

**Nova Southeastern University
Institutional Review Board
Policies and Procedures**

IRB Meeting Operations

Effective 03/08/2007; Revised 12/13/2007, 12/10/2009, 10/14/2010, 08/29/2011; 5/10/13

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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). The IRB will consist of nine voting members. If there is no IRB business for the month, the Chair, or other designee, may cancel the meeting and notify all voting members, members, and alternate members of such action. Emergency meetings may be convened, as appropriate, and require at least 48 hours' notice.

The IRB office makes available to all voting members, members, and alternate members the documents needed to conduct their review with sufficient time to review prior to the meeting (approximately 7 business days in advance of the meeting). Documents for review are made available via a password protected area on the IRB website or an equally secure location. During the convened meetings, voting members may view the documents on personal portable devices or may print a paper copy of the documents and bring them to the meeting. The documents provided for review include the following:

- A meeting reminder
- An agenda
- Minutes of the previous meeting that includes a listing of all expedited review approvals for the prior month
- 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
- Material related to adverse events reports or Investigational New Drug (IND) safety reports and Adverse Events subcommittee report. Any additional documents related to the IRB, including but not limited to, policies and procedures, information related to noncompliance, and educational materials.

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For studies involving FDA-regulated products, when a sponsor protocol and/or clinical investigator brochure exist, these documents will also be provided for review. The lead reviewer(s), the adverse events/IND safety subcommittee members, the Chair of the IRB (or designee), and the IRB Director are expected to review these documents as part of their review process.

For externally funded studies, the funding proposal will be provided. At least one member of the IRB (to be determined by the Chair) is expected to review the funding proposal in conjunction with the review of the IRB protocol.

In order for review items to be added to the agenda, they must be received by 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 Director and Chair.

2. Quorum

A quorum is defined as 50% + 1 of the voting members documented on the roster retained by the IRB Director at the time of the meeting.

3. Attendance

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. If no physician members are available, the IRB may invite an external physician to consult at the convened meeting of the Board. 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.

In order to document attendance, the IRB staff will circulate at convened meetings of the Board a sign-in sheet for individuals to initial next to their names. In instances where the distribution of the sign-in/initial sheet is not possible or a member fails to initial the sheet as required, but can be verified as being present by the IRB Director, the Director is authorized to “check off” the attendance form provided the attendance can be corroborated by another board member or the chair.

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4. Voting

All decisions are based on a majority rule. Each voting 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 voting 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. In instances when the Chair does not vote, his/her vote will be counted as an abstention.

5. Reviews Conducted

At the convened meeting of the IRB, the following may be reviewed:

- 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
- Any other documents received related to IRB operations or policies and procedures
- Additional documents as determined by the IRB Director or Chair

6. Lead Reviewer(s)

The Chair and Director will select one to two individuals who will be asked to review each new protocol or protocol for continuing review on the agenda in keeping with the Lead Reviewers policy.

7. 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 for Institutional Effectiveness) in writing (via electronic mail) 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 (via the approved minutes).

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Minutes of IRB meetings will list the documents reviewed by the IRB (a class of documents, such as recruitment flyers may be noted as such in the minutes rather than an itemized list); attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; 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 document any discussion with respect to adverse events/unanticipated problems/IND safety reports presented by the adverse events subcommittee.

The minutes will also include a list of all protocols reviewed and approved under an expedited procedure for initial, continuing review, or amendment.

The IRB Director will also provide the institutional official and other individuals he/she deems appropriate with a copy of the final approved minutes of the IRB convened meeting of the Board within 30 days of approval.

8. Conflict of Interest

No voting member, member or alternate 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 voting member, member or alternate member 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 voting member, member or alternate member 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.

Voting members, members, and alternate members 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.

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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.

8. External Experts

When necessary, the IRB may invite 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. These individuals may not vote with the 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)

Procedures:

1. Investigators, their staff, or center representatives may transmit to the IRB office protocol documents for review at a convened meeting of the Board. The IRB office must receive one original set of all documents, including one set of all paper or web based instruments, and 2 copies of the New Protocol Form, consent/assent forms, and any other protocol support documents. For FDA-regulated studies where a sponsor protocol and/or clinical investigator brochure exist, 3 copies of the aforementioned documents must be provided to the IRB.

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2. Staff within Human Subjects Protections Program/IRB Office will coordinate the dissemination of the meeting documents as outlined in this policy after approval of the agenda by the IRB chair. The meeting documents may include, but will not be limited to, a meeting reminder, agenda, protocol documents, and additional documents associated with new or old business. For new submission, the documents may include but are not limited to, the New Protocol Form, informed consent and/or assent forms, and recruitment materials. The IRB staff will bring to the meeting any applicable data collection instruments for review by the convened Board. For continuing review, the documents may include but are not limited to Submission Form for Continuing Review of IRB Approved Studies, informed consent and/or assent forms, recruitment materials, and updated/new information applicable to the study. For amendments, the documents may include but are not limited to, the Submission Form for Amendment of IRB Approved Studies any documents affected by the proposed amendments. Meeting documents will be made available to voting members, members, and alternate members via a password protected areas on the IRB website or an equally secure location. During the convened meetings, voting members may view the documents on personal portable devices or may print a paper copy of the documents and bring them to the meeting.

If the agenda includes a protocol that involves an FDA-regulated product and there is a sponsor protocol and/or clinical investigator brochure, the IRB staff will make these documents available with the rest of the submission documents on the password protected area of the IRB website or an equally secure location.

If the agenda includes a federally funded study, a copy of the grant proposal will be made available on the password protected area of the IRB website for review in conjunction with the research protocol submitted to the IRB.

3. The IRB Chair (or person designated by the IRB Chair) will conduct the meeting. The lead reviewer(s) will provide a brief summary of the research protocol. In the absence of both lead reviewers, the IRB Chair or designee may provide the brief summary. The lead reviewer checklists will be disseminated to the Board in keeping with the Lead Reviewer policy.
4. The voting for all motions will be recorded in writing by the IRB staff. In addition, the Chair, or designee, will confirm the votes for, against, and abstention in a manner that allows for determination of total votes during a review of the audio recording. The Chair, or designee, may ask members to articulate their vote or may announce the totals for the aforementioned categories.

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5. The IRB staff 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 electronically.
6. The IRB staff will document meeting decisions in the minutes, as outlined in this policy. In order to assure accountability, the IRB Chair (or designee leading the meetings) will articulate the number for, against, and abstaining so as to record the information in the audio recording of the meeting. In addition, the individual leading the meeting will review the completed minutes to verify that the accounting of votes for, against, and abstaining are accurate.
7. The IRB staff will make a copy of each month's meeting minutes available to all voting members, members, and alternate members. This will be done via the password protected area on the IRB website or an equally secure location. The meeting minutes will include a listing of all expedited review approvals. IRB staff will provide a copy of the approved minutes to the institutional official and other individuals as determined by the IRB Director. The PDF version of the signed minutes will be sent electronically.
8. 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 also for seven years.