

**Nova Southeastern University
Office of Grants and Contracts
Institutional Review Board
Policies and Procedures**

IRB Meeting Operations

Effective 03/08/2007; Revised 12/13/2007

Page 1 of 4

Purpose:

To establish policy and procedures related to the operations of the IRB and its meetings.

Definitions:

None

Policy:

1. Frequency of Meetings and Review Process

The university's IRB is convened by the Chair, or the Chair's designee, at a minimum of once a month (currently the 2nd Thursday of the month). If there is no IRB business for the month, the Chair, or other designee, may cancel the meeting and notify all members of such action. Emergency meetings may be convened, as appropriate, and require at least 48 hours' notice.

The IRB office disseminates to all members of the IRB the following documents on the first business day of the month:

- A meeting reminder
- An agenda
- Minutes of the previous meeting that includes a listing of all expedited review approvals
- A copy of all protocols for initial review
- A copy of all protocols for continuing review
- A copy of all amendments for review
- A copy of any revisions previously requested by the IRB for review
- At the Chair's discretion, material related to adverse events reports may be included

2. Definition of Quorum

A quorum is defined as more than one-half of the voting members. At least one non-scientist must be present for quorum. During the review of studies of FDA regulated articles, at least one physician member must be present. During review of studies with prisoners, at least one prisoner advocate must be present.

When necessary the Board may arrange for the meeting to be held using teleconferencing technology.

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Institutional Review Board
Policies and Procedures**

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Page 2 of 4

3. Voting

All decisions are based on a majority rule. Each member is permitted one vote, and this vote is passed to the alternate should he/she be there in place of the member. If both a member and his/her alternate are present, only one vote is permitted. No proxy votes are permitted. The Chair only votes in a tie situation, to break a tie vote.

4. Reviews Conducted

At the convened meeting of the IRB, the following review activities are conducted:

- Initial review of protocols
- Continuing review of protocols
- Review of adverse events/serious adverse events reported
- Review of amendments to previously approved research
- Review of revisions previously requested by the IRB

5. Reporting of Findings and Meeting Record

The IRB may request additional information from the Principal Investigator. The IRB will report to the Principal Investigator and the institutional official (VP) in writing (via postal mail as well as electronically) the decisions made at convened meetings of the IRB. The investigator may be asked for additional information.

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 letter.

For items reviewed at an expedited level, the IRB office will also report these decisions to the investigator, other IRB members (via the published minutes), and the institutional official in writing.

Minutes of IRB meetings will show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining (including the reason for the abstention); the basis for requiring changes in or disapproving research; and a written summary of issues of dispute and their resolution, and any adverse events reviewed. The minutes may also include votes of the IRB on changes to policies and procedures.

The minutes will also include all protocols reviewed under an expedited procedure for continuing review.

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Institutional Review Board
Policies and Procedures**

IRB Meeting Operations

Effective 03/08/2007; Revised 12/13/2007

Page 3 of 4

6. Conflict of Interest

No member of the IRB may participate in the review and approval process for any project in which he or she has an actual or potential conflict of interest. Any IRB member or alternate whose name appears anywhere in the application, or who has any reason to believe that he or she will have a role in the research must so state and will be excused automatically. Any IRB member or alternate who feels he or she might not be completely objective in doing the review for any reason may excuse himself or herself. Where the investigator-member has a conflicting interest, he or she should be absent from the meeting room during discussion and voting phases of the review and approval process; IRB minutes should reflect whether these requirements have been met.

IRB Center Representatives are encouraged to abstain from votes on protocols originating from their academic units, and are required to do so if their relationship with the investigator(s) may appear to compromise objectivity.

7. Vulnerable Populations

When the IRB reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or mentally disabled persons) the IRB may include one or more individuals with specific knowledge and experience in working with these subjects who would be invited as consultants for the project's review. Such individuals may not vote with the IRB in these instances.

In the case of research involving prisoners, a majority of the IRB (exclusive of 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 must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except where a particular research project is reviewed by more than one IRB, in which case only one IRB need satisfy this requirement. In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB will choose a prisoner representative who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.

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)

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Policies and Procedures**

IRB Meeting Operations

Effective 03/08/2007; Revised 12/13/2007

Page 4 of 4

Procedures:

1. The IRB Administrator will coordinate the dissemination of the meeting packets as outlined in this policy after approval of the agenda by the IRB chair.
2. The IRB Chair (or person designated by the IRB Chair to chair the meeting) will conduct the meeting. The Center Representative or alternate, when present, will provide a brief summary of the research protocol.
3. The IRB Administrator or support staff member for the IRB will transmit in writing to the PI decisions made at convened meetings where the PI's protocol is being reviewed for initial, continuing, or amendment review. This communication is done via postal mail as well as electronically.
4. The IRB Administrator or support staff member for the IRB will document meeting decisions in the minutes, as outlined in the policy.
5. The IRB Administrator or support staff member for the IRB will provide members of the IRB copies of each month's minutes, including a listing of all expedited review approvals.
6. The IRB office retains the IRB minutes for a minimum of seven years; effective August 2006 digital audio recordings of the IRB meetings are retained.