

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

IRB Authority

Effective 02/08/2007; Revised 12/10/2009; Revised 8/29/2011

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Purpose:

To establish policy and procedures related to the IRB's authority to review all research involving human subjects.

Definitions:

1. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - a. Data through intervention or interaction with the individual, or
 - b. Identifiable private information.Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
2. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
3. Research subject to regulation, and similar terms, are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

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4. Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that:
 - a. Identifies or could identify an individual; and
 - b. Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
 - c. Relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual
5. Covered entity includes a health plan, a healthcare clearinghouse, or a health care provider who submits standard transactions (such as claims submission) electronically. Health care providers are covered entities if they submit bills electronically to insurance or other payors.

Policy:

Nova Southeastern University recognizes the Institutional Review Board as leader of the institution's human subjects protection program and as having full jurisdiction over all research conducted with human subjects by NSU faculty, staff, or students, whether funded or unfunded. The IRB has full authority to disapprove, modify, or approve studies in keeping with ethical and sound research design and in adherence to the guiding principles of the IRB which include the

Belmont Report and by 45 CFR 46, 21 CFR 50, and 21 CFR 56.

Principal investigators (PIs) who propose human subject research must follow the guidelines for preparing and submitting proposals to the IRB outlined in the NSU-IRB procedures manual. This includes all research activities that involve human participants in any manner or that involve records about human subjects.

Such research activities must be reviewed by the IRB prior to the start of research activities. However, there are multiple levels of review that depend upon the nature of the research, the populations involved, the potential for harm, and the potential for violation of confidentiality rules which control the level of the review. If additional information/clarification is necessary, the IRB Chair or IRB staff should be contacted.

The IRB Center Representative (CR) is responsible for recommending the level of review that applies to a given research project; however, the IRB Chair may review and amend the CR's decision. The three possible levels of review include: Center Level Review, Expedited Review, and Full Review. The Center Representative is authorized to consult with the Chair and/or other members of the IRB about the type of review necessary for a protocol. The determination of exemption from IRB review (done during the center level review) is vested with the Center Representative, however the IRB Chair or any member of the IRB may request that an exempted study be reviewed. At no time are researchers permitted to exempt their own research from IRB review, at any level.

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Once a study is approved, the IRB retains the authority to require progress reports from investigators and to oversee the conduct of the study. Additionally, the IRB is authorized to place restrictions on a study as it sees fit.

The IRB Chair and IRB staff are authorized to consult with university counsel, as necessary. While elements involved in appropriate disclosure of PHI relate to confidentiality, policies and forms related to PHI and HIPAA authorizations are under the auspices of the university's Office of Corporate Compliance. The confidentiality section must inform the subject of uses of his or her information, regardless of whether it pertains to a medical condition. This is equally true of data that is obtained outside a covered entity.

References:

45 CFR 46.109(a)

21 CFR 56.109(a)

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

21 CFR 56.108(a)(1), 56.109(a) and 56.113

Procedures:

1. The PI must submit the research protocol for initial review using the IRB Submission form available on the IRB website at www.nova.edu/irb. This document and all supporting documents are submitted to the CR for center level review.
2. The IRB does not review separate HIPAA authorizations as a part of the review of research. PIs whose research includes Protected Health Information are advised to review the HIPAA policies (<http://www.nova.edu/irb/manual/policies.html>).
3. If the CR determines that the study is exempt from further review, in keeping with the exempt categories as defined by applicable federal regulations, the PI will be notified in writing. The exempted protocol, all supporting documents, the center level review decision list, and a copy of the memorandum sent to the PI will be forwarded to the IRB office for recording and archiving. The CR also logs his/her decision in the IRB protocol log (www.nova.edu/irb/secure/log.html).
4. If the CR determines that the protocol requires either an expedited review (based upon the federal categories of research that may be reviewed via an expedited procedure) or full review the protocol is logged into the IRB log and forwarded to the IRB office. If the protocol requires full review, 23 copies of the protocol and supporting documents (in addition to one original), and one set of all test instruments, must be forwarded to the IRB by the last day of the previous month to be included in the next month's agenda.

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5. The expedited and full review procedures will be followed as outlined in “Levels of Review and Decisions” policy.
6. For approved studies, the IRB’s reminder of continuing review will be sent to the PI in writing three months and then one month before the continuing review date. The PI must respond by the continuing review date or the file will be closed and no further research related to the approved study will be permitted.