

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

IRB Levels of Review and Decisions

Effective 03/08/2007

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Purpose:

To establish policy that addresses the various levels of IRB review that exist at NSU and to delineate the different decisions that may be made by the IRB.

Definitions:

1. IRB approval means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.
2. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Policy:

1. Types of Review
 - A. Center-Level Review (formerly titled Exempt Review)

This level of review is reserved for research that represents no more than minimal risks to participants and does not involve subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. This level of review is conducted by the Center Representative (CR), at which time the CR determines that the protocol does not warrant an expedited or full review (is exempt from further review). CRs may not review studies in which he or she has an actual or apparent conflict of interest, is an investigator, or is a study in which another CR or alternate representative is an investigator. These protocols are to be reviewed by the Chair or Chair Designee. The CR reports the determination to the IRB.

Protocols must fall into at least one of the following categories to be determined as exempt from further review:

- 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula,

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or classroom management methods.

- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 5) Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
 - (i) public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6) Taste and food quality evaluation and consumer acceptance studies,
 - (i) if wholesome foods without additives are consumed or
 - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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B. Expedited Review

This category is reserved for studies that exceed what is permissible as exempted research, but also do not represent more than a minimal risk to the subjects involved. The CR reviews the study and recommends this level of review. At the discretion of the Chair or Chair Designee, a protocol may be elevated from expedited to full review.

Investigator requests for approval of minor changes to a protocol that initially received full board approval may be approved via expedited review. Minor changes are limited to changes to the protocol to add research sites or add to the number of subjects (as long as such increases would not elevate potential risk to human subjects), changes to informed consent documents that do not change the informed consent procedures, and/or changes to instruments that do not increase the potential risk to human subjects.

IRB members are informed of expedited decisions via the IRB minutes.

In order for a protocol (either initially or via continuing review) to qualify for expedited review, it must meet one of the following categories:

- 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which
 - (i) an investigational device exemption application (21 CFR Part 812) is not required; or
 - (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

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- b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3) Prospective collection of biological specimens for research purposes by noninvasive means.
 - a. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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- 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt from further review and thus not qualifying for center level review.)
- 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)
- 8) Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
- 9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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C. Full Review

Full review by the entire IRB panel is intended for research that does not meet the center or expedited levels of review, studies that have more than minimal potential risk to human subjects, and/or involve vulnerable populations. It should be noted that a CR may always recommend, at his/her discretion, to advance a study for full review even though it may qualify for expedited review. Additionally, if the PI is not satisfied with requested revisions, she/he may request a full review of his/her protocol.

2. Types of Decisions

A. Approved

The protocol is approved as submitted, in keeping with OHRP and FDA criteria for IRB approval. Approval is reserved for studies reviewed at the expedited or full review level while studies reviewed at the center level are determined as exempt for further review. Approval is valid for the time period specified in the correspondence to the primary investigator. The date of continuing review (expiration of approval) for full reviewed studies is determined by the convened IRB, even if the approval is contingent upon revisions or corrections, and may not exceed 364 days from the convened meeting date of the IRB where the protocol was approved. The date of continuing review for expedited studies is determined based on the date of approval and the nature of the study and may not exceed one year (364 days), but may be for a lesser time. As indicated in the Monitoring of Approved Research, Approval Duration, and Continuing Review policy, the period of approval duration is based on a number of items and may be significantly less than the maximum period allowed by regulation (364 days).

B. Pending (Revisions or Further Information Requested)

A protocol is considered pending when the problems identified in the protocol are not serious and generally fall into two categories: 1) the investigator needs to clarify an aspect of the study or provide additional information, or 2) minor changes are required. In these cases, approval may be given after the investigator revises the protocol and/or informed consent and submits to the Chair or Chair Designee, a written response to the questions, concerns, or revision items. For proposals requiring Full Review, the Chair can then poll IRB members to receive final approval, as appropriate, or can approve the changes as submitted, if that option had been the vote of the convened IRB during initial review.

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C. Disapprove

The IRB will disapprove the proposed research if it does not have a reasonable relationship between risks and anticipated benefits, has inequitable subject selection, does not appropriately provide for informed consent/assent, does not safeguard data and have adequate provisions to protect patient confidentiality, or if it raises such ethical questions as to be unacceptable. A research activity may be disapproved only after a full IRB review has been conducted.

D. Table

During full board meetings the Board may table a protocol when questions about the protocol are substantial, and level of risk cannot be ascertained, and/or the study requires major revisions. The tabled protocol will be returned to the CR and PI to address the IRB's concerns.

References:

45 CFR 46.101(b)

45 CFR 46.110(a – c)

21 CFR 56.108(a)(1) and 56.110(a - c)

Procedures:

1. If a study qualifies for Center-Level Review, the CR determines which exempt category is applicable. The CR logs all protocols reviewed and determined as exempt from further review via the university's IRB log (<http://www.nova.edu/irb/secure/log.html>). The CR then sends the reviewed protocol and exempt category information to the IRB office for archiving.
2. When the CR determines that a study qualifies for expedited review, the CR will work with the investigator to revise the study as appropriate to facilitate approval. When the CR believes the submission is in inappropriate form for review, he/she will forward a single copy of the submission to the IRB office. The CR will log the study via the university's IRB log (<http://www.nova.edu/irb/secure/log.html>).

This expedited level of review is conducted by the Chair or Chair Designee. The Chair or Chair Designee may approve the study, or request more information or study modifications. The Chair or Chair Designee will determine the appropriate length of the approval period, using the guidelines set out in the policy "Monitoring of Approved Research, Approval Duration, and Continuing Review". If the study is not approvable, the Chair will request Full Board review. The Chair or Chair Designee's action on

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studies is sent to the PI and CR in writing. Stamped consent forms and/or advertisements are returned to the PI with the approval letter. Additionally, the PI, CR, and faculty sponsors are informed via electronic mail.

3. If a submitted study requires full review, the CR will work with the investigator to revise the study as appropriate to facilitate approval. When the submission is in appropriate form for review, the CR will log the study as requiring full review via the university's IRB log (<http://www.nova.edu/irb/secure/log.html>).

Twenty-three (23) copies and one original of the protocol and supporting documents are to be sent to the IRB office. Protocols received on or before the last day of the month will be placed on the IRB meeting agenda for the next month. Only one copy of test instruments is required. In the case of investigational studies for FDA approval or other similar sponsored studies, the investigator will also forward five copies of materials such as the investigator brochure and related materials, with copies to be distributed to the adverse events committee members and the Chair.

The Board will vote to approve, disapprove, table, or consider a study pending. If a study is considered pending, the Board may elect to approve the study contingent upon the Chair receiving satisfactory study modifications/explanations, or may require full Board review prior to approval. If a study is approved, the Board will determine the appropriate length of approval using the guidelines set out in the policy "Monitoring of Approved Research, Approval Duration, and Continuing Review". The Board's action on studies is sent to the PI and CR in writing. Stamped, original consent forms and/or advertisements are returned to the PI with the approval letter. Additionally, the PI, CR, and faculty sponsors are informed via electronic mail.