

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

IRB Record Requirements

Effective 06/14/2007; Revised 01/02/2008, 10/14/2010, 08/29/2011

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Purpose:

To establish policy and procedures for the management and maintenance of IRB records.

Definitions:

1. Unanticipated Problems (non FDA research) are considered to include any incident, experience, or outcome that meets all of the following criteria:
 - Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related outcomes, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
 - Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
 - Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
2. For FDA governed research, please note that the criteria of an unanticipated problem are slightly different.
 - Unexpected
 - Serious
 - Would have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator's brochure).
3. Serious Adverse Events are defined as follows:
 - Death
 - Congenital Anomaly/Birth Defect
 - Hospitalization Required or Prolongation of a Hospitalization
 - Life Threatening Event
 - Significant or Persistent Disability/Incapacity

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Policy:

1. IRB membership roster showing member qualifications

The IRB Director will retain the curriculum vitae of IRB members and alternates. In addition, the IRB Director will maintain a roster on the IRB Web site that also reflects the individuals' academic qualifications. This Web site roster will be updated whenever the IRB roster recorded by the Office for Human Research Protections (OHRP) is updated. In addition, the Director will maintain a roster to include the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc, sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.

2. Written policies and procedures

The IRB Director will maintain the IRB's policies and procedures that will review them annually. These policies and procedures are to be maintained in writing in the IRB office and also on the IRB's Web site (www.nova.edu/irb). When applicable, policies may have referenced attachments that will be maintained with the respective policies. Old versions of IRB policies are to be retained for three years from the year the policy version was in effect.

3. Record Retention

The IRB office retains all records for a period of at least seven years from the date a study concludes. The IRB retains as a part of these records all versions of protocols and consent documents received—including the versions ultimately approved. Consent documents approved are stamped as such, and retained in order of most current first. The IRB also retains for seven years all records relating to protocols never initiated whether due to revisions requested but never received or other investigator related reasons. The IRB office, at the discretion of the Director, may retain archived records either on-site or using the NSU approved document retention service.

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4. Communications to and from the IRB

- a. Unanticipated Problems/Adverse Events/Serious Adverse Events (UP/AE/SAE) or IND Safety Reports

The IRB Director will record within the respective protocol's file any UP/AE/SAE received. The IRB Director also records any Investigational New Drug (IND) Safety Reports received related to the protocol. The IRB acknowledges receipt of the AE/SAE/IND reports to the investigator and research coordinator when appropriate. The IRB office then transmits the UP/AE/SAE/IND reports to the adverse events subcommittee for review and adds the subcommittee's report to the agenda of the next scheduled meeting.

The IRB Director documents the adverse events subcommittee's AE/SAE/IND safety review presented to the full Board via the minutes for that meeting. The Board may vote to suspend/terminate approval for a study based on this report.

- b. Correspondence to Investigators

Preparation of all correspondence to investigators, including drafts of feedback created by the IRB Chair, his or her designee, and the IRB Director will be done using electronic media. All correspondence to investigators is stored in the files of the respective protocols. Additionally, all approval letters and supporting documents (e.g., informed consent materials, recruitment materials) are digitally saved in PDF format and stored on the IRB office's server. The IRB staff sends the principal investigators, faculty sponsor, and center representative(s) a copy of the PDF file the day approval is granted in addition to the hardcopy that is mailed to the investigator and the IRB Center Representative(s).

- c. Correspondence to the Board and Signatory Official (Vice President for Institutional Effectiveness [VP])

All correspondence to the Board and VP are to be maintained by the IRB office.

5. Budget and Accounting Records

The IRB's budget and accounting records are managed internally by a clerical staff member who is a part of the Office of Grants and Contracts. Additionally, the university's accounting office provides general oversight to the IRB's budget and accounting records.

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6. Statement of significant new findings provided to subjects

Researchers are reminded that if the researcher wishes to provide subjects with a statement of new findings, he/she must submit it to the IRB prior to dissemination, unless it is an emergency statement where the well-being of a subject requires an immediate notification. The IRB also reserves the right to request that researchers provide statements of significant new findings when warranted. Any statements of significant new findings provided to subjects by investigators are recorded by the IRB office in the protocol's file.

References:

45 CFR 46.108(a)
45 CFR 46.115(a)(1, 3 - 5 and 7)
45 CFR 46.115(b)
21 CFR 56.108(a)
21 CFR 56.115(a)(1, 3 - 5 and 7)
21 CFR 56.115(b)

Procedures:

1. The IRB Director will maintain a record of the all NSU IRB Policies and Procedures. In addition, the IRB Director will maintain a tracking system/log of policy and/or procedures to document review progression.
2. The PI must provide the IRB with any statements of significant new findings that are to be issued to subjects.
3. The IRB will maintain an accurate accounting of all current protocols as well as all IRB documents that have been sent to the NSU archives.
4. All correspondence to the Board is saved in either hardcopy or electronic format by the IRB staff in binders or using the office's shared drive. The binders are maintained at the IRB office. All official correspondence to the signatory official (VP), including notice of each month's minutes of the IRB, is stored by the IRB Director within the IRB office either in hardcopy format or in electronic format on the shared drive.