

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

IRB Record Requirements

Effective 06/14/2007; Revised 01/02/2008

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Purpose:

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

Definitions:

1. Unanticipated Problems 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. Adverse Events are any unanticipated problems involving risks to subjects or others that do not fall into the different categories under Serious Adverse Events (SAEs). For example:
 - Breach in confidentiality that may present a risk to a subject.
 - A participant's complaint of an unanticipated risk that cannot be resolved by the research staff
 - Change to the research protocol that may result in unanticipated risks
 - Rash

3. Serious Adverse Events are defined as follows:
 - Cancer
 - Death
 - Congenital Anomaly/Birth Defect
 - Hospitalization Required
 - Life Threatening Event
 - Overdose
 - Significant or Persistent Disability/Incapacity

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Policy:

1. IRB membership roster showing member qualifications

The IRB Administrator will retain the curriculum vitae of IRB members and alternates. In addition, the IRB Administrator 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.

2. Written procedures and guidelines

The IRB Administrator will maintain a Standard Operating Procedures (SOP) manual that is to be updated at least annually.

3. Record Retention

The IRB Administrator 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.

4. Communications to and from the IRB

- a. Unanticipated Problems/Adverse Events/Serious Adverse Events (UP/AE/SAE)

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

The IRB Administrator documents the adverse events subcommittee's AE/SAE 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.

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b. Correspondence to Investigators

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 Research and Technology Transfer [VP])

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

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.

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.

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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 Administrator will maintain a Standard Operating Procedure (SOP) manual that outlines adherence to the elements of this policy statement.
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 hardcopy format by the IRB Administrator in binders. These 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 Administrator within the IRB office.