

NDSU research activities involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the categories described in the Federal Register may be eligible for review by the expedited review procedure. Such projects are subject to the same regulatory and ethical standards as projects reviewed at a convened meeting.

1.0 Eligibility for expedited review.

Human subjects research involving no more than minimal risk, and procedures limited to those listed in one or more of the following categories may be reviewed by the IRB by the expedited procedure. Note:

- Activities listed are not automatically considered to involve **minimal risk**; the specific circumstances of each project must be considered to evaluate risk for the research.
- Categories in this list apply regardless of the age of subjects, except as noted.
- the research must implement reasonable and appropriate protections to ensure that risks related to privacy and confidentiality will be no more than minimal if identification of subjects or their responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.
- Expedited review may *not* be used for **classified research** involving human subjects.
- Standard requirements for informed consent (or its waiver or alteration) apply regardless of the type of review--expedited or full board review.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
- Categories eight (8) and nine (9) pertain only to continuing IRB review.

Expedited review categories.

1.1 Category #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 (IND) 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 (IDE) 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.

1.2 Category #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.

1.3 Category #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 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.

1.4 Category #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.

1.5 Category #5.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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.)*

1.6 Category #6.

Collection of data from voice, video, digital, or image recordings made for research purposes.

1.7 Category #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.)*

1.8 Category #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.

1.9 Category #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.

2.0 Initial review of new protocols.

2.1 Application materials and submission process.

Principal investigators may submit applications and required supplemental materials electronically via email. Electronic submissions must be sent to ndsu.irb@ndsu.edu from the PI's official NDSU email account, copying all co-investigators and the department chair, dean or director. The department chair, dean or director must indicate their approval via their official NDSU email account.

Hard copy submissions are also acceptable. These must be signed by the PI, co-investigators(s), and department chair dean or director and delivered/campus mailed to Research 1 or mailed to:

Human Research Protection Program
NDSU Dept. 4000
PO Box 6050
Fargo, ND 58108-6050

The most recent version of protocol form and relevant attachments may be found on the IRB website. Protocol applications must be completed thoroughly and contain sufficient detail regarding procedures involving human subjects so that a thorough IRB review may be

performed. Guidance is available on the IRB website to assist in preparing a complete application for submission to the IRB office.

A minimum of 10 business days should be allowed for processing and review; additional time may be required if the submission is incomplete, contains conflicting or insufficient information, or the project is not eligible for expedited review.

2.2 Pre-review procedures.

HRPP staff process the protocol application, verify training documentation and ensuring the application is complete.

2.2.1 Incomplete application.

If the application is incomplete, a qualified HRPP staff member communicates with the investigator(s) to obtain the necessary forms, attachments, or additional information. Communication is documented in the protocol record.

2.2.2 Project not eligible for expedited review.

HRPP staff may consult with the IRB Chair/designee if there is a question regarding eligibility for expedited review. If a protocol is determined ineligible for expedited review, it will be scheduled for review by the full board at the next available convened meeting (based on submission deadlines). The IRB retains the final authority to determine the eligibility for expedited review.

2.2.3 Complete application.

HRPP staff process completed protocol applications for review (see section 2.3 on IRB review procedures). Investigators or members of the research team who have not yet completed training requirements may do so while the protocol is under review, however final approval will be withheld pending training documentation for all members of the research team.

2.2.4 Special representation or consultants.

An IRB may invite individuals with competence in special areas to assist in review of issues requiring expertise beyond or in addition to that available on the board. Examples may include, but are not limited to, individuals with experience with cognitively impaired persons, prisoners, individuals of a particular culture, or locale, etc. These consultants will provide written or verbal information to the IRB on the acceptability of the research with the proposed population, but will not vote with the board. A qualified HRPP staff member, IRB Chair/ designee determine the need for any special representation.

2.3 IRB review procedures.

2.3.1 Selection of reviewers.

The IRB Chair/designee or one or more experienced IRB members as designated by the chair, conduct reviews by the expedited method. A member is considered experienced to conduct expedited review if s/he has completed orientation and training, attended at least three (3) IRB meetings, and the Chair or designee has verified that they are sufficiently familiar with the interpretation and application of ethical and regulatory requirements for IRB approval. At least one of the reviewers should have applicable

scientific and/or disciplinary expertise. HRPP staff assign protocols for expedited review based on members' experience and background related to the type of research procedures, or subject population.

No IRB member may participate in review of a protocol for which they have a conflict of interest (e.g., investigator or co-investigator, financial, department level, or personal relationship) that would affect their ability to consider the rights and welfare of participants. A reviewer may be selected from a researcher's department if the reviewer/researcher relationship does not have a perceived power differential (e.g., chair/faculty). Those members with a conflict of interest not readily apparent to HRPP staff are to notify the IRB office so a reassignment may be made. Refer to *Section 6 Conflicts of Interest* for more information.

2.3.2 Review process and criteria.

Expedited review is conducted based on the same ethical and regulatory requirements as full review, in accordance with the specified determinations in *SOP 7.2 Criteria for IRB Approval*. HRPP staff notify reviewer(s) of an assignment, provide them with the complete protocol submission and appropriate review guide. Reviewer(s) return the completed review guide to the IRB office (typically within 5 working days).

