

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

**IRB Levels of Review and Decisions**

**Effective 03/08/2007; Revised 02/11/2010, 10/14/2010; 01/4/2011; 8/29/2011; 9/12/2013**

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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, state, and local 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. This level of review may not be used for research involving prisoners. This level of review is conducted by the Center Representative (CR), at which time the CR determines that he or she believes the protocol does not warrant an expedited or full review (is exempt from further review). CRs may not conduct center-level review of 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 IRB staff, IRB Chair or a designee from the Board determined by the Director or Chair. The CR reports the recommendation that the study is exempt from further review to the IRB. The IRB Director or Chair may review the center level representative's determination and may require a higher level of review.

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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, 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.This category does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.
- 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.

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- 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.

**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 Director, Chair or Chair Designee, a protocol may be elevated from expedited to full review. In addition, the IRB Chair or IRB staff may determine that a study meets the exempt criteria listed above, and may return the study to the CR to exempt from further IRB review. The expedited review is typically conducted by the Chair; however, the IRB Chair (or the IRB Director in the absence of the Chair) may assign an experienced IRB member to conduct the expedited review.

Investigator requests for approval of minor changes to a protocol that initially received full board approval may be reviewed and approved via expedited procedures. Minor changes involve procedures that are no more than minimal risk, or risks to subjects are not increased, and/or the revision is not a significant alteration of the study design. Minor changes may include but are not 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), clerical changes to documents, changes to advertisements or informed consent documents that do not significantly alter the informed consent procedures, and/or changes to instruments that do not increase the potential risk to human subjects.

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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 and contain only procedures described in one or more of these 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
  - 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. 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

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- a. 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.
  
- 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

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- 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.

C. Full Review

Full review by the entire IRB 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 certain vulnerable populations including, but not limited to, prisoners. 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 does not agree with requested revisions, she/he may request a full review of his/her protocol. Full review must occur in keeping with the requirements stipulated in the IRB Meeting Operations policy.

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

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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, including but not limited to the level of risk, the nature of the research, or the population, and may be significantly less than the maximum period allowed by regulation (364 days).

**B. Approved as Modified by the IRB**

The protocol is approved with revisions, clarifications or other changes to the protocol or to the informed consent or other documents as made by the IRB. 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.

If the PI does not concur with the changes made by the IRB, he/she may not initiate the study pursuant to the IRB approval. The IRB approval is void. The PI may withdraw the study, appeal to the IRB (see the IRB policy on Appeal of IRB Actions/Determinations at [http://www.nova.edu/irb/manual/forms/appeals\\_process.pdf](http://www.nova.edu/irb/manual/forms/appeals_process.pdf)) or make revisions to the study for review by the IRB. The study may not be started until the protocol as the PI intends to conduct the study is reviewed at a convened meeting of the IRB and approved.

**C. Deferred for Expedited Review by the IRB Chair or Designee (Approved with Conditions)**

The protocol has been approved by the IRB but with conditions that require revisions and/or clarifications that the IRB determined to be nonsubstantive, minor, and not directly relevant to the IRB determinations required under 45 CFR 46.111/21 CFR 56.111. Such revisions or clarifications may be reviewed and approved by the IRB Chair or designee on an expedited basis. The IRB shall clearly specify the action(s) needed and who has the authority to review and approve the revised or requested materials on an expedited basis. The IRB Chair at his/her discretion may return the revised protocol for review at a convened meeting of the IRB.

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Required revisions or clarifications must be submitted to the IRB office within 6 months following notification. If the revisions or clarifications are not received within 6 months, the approval is considered to be void and the protocol will need to be resubmitted for review at a convened meeting of the IRB.

**D. Deferred for Re-Review by the Convened IRB**

The protocol is not approved and requires revisions or clarifications for subsequent review by the convened IRB. This motion is applicable to circumstances where the convened IRB has determined that the revisions or clarifications are substantive and directly relevant to the IRB determinations required under 45 CFR 46.111/21 CFR 56.111.

**C. Disapproved**

The IRB will disapprove the proposed research if it does not have a reasonable relationship between risks and anticipated benefits, or has inequitable subject selection, or does not appropriately provide for informed consent/assent, or 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. Tabled**

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 and the Board is unable to review and/or vote on the protocol. The tabled protocol will be returned to the CR and PI to address the IRB's concerns. Protocols may also be tabled if there is not sufficient time to complete a comprehensive review of the study.

**References:**

45 CFR 46.101(b)  
45 CFR 46.110(a – c)  
45 CFR 46.111  
21 CFR 56.108(a)(1) and 56.110(a - c)  
21 CFR 56.111

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**Procedures:**

1. If a study qualifies for Center-Level Review, the CR recommends 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. In instances where the study is funded, the CR must review the funded proposal as a part of the Center-Level Review. A copy of the funded proposal must also be sent to the IRB office. The IRB staff reviews the titles of all Center-Level Reviewed studies and examines those that appear not to qualify for Center-Level Review. The Director, Chair, or Chair's designee may revise the recommendation upon review of the protocol. If the level of review is revised, the IRB Director will notify the principal investigator and CR via electronic mail. In instances where a CR has an actual or apparent conflict of interest, is an investigator, or another CR or alternate representative is an investigator, the IRB staff, IRB Chair or his/her designee may conduct the review and determine that the study is exempt from further IRB review. In addition, in times where the CR or his/her alternate are not available to review the submission, the exempt determination may be made by IRB Staff, the IRB Chair or his/her designee.
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 appropriate form for review, he/she will forward a single copy of the submission to the IRB office. The submission will include, but is not limited to, the completed New Protocol Form, consent and/or assent forms, test/data collection instruments, investigator brochures/sponsor protocols (when applicable), a copy of the funded proposal (when applicable), program manuals, and approvals/authorizations from other IRBs or administrative agencies. 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 Chair or Chair Designee believes that the study is not approvable, the Chair will request Full Board review. The Chair or Chair Designee's action on 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. The PI, CR, and faculty sponsors, when applicable, 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

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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>).

Two (2) copies and one original of the protocol and supporting documents are to be sent to the IRB office. Submissions received on or before the last day of the month will be placed on the IRB meeting agenda for the next month. The submission should include, but is not limited to, the completed New Protocol Form, consent and/or assent forms, test/data collection instruments (only one copy is necessary, although investigators may elect to reproduce 2), investigator brochures/sponsor protocols (when applicable), one copy of the funded proposal (when applicable), program manuals, and approvals/authorizations from other IRBs or administrative agencies. In the case of FDA-regulated studies where a sponsor protocol and/or clinical investigator brochure exist, three copies of the aforementioned documents must be provided to the IRB office. For federally funded research, the investigator will forward one copy of the funded proposal to be reviewed by the IRB Chair or his/her designee.

The IRB Director will provide an electronic copy of the submission materials (including the sponsor protocol, clinical investigator brochure and funded proposal when applicable) to all IRB members and the Institutional Official via the password protected area of the IRB website or an equally secure location. During the convened meeting, voting members may view the documents on personal portable devices or may print a paper copy of the documents and bring them to the meeting.

The Board will vote to approve, approve as modified by the IRB, defer for expedited review by the IRB Chair or Designee (approve with conditions), defer for re-review by the convened IRB, disapprove, or table the study. 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. The PI, CR, and faculty sponsors (when applicable) are informed via electronic mail.

4. In instances when a difference of opinion exists between the IRB Director and Chair as to the appropriate level of review, the protocol will be referred for discussion to the Institutional Official or his/her designee.