

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

**Monitoring of Approved Research, Approval Duration, and Continuing Review  
Effective 03/08/2007  
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**Purpose:**

To establish policy and procedures for the monitoring of approved research, the approval duration of protocols, and continuing review requirements.

**Definitions:**

None

**Policy:**

1. Continuing Review and Approval Duration

It is the responsibility of the IRB to govern research that has been approved to ensure that research is conducted in accordance with governmental guidelines and regulations and with IRB requirements. In order to effectively do this, the IRB must conduct—as prescribed by regulation—continuing review of approved research not less than once a year. When approving the study, the IRB (or IRB Chair/Designee in the case of an expedited review) will determine if the risks are of a sufficient magnitude that continuing review is required more often than annually. Continuing review is required for any active protocol including those where the only activity that remains is data analysis.

The factors that shall be considered to determine whether a study requires continuing review more frequently than annually include, but are not limited to;

- studies that involve experimental therapies or procedures in which a clear potential for significant adverse experiences has been identified at the time of review,
- the nature, probability and magnitude of anticipated risks to subjects,
- the medical, psychological, or physical conditions of the proposed subjects,
- age of subjects,
- qualifications of the PI and other members of the research team,
- nature and frequency of adverse events observed in similar research,
- vulnerability of the population being studied including familiarity with the language on consent forms and other documents, and
- other facts the IRB deems relevant.

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2. Audits of Research/Monitoring of Informed Consent Procedures

The IRB and the institution have the right to conduct audits of approved research to ensure that all requirements have been met—in particular, the manner in which informed consent has been conducted. The IRB is authorized to monitor or to have a third-party monitor the informed consent process. Additionally, governmental agencies may also review research records. The university may randomly audit approved studies and may elect to target audit studies.

**References:**

45 CFR 46.103(b)(4)(i-iv) and 46.109(e)

21 CFR 56.108(a)(1) and 56.109(a - f)

21 CFR 56.108(a)(1) and 56.109(e)

21 CFR 56.108(a)(2)

21 CFR 56.115(a)(3)

**Procedures:**

1. For Continuing Review:
  - a. PIs who require continuation of study approval must request continuation at least two months before the end of study's approval. Federal regulations and university policy do not allow for any form of grace period. As a result, research with human subjects and/or their data must end should approval of continuing review not be obtained before the end of the approval period and may not begin again until the study has been approved for another continuing review period.
  - b. The protocol submitted for continuing review will be reviewed at the appropriate level (expedited or full review). Typically, studies are reviewed at the same level for continuing review as for initial review. For this reason, the PI will submit 23 copies of the continuing review documents if his/her study was originally reviewed by the full board. In some instances, continuing review of full reviewed protocols may be conducted at the expedited level; however, this will be determined by the IRB office in keeping with the expedited categories enumerated by the OHRP and FDA. The policy Level of Review and Decision describes the situations in which a renewal/revision of a study, initially receiving Full Review, qualifies for an expedited approval.
  - c. Once a decision has been made the PI and Center Representative are notified in writing. Additionally, these individuals and faculty sponsors are informed via electronic mail.

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- d. The IRB maintains all records of continuing review within the respective protocol's file. For continuing review conducted at convened meetings, the minutes also reflect any discussions related to the continuing review process.
2. For audits of research:
- a. The university will contact the PI in writing to request delivery of research records within thirty (30) days to the vice president of research, planning, and governmental affairs.
  - b. Studies that have been concluded may also be reviewed by the institution, IRB, or governmental agencies, and as a result the investigator should retain research-related (including informed consent) documents for a minimum of three years from the date the study was concluded or in the case of funded research, the time specified in the award document if longer than three years. For multi-site studies, researchers are reminded that the date of conclusion of the study is the date when the sponsor closes the research and/or the last research site had concluded research activity—not the date research activities ended at the local site.
  - c. Informed consent documents must state that the university, the IRB, and regulatory agencies are permitted to review research records which may contain personal/confidential information.
  - d. Researchers may be asked to meet with the individuals conducting the audit. Prior to submitting the audit report to the vice president, feedback will be solicited from the researchers.
  - e. At the conclusion of the audit, the final report will be submitted to the vice president.