OBJECTIVE

To describe policies and procedures for the scheduling, attendance, preparation, and conduct of convened meetings of the Institutional Review Board (IRB).

GENERAL DESCRIPTION

The Nova Southeastern University IRB conducts convened meetings in accordance with applicable federal requirements for full review (i.e., 21 CFR 56.108, 45 CFR 46.108, and 38 CFR 16.108) and as outlined in this SOP.

RESPONSIBILITY

Execution of SOP: IRB Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Meeting Frequency

1. The convened IRB will meet at least once a month, on the 2nd Thursday, unless otherwise dictated.

2. Emergency meetings may be convened as necessary and require a minimum of 48 hours' notice.

3. The meeting may be canceled if there are neither protocol submissions nor other business requiring convened IRB review. IRB Members will be given notice about the cancellation of a monthly meeting as soon as possible.

B. Quorum and Attendance

1. The convened IRB consists of nine voting members with quorum defined as 50% + 1 of the voting members documented on the roster retained by the IRB Office at the time of the convened IRB.

2. At least one non-scientist must be present for quorum.

3. For review of studies involving FDA- regulated articles, at least one physician member must be present. If no physician members are available, the IRB may invite an external physician to consult at the convened IRB.

4. For review of studies involving prisoners, a majority of the IRB (except for prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB. At least one member of the IRB present must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

5. For protocol submissions, involving a vulnerable category of participants (as outlined in *Vulnerable Participants* SOP) the IRB may include one or more individuals with specific knowledge and experience in working with these participants, who would be invited as consultants for the project's review. Such individuals may not vote with the IRB in these instances, unless they are a voting member of the convened IRB.

6. When necessary, the individuals with competence in special areas may be invited to the convened IRB to assist in the review of issues, which require expertise beyond or in addition to that available on the convened IRB. Such individuals may not vote with the IRB in these instances, unless they are a voting member of the convened IRB.

7. To document convened IRB attendance, a sign-in sheet will be available at the convened IRB for attendees to initial next to their names. All members and other attendees are required to initial the sign-in sheet. In instances where the distribution of the sign-in sheet is not possible or a member fails to initial the sheet as required, but can be verified as being present by the IRB Office, the IRB Office is authorized to “check off” the attendance form, provided the attendance can be corroborated by another IRB member or the Chair.

8. Meeting attendees who are not IRB Office personnel, the Institutional Official, or an IRB member or alternate will be reminded that the IRB meetings are confidential and will be asked to sign a document acknowledging meeting confidentiality.

C. Review Process

1. In order to be added to the next convened IRB agenda, a protocol submission requiring full review must be submitted by the College Representative to the IRB Office no later than the last business day of the previous month. Any deviation from this requirement is at the discretion of the IRB Office and/or the Chair.

2. The IRB Chair, or their designee, will conduct meetings of the convened IRB.

3. At the convened meeting of the IRB, the following may be reviewed:
    a. Meeting minutes for prior convened IRB meeting
    b. Initial review of protocols
    c. Continuing review of protocols
    d. Review of adverse events/serious adverse events reported
    e. Review of amendments to previously approved research
    f. Review of revisions previously requested by the IRB
    g. Any other documents received related to IRB SOPs
    h. Additional documents as determined by the IRB Office and/or Chair

4. The IRB Office will forward the necessary protocol submission documents to IRB members with sufficient time to review prior to the meeting (approximately 5 business days in advance of the meeting, unless otherwise dictated). These documents must be viewed in a secure manner and only by authorized reviewers.

5. For studies involving FDA-regulated products, when a sponsor protocol and/or clinical investigator brochure exist, these documents will also be provided for review.

6. Lead reviewers will be assigned to provide an advance review of protocol submissions prior to meeting and will present to the convened IRB as outlined in Section IV of this SOP.

