion, may end the term of a chair or vice chair by requesting the Board to replace the individual with a new nominee.

iii. The IO, at his or her discretion, may end the term of a chair or vice chair by requesting the Board replace the individual with a new nominee.

2. Chair and Vice-Chair(s) of the IRB

A. The Chair is selected via nominations from the Board, with recommendation to the IO.

B. The Chair is appointed for a two-year term.

C. The Chair is responsible for conducting the IRB meetings, expedited reviews, and for delegating these duties to other IRB members.

D. The Chair is granted appropriate release time from his/her assigned teaching responsibilities for the term of the appointment, as agreed upon by his/her Dean.

E. In order to provide IRB chairs with further experience prior to serving as Chair, and to facilitate the review of expedited proposals that cannot be reviewed by the Chair, the IRB will nominate a Vice Chair, and Vice Chair-elect, and may elect to nominate a Second Vice Chair-elect. These elections follow the same procedures as outlined for the Chair.

3. College Representatives

A. Each College Representative has the following Authorities and Responsibilities:

   i. Serve as primary point of contact within their unit at Nova Southeastern University for issues regarding human subjects research

   ii. Review protocols for the policies, procedures, and requirements of that unit

   iii. Conduct College-Level Reviews of protocols, as applicable. College Representatives may request revisions or changes to protocols in order to fulfill the regulatory requirements of College-Level Reviews
iv. Keep the IRB Office informed of internal issues for their unit that might affect review and approval of human subjects research.

B. The Dean of any College at Nova Southeastern University whose staff, students, or faculty engages in human subjects research may nominate a College Representative to the IO for approval. The IO shall consult with the IRB Chair and IRB Director on appointments.

C. The Dean of a unit may nominate any number (including zero) of alternates to assist the College Representative or to act as College Representative if the College Representative is unable to fulfill his or her duties. The alternate(s) have the full authority of the College Representative when acting as College Representative.

D. The qualifications and requirements for College Representatives are the same as IRB Members. Terms will begin and end on January 1st, except in the case of vacancies.

4. Compensation for members

No member of the IRB is compensated monetarily for his/her participation. In-kind compensation for service shall be handled by members’ College or Dean, if applicable.

5. Liability

All members of the IRB are covered under the university’s liability coverage for participation and actions related to the IRB.

References:

45 CFR 46.103(b)(3)
45 CFR 46.107(a - d)
21 CFR 56.107(a - d)
21 CFR 56.115(a)(5)

Procedures:

Deans recommend individuals to act as College Representatives and alternates to the IO. If the IO concurs, then the IO sends the individual an appointment letter. Appointments are to occur beginning January 1st of each year, except in circumstances where a replacement must be sought due to unforeseen circumstances. At the end of each year, Deans will be notified of the members whose terms expire that year to allow for reappointment/new appointments by the next January 1.

The IRB office records the appointment and requests a current vita from the appointed individual. The IRB office retains all vitas for current and past voting and alternate members for a period of seven years.

The IRB staff will update the IRB membership roster on the IRB Web site and with OHRP. The IRB staff will also retain a detailed roster, to include the IRB members identified by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations; and

At a time deemed appropriate by the Chair and Board, nominations and self-nominations are solicited for Vice Chairs. At a minimum, the Board will have elected a vice chair and one vice chair elect. Majority vote of the IRB present at a convened meeting is required to forward a nomination to the IO. The IO may accept or reject the nomination. If rejected, the nomination
process will return to the Board.