

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

General Responsibilities of the Principal Investigator

Effective 08-09-2007

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Purpose:

To establish policy and procedures related to the principal investigator's responsibilities for submitting research protocols that provide sufficient information to evaluate the study protocol, the experiment's risks and benefits, and the qualifications of the researchers.

Definitions:

None

Policy:

1. Information the principal investigator (PI) provides to the IRB.
 - a) The PI provides study-related information to the IRB using the appropriate forms (i.e., Submission Form for Initial Review, Submission Form for Continuation or Amendment, the Research Protocol, etc. are available at www.nova.edu/irb).
 - b) The PI provides a research protocol that includes the following information:
 - Title of the study
 - Names and contact information of the PI and all Co-Investigators (Co-I)
 - Funding/Sponsorship information
 - Purpose and Potential Benefits
 - Brief background to the research, including brief historical or literature review
 - Rationale and nature of the proposed research
 - Significance of the proposed research
 - Potential benefits of the research to scientific/professional knowledge
 - Location of where research is to be conducted
 - Dates of the study
 - Subject information
 - Sample Size and Compositions
 - Gender
 - Ethnicities of subjects if ethnicity is used as a subject inclusion or exclusion criteria
 - Primary languages (if other than English)
 - Conditions that would make the subjects a vulnerable population
 - Subject Selection, Recruitment and Eligibility Requirements
 - Methods and Procedures
 - Information on subject compensation and any extra costs to subjects as a

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- result of their participation
 - Time commitment for the subject for each component of the procedure.
 - Measure and Administration
 - Risks to Subjects
 - A discussion of minimizing risks to subjects
 - Risks to and protection of privacy/confidentiality
 - Benefits to Subjects
 - Compensation to Subjects
 - Risk/Benefit Ratio
 - Consent Form information
 - Discuss the ways in which the investigator will communicate study-related information to the participants, including the amount of time the subjects have to decide whether they wish to participate.
 - Procedures for documenting informed consent, including obtaining assent from minors, using witnesses, translators, and document storage
 - Protected Health Information (PHI) usage information
 - Investigators must provide all recruitment materials at the time of initial review
 - Professional qualifications of the PI and Co-Is (see policy 3 below).
- c) Investigators also provide copies of the informed consents/assents they plan to use. Investigators should review the Informed Consent policy for more information as to informed consent requirements. Once the consent forms are approved, the IRB provides researchers with copies that are stamped “approved” and indicate the date of approval of the document and the date of continuing review of the research.
- d) For clinical trials where an Investigator’s Brochure exists, this must also be provided to the IRB during initial review. Any changes to the Investigator’s Brochure must also be transmitted to the IRB.
- e) As noted in the Adverse Event/Unanticipated Problems policy, investigators must report adverse events to the IRB. Please see that policy for further information.
- f) As noted in the Monitoring of Approved Research, Approval Duration, and Continuing Review policy, investigators must report to the IRB information related to the study during continuing review periods. Additionally, the IRB requires a final report at the conclusion of the study.
- g) For all studies approved at the expedited or full review levels the PI must provide a closing report within 30 days of the completion of the study. Completion of the study occurs when research activities with subjects and the analysis of data have stopped.

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2. Ensuring prompt reporting to the IRB of changes (amendments) in research activities

An investigator must also notify the IRB of any proposed changes in the protocol or consent forms prior to the initiation of these changes. The investigator does this via the Submission Form for Continuation or Amendment. Changes may include (but are not limited to): modification of protocol procedures, modification of informed consent procedures, or changes in data collection instruments. These changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards. This is also referenced in the Amendments to Research policy.

3. Professional Qualifications to Conduct Research

An investigator must demonstrate to the IRB that he/she is qualified to conduct the research. Additionally, as noted in the Human Subjects Research Training policy, the investigators must demonstrate completion of the CITI training.

4. Federal/State Regulations

An investigator must follow all federal and state regulations when he/she conducts research.

5. Record Retention

Investigators are required to retain all research records (including any signed informed consents/assents) for a minimum of three (3) years from the end-date/closing of the research study. In the case of funded research, the investigator must adhere to the funding source's requirements of record retention which may exceed the three year minimum. Included in the research records must be copies of all documented informed consent form materials. Researchers are reminded that for FDA-related research, the retention period begins on the date the study is closed by the sponsor—which may be many months after the study was closed at NSU.

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References:

45 CFR 46.108(a)
45 CFR 46.109
45 CFR 46.111
21 CFR 56.103(a) and 56.115(a)(1)
21 CFR 56.111 (a)(1 - 2, 4 - 5)
21 CFR 56.108(a)(1, 4)
21 CFR 56.108(b)(1), 56.115(a)(3 - 4)
21 CFR 56.113
21 CFR 56.115(a)(1, 3 and 4)
21 CFR 56.115(b)(1)
21 CFR 312.55

Procedures:

1. The PI submits the submission form, protocol and informed consent/assents following the IRB models for the consent/assent forms provided on the IRB website (www.nova.edu/irb) and in the IRB Procedures Manual in order to meet all of the stated requirements of the policy.
2. The PI must follow the policies and procedures outlined in other areas related to adverse event reporting, amendments to approved research, informed consent requirements, and continuing review.
3. The PI must submit the closing report to the IRB office either by hardcopy or electronically. The closing report should briefly describe the research that occurred, report the findings of the study, and provide pertinent information related to subject participation.