D. Lead Reviewer(s)

1. To facilitate the review of protocol submissions that require full review, one or more voting members will be assigned as lead reviewers to review protocol submissions in advance of the convened IRB. Assignment of the lead reviewers will be based on fair distribution of workload for IRB members and in consideration of their expertise. Whenever possible, lead reviewer(s) will represent the academic unit the research originated from and will have served on the convened IRB for a minimum of two months. IRB Office Staff may not serve as a lead reviewer; however, the reviewers may call upon the IRB Office for guidance as necessary.

2. The IRB Office will contact an IRB member, notifying them of their designation as a lead reviewer. If the IRB member is unable to complete a timely review, the IRB Office will designate a new lead reviewer(s).

3. The IRB Office will forward the necessary protocol submission documents to the lead reviewer(s). Lead reviewers will evaluate the protocol submission using a Lead Reviewer Checklist.

4. Should the lead reviewer(s) have questions regarding the submission, they should contact the IRB Office. Depending on the nature of the question(s), the IRB Office may contact the investigator through email and forward the communication to the lead reviewer(s). Communications with the investigator will be documented.

5. Lead reviewers will submit their analysis of the protocol submission to the IRB Office sufficiently in advance of the convened IRB to allow for dissemination.

6. Lead reviewers will be responsible for providing a summary and their review of the protocol submission to the convened IRB. The College Representative or other IRB members with information about the protocol, if present, will provide additional information if necessary.

7. The convened IRB may elect to accept any or all aspects of the review provided. The convened IRB will not be limited by the reviews conducted and may seek further clarification or revision as necessary.

8. At the discretion of the convened IRB, review of a protocol submission may occur in the absence of lead reviewer information.

E. Voting of the Convened IRB

1. All decisions are based on a majority rule.

2. Each voting member is permitted one vote, and this vote is passed to the alternate should they be there in place of the member. If both a voting member and their alternate are present, only one vote is permitted.

3. No proxy votes are permitted.

4. The Chair only votes to break a tie vote. In instances when the Chair does not vote, his/her vote will be counted as an abstention in the meeting minutes.

5. Voting for all motions will be recorded in writing by IRB Office Staff in the meeting minutes as outlined in Section IV of this SOP.

F. Reporting of Findings and Meeting Record

1. The IRB will report the findings and decisions of the convened IRB, via email, to the Principal Investigator, their College Representative, and other appropriate individuals, as necessary. Investigators may be asked for additional information.

2. If the study is sponsored, it is the responsibility of the researcher to convey IRB approval to the sponsor by providing a copy of the IRB approval memorandum.

3. Minutes of IRB meetings will list the:
    a. Documents reviewed by the IRB
    b. De-identified meeting attendance
    c. Actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining
    d. Basis for requiring changes in or disapproving research
    e. Written summary of issues of dispute and their resolution
    f. Adverse events reviewed, their discussion, and resulting decision
    g. Votes of the IRB on changes to policies and procedures
    h. Decisions for items reviewed and approved at an expedited level

4. A copy of the approved monthly meeting minutes will be made available to the Chair or their designee for review and approval. A copy of the approved minutes for the previous month's meeting will be made available to all voting members, members, and alternate members prior to the next convened IRB.

5. The IRB Office will provide the Institutional Official and other individuals deemed appropriate with a copy of the final approved minutes of the IRB convened meeting of the Board within 30 days of approval.

6. The IRB office retains the convened IRB minutes for a minimum of seven years, but may retain longer at their discretion.

G. Conflicts of Interest

1. No voting member, member or alternate member of the IRB may participate in the review and approval process for any project in which they have an actual, perceived, or potential conflict of interest as outlined in the "Conflict of Interest" SOP.

2. If a voting member believes they have a conflict of interest concerning a protocol submission on the convened IRB agenda, they must notify the IRB Office prior to the meeting of the convened IRB.

3. Voting members with a conflict of interest may be present during presentation of a protocol submission but must excuse themselves during discussion and voting by the convened IRB.

REFERENCES

45 CFR 46.107(e)
45 CFR 46.108
21 CFR 56.108(a)(1) and 56.109(a - f)
21 CFR 56.107(e)
21 CFR 56.107(f)
21 CFR 56.115(a)(2)