2.4 Possible IRB actions and notification.

2.4.1 Approved as submitted.

The IRB may determine that the protocol materials and consent form(s) are satisfactory as presented, and meet all required criteria for approval. The initial effective approval date is the date at which this determination was made. HRPP staff forward a signed letter of approval to the investigator, and the research may begin. The letter will include the investigator's responsibilities, the dates of approval and expiration. The approval is documented in the protocol file and database.

2.4.2 Approved with conditions.

The IRB may determine that the criteria for approval can only be met with specific, minor modifications, alterations or clarifications to the protocol, associated attachments, and/or consent form(s). Such conditions would involve specific changes or confirmations, such as:

- confirmation of specific assumptions or understandings regarding how the research will be conducted (e.g., confirmation that the research excludes children),
- submission of additional documentation (e.g., training documentation),
- precise language changes to the protocol or informed consent document(s), or
- substantive changes to the protocol or informed consent documents along with clearly stated parameters that the changes must satisfy (e.g., requiring simplification of the description of risks in the consent document to be at an 8th grade comprehension level).

Qualified HRPP staff compiles reviewer(s) determinations and comments, and may consult with reviewers, IRB chair/designee in cases of conflicting determinations. HRPP staff communicates the determination in writing to the investigator; all documentation is

retained in the protocol file. If the investigator does not respond with the revisions or additional information within 60 days, the protocol is withdrawn from consideration.

An assigned reviewer, IRB Chair/designee, or other experienced member (which may include an HRPP staff member) reviews the revised materials to determine that conditions have been satisfied, and further review is not required. The initial approval date is the date on which the materials are determined satisfactory, documented by an email response or in written comments within the protocol file. HRPP staff provide a letter of approval to the investigator, and the research may begin. The letter includes the investigator's responsibilities, the dates of approval and expiration. Documentation is retained in the protocol file and database.

2.4.3 Deferred.

The IRB may determine that the protocol materials contain insufficient information or would require more than minor changes to meet criteria for approval. Qualified HRPP staff notify the investigator in writing, outlining the reasons for deferral, including a description of the additional information or revisions needed for review. Upon receipt of the revised protocol, it is returned to the assigned IRB member(s) for further review.

2.4.4 Referred for full board review.

The IRB may determine that the project, as submitted, does not meet the criteria for review by the expedited method, and would require review at a convened meeting, per *SOP 7.4 Full Board Review*. Qualified HRPP staff notify the investigator in writing of the determination, including an explanation of why the project is ineligible for expedited review; additional materials or information may be required. The IRB retains the final authority in determining project eligibility for expedited review, and may err on the side of caution to require full review to ensure protection of subjects, and compliance with the terms of NDSU's FederalWide Assurance with the Office of Human Research Protections (OHRP).

2.5 Appeals process

The investigator may appeal the IRB determination if new information becomes available, or evidence is provided that the IRB has failed to follow their own procedures, or incorrectly applied federal regulations, state law, or NDSU policy for the protection of research participants. A written appeal, citing specific federal regulations, NDSU policy or procedures, may be made to the HRPP office or IRB Chair within 10 business days after receipt of communication from the IRB.

In consultation with HRPP staff, the IRB Chair or designee makes a determination, and may forward the appeal to the board for consideration at the next convened meeting. The board's determination is considered final, and communicated in writing to the investigator and other entities as applicable.

2.6 Notification to IRB and institutional officials.

IRB members are provided with a report listing the protocols that were determined to be exempt, and the new and continuing protocols reviewed by the expedited method since the last report. All members have an opportunity to review the list and ask questions about any of the actions performed outside of full board deliberations. These documents are also available to the Institutional Official (IO) .

2.7 Other institutional approval.

Some projects may be subject to further review and approval or disapproval by officials of the institution. These officials may not approve the research, however, if it has not been approved by the IRB.

3.0 Post-approval procedures:

3.1 Protocol changes.

Prior IRB approval is required for proposed changes to any aspect of the protocol, except when necessary to eliminate apparent immediate hazards to the participants. These changes may include, but are not limited to changes in:

- subject population,
- recruitment procedures,
- informed consent process,
- research or data collection procedures,
- research site.

Amendments to a protocol originally reviewed by the expedited method may also be reviewed by the expedited method, providing the proposed changes do not involve more than minimal risk, and are eligible under one or more of the applicable categories. Proposed amendments to protocols originally reviewed by the full board may be eligible for review by the expedited method as long as the changes are considered minor. Refer to SOP 7.5 *Protocol Amendments* for more information.

3.2 Status Updates

Unless the IRB determines otherwise (e.g. in cases of past noncompliance, or other special circumstances), continuing review of research is not required for research reviewed under expedited procedures in accordance with §____.110; however, a project status update will be requested by the IRB office after three years. The IRB office will typically send a notice approximately two (2) months prior to the three-year anniversary date. Status updates are due two weeks prior to the three-year anniversary date of the protocol.

Research conducted without current IRB approval or