

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

Changes to Policies

Effective 08/09/2007; Revised 01/02/2008, 10/14/2010, 09/16/2011

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 Institutional Effectiveness. 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 Director. If there is a significant revision, then a draft of the policy must be presented to the Board for review and vote at a convened meeting. Minor revisions may be made at the discretion of the IRB Director without presentation to the Board. The IRB Director will notify the IRB Chair of the minor revision(s). Minor revisions are limited to changes in the titles of individuals listed, changes to numbers of members based upon quorum changes, title changes to the names of policies or procedures, revisions to the layout of the policy as needed for formatting purposes, or changes to attached documents associated with a policy or the descriptions/references of those documents within a policy.

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

Changes to Policies

Effective 08/09/2007; Revised 01/02/2008, 10/14/2010, 09/16/2011

Page 2 of 2

2. Once the policy is approved by a majority vote of those members present, it is forwarded to the vice president for institutional effectiveness 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. Minor revisions may be implemented without review by the VP. The minor revision will be discussed via electronic mail between the IRB Director and Chair.
3. After the VP has approved the policy it is recorded by the IRB office on a Policy Tracking Log and transmitted to the Office of Information and Technology for addition to the IRB Web site.
4. A copy of the old policy and the new policy are retained in the IRB Director's office.