

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

**Lead Reviewers**  
**Effective 03/12/2009**  
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**Purpose:**

To establish policy and procedures related to the IRB's use of lead reviewers for new protocols requiring full board review.

**Definition:**

1. Lead Reviewers: Individuals appointed by the IRB Chair to provide thorough protocol review prior to presentation to the convened Board.

**Policy:**

In order to facilitate the review of new protocols at convened meetings of the board, two lead reviewers will be assigned to each new protocol in advance of the convened meeting at which that protocol is to be discussed. Each individual will be responsible for advanced review of the submission, noting areas requiring further inquiry or that may require revision. When necessary, lead reviewers will communicate with the principal investigator, either directly or via the IRB Administrator, to secure information to facilitate the review of the protocol. The reviewers will submit their analysis of the proposed research to the IRB in writing sufficiently in advance of the convened meeting to allow for duplication and dissemination.

The Board members will be provided the information related to the study, irrespective of the use of lead reviewers. The convened membership of the Board may elect to accept any or all aspects of the reports provided by the reviewers. The Board will not be limited by the reviews conducted and may seek further clarification or revision as necessary.

**References:**

45 CFR 46

**Procedures:**

1. The IRB Chair or designee will assign two lead reviewers for each protocol received within two business days of receipt the protocol by the IRB office. Assignment of the lead reviewers will be based on fair distribution of workload of the IRB and in consideration of expertise. Whenever possible, neither of the lead reviewers will come from the originating center of the research and will have served on the Board for a minimum of two months. Neither the IRB Administrator nor the IRB Chair may serve as a lead reviewer; however, the reviewers may call upon the IRB Chair or IRB Administrator for guidance as necessary. Should either reviewer be unable to fulfill his or her duties, the IRB Chair or designee will appoint new reviewers in keeping with the aforementioned procedures.

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2. The IRB Administrator, or his/her designee, will contact the lead reviewers, notifying them of the appointment and will send them an electronic version of the protocol for review.
3. The lead reviewers will evaluate the protocol using the IRB Checklist Form for Reviewers.
4. In completing the checklist, should the reviewers find it helpful to contact the principal investigator, they may do so. Reviewers may elect to contact the principal investigator individually, together, or nominate one person to present all questions that the reviewers may have. Alternatively, reviewers may elect to give questions to the IRB Administrator, who will relay them to the principal investigator.
5. Communications with the principal investigator will be documented. If the principal investigator provides additional information or documentation, then the principal investigator will be encouraged to submit that documentation in writing.
6. The reviewers will submit their checklist forms to the IRB Administrator for dissemination and duplication no later than 48 hours prior to the convened meeting of the Board.
7. The IRB Administrator will send an electronic copy of the forms to all members and will duplicate the completed checklist forms for dissemination at the convened meeting at which the protocol is scheduled for review. While the IRB Chair or Administrator may review the checklist form prior to the IRB meeting, they may not make revisions to the checklist prior to Board review.
8. At the convened meeting, the lead reviewers will be responsible for providing substantive summarizing information about the study. The center representative will provide additional information from his or her review.