

<b>Nova Southeastern University – Institutional Review Board Standard Operating Procedures</b>		
<b>SOP #1-2 Version #2</b>	<b>TITLE: IRB Membership, Roles, and Responsibilities</b>	
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**OBJECTIVE**

To describe policies and procedures relating to IRB membership, membership requirements, and their roles/responsibilities.

**GENERAL DESCRIPTION**

The IRB at Nova Southeastern University (NSU) consists of nine voting members sufficiently qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. The membership includes voting members and their designated alternates with comparable qualifications. The voting members are either College Representatives or Alternates, which have been designated as voting members by the IRB Office.

IRB membership complies with federal requirements outlined in 45 CFR 46.107, 21 CFR 56.107, and 38 CFR 16.107, along with institutional policy to ensure overall diversity of gender, race, ethnicity, and cultural backgrounds appropriate for the NSU student body and the human participant research reviewed by the convened IRB. IRB membership includes voting IRB members and their alternates, as listed on the official roster registered with the Office of Human Research Protection (OHRP). If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership should include individuals who are knowledgeable about and experienced in working with those subjects.

The IRB includes at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated (i.e., not affiliated with NSU and not part of the immediate family of a person affiliated with NSU), and a physician (at convened IRB that review FDA regulated studies). In addition, the IRB invites 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.

**RESPONSIBILITY**

Execution of SOP: Institutional Official, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chair

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**PROCEDURES**

A. College Representative and their Alternate Representatives Appointment Procedures

1. Approximately once a year, the IRB Office will solicit the Deans of each academic unit whose faculty, staff, and/or students engage in human subject research for nominations of a College Representative and Alternate Representatives for appointment to the IRB; they may choose to re-appoint the current Representatives. The Dean of an academic unit may nominate any number of Alternate Representatives to assist the College Representative. The Alternate Representative(s) have the full authority of the College Representative when acting as a College Representative. The Dean is responsible for providing the IRB Office with the curriculum vitae that documents the expertise, degrees, and/or license numbers for each nomination. The IRB Office will retain all appointments and vitae for current and past members for a period of seven years.
  
2. IRB College Representatives and Alternate Representatives must be either full-time faculty or professional staff with experience in human participant research. Full-time administrative staff may be eligible. All appointments are at the discretion of the Institutional Official, to ensure all members have sufficient experience and expertise to be competent in reviewing research submissions involving human participants.
  
3. Departments and Administrative Units with regular, sustained, and substantive topics of interest with the IRB may request to appoint a member ex officio. The Institutional Official shall review the requests, and all appointments are at their discretion.
  
4. IRB Office staff will review these recommended appointees and their qualifications and a recommendation to the Institutional Official, who provides final approval of the appointment. Appointments for IRB College Representatives and their Alternates are for two-year terms. Terms will begin January 1<sup>st</sup>, except for in the case of vacancies. Terms will be staggered so that no more than half of the terms will expire at any given time. There is no limit on the number of terms a College Representative or an Alternate may serve on the IRB and they may be re-appointed each term.
  
5. Upon appointment, all College Representatives and Alternate Representatives must complete CITI training in the following areas: Human Subjects Protection, HIPAA, and Conflicts of Interest. This training must be completed every three years. Additionally, members must complete training regarding the use of IRBManager and their duties as an IRB member.

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6. College Representatives and their Alternate Representatives responsibilities include:
  - a. Serving as the primary point of contact within their academic unit at NSU for issues regarding human participant research and academic standards for their unit.
  - b. Reviewing protocol submissions for scientific merit/validity along with the policies, procedures, and requirements for their unit.
  - c. Conducting College-Level Reviews of protocol submissions, as applicable.
  - d. Keeping the IRB Office informed of internal issues for their unit that might affect review and approval of human subject research.
  - e. Contacting members of their College and assisting IRB Office in finding current status of students, faculty, or staff as needed.
  
7. All College Representatives or Alternate Representatives are listed on the official roster registered with OHRP as IRB members. A College Representative or Alternate may be designated as either a regular voting member or an alternate member on the convened IRB by the IRB Office, based on individual expertise, their academic unit’s overall use of the IRB, and time available, since that academic unit had a Representative serve as a voting member. Refer to section “Regular (Voting) IRB Member Procedures” for more information.
  
8. All College Representatives or Alternate Representatives shall keep IRB submission information confidential except as required by regulations or as directed by the IRB Office. Only a listing of the dates of reviews and approval may be released. Any request to release additional information should be made to the IRB Office along with the reason for the release, a specific list of the information requested, and the proposed use of the information.
  
9. No IRB member is compensated monetarily for their participation. In-kind compensation for service shall be handled by the members’ College or Dean, as applicable.
  
10. All members of the IRB are covered under the NSU liability coverage for participation and actions related to the IRB.

**B. Convened IRB Member Procedures and Responsibilities**

1. The voting IRB members are either College Representatives or Alternates, which have been designated as voting members by the IRB Office and are listed on the official roster registered with OHRP.

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2. The term for voting members will be for two years, unless otherwise indicated. Terms will begin January 1<sup>st</sup>, except in case of vacancies. Terms will be staggered so that no more than half of the voting members’ terms will expire at any given time.
  
3. Alternate voting members can replace voting members who are unable to attend convened meetings of the IRB, as requested by the IRB Office. An alternate voting member may be designated as an alternate for more than one voting member. Alternate voting members have qualifications comparable to the applicable voting member. The IRB Office maintains lists of alternate voting members on the official membership list approved by OHRP. Terms of appointment, length of service, and duties are identical to those for voting members.
  
4. Alternate voting members attending a meeting or conducting a protocol review have all the authority of voting members and receive the same training and protocol review application materials as the regular members. If the regular member and his/her alternate attend the same convened meeting, only one individual may vote.
  
5. For IRB review of research on prisoners, at least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. In addition, the majority of the IRB (exclusive of the prisoner representative) must have no association with the prison involved, apart from their relationship on the IRB.
  
6. When a voting member fails to attend at least one-half of the scheduled meetings per year, the voting status of the member may be reviewed by the IRB Office. The IRB Office may recommend that a member be removed for cause by the Institutional Official.

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

1. The Chair, Vice Chair, and Vice Chair-elects are selected via nominations and a vote from the convened IRB, with recommendation to the Institutional Official. The Institutional Official may accept or reject the nomination, with rejected nominations being returned to the convened IRB.
  
2. The Vice Chair and Vice Chair-elects facilitate the reviews of expedited proposals that cannot be reviewed by the Chair. At the end of the Chair’s term, the Vice Chair will assume the position of Chair with the Vice Chair-elect assuming the position of Vice Chair. This will provide future Chairs with additional experience prior to serving as Chair.

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3. Upon approval, the Institutional Official will appoint the Chair, Vice Chair, and Vice Chair-elects for a term of two-years. The Chair, Vice Chair, and Vice Chair-elects are granted appropriate release time from their assigned teaching responsibilities for the term of the appointment, as agreed upon by their Dean.
  
4. The Chair is responsible for conducting the IRB meetings, expedited reviews, and for delegating these duties to other IRB members.

**REFERENCES**

21 CFR 56.107  
21 CFR 56.115(a)(5) & 56.106  
38 CFR 16.107  
45 CFR 46.103(b)(3) & 115(a)(5)  
45 CFR 46.107  
45 CFR 46 Subpart E  
U.S. Department of Health and Human Services (HHS) Registration of an IRB (Notes)