

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

Changes to Policies

Effective 08/09/2007; Revised 01/02/2008

Page 1 of 2

Purpose:

To establish policy and procedures for approval, implementation, and dissemination of new policies or changes to IRB policies.

Definitions:

None

Policy:

The IRB is charged with monitoring its policies, not only to be in keeping with the mission and objectives of the university, but also to maintain the university's Federal-Wide Assurance with the Office of Human Research Protections (OHRP) by keeping policies and procedures consistent with federal regulations governing research with human subjects, and to assure compliance with applicable Food and Drug Administration (FDA) regulations.

The IRB can implement or modify policies and procedures only by a vote of the Board at a convened meeting. New policies and policy modifications adopted by the IRB also must be approved by the vice president for research and technology transfer. The IRB must disseminate modified policies and procedures to the university community.

References:

None

Procedures:

1. New policies or revisions to existing policies may be proposed by IRB members, the IRB chair, or the IRB Administrator. A draft of the policy must then be presented to the Board for review and vote at a convened meeting.
2. Once the policy is approved by a majority vote of those members present, it is forwarded to the vice president for research and technology transfer for review and approval. Should the VP reject the policy, the policy will be returned to the Board for additional review along with any comments/suggestions from the VP. The process is repeated once there is a majority vote for the revised policy.

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Page 1 of 2

3. After the VP has approved the policy it is recorded by the IRB office and transmitted to the Office of Information and Technology for addition to the IRB Web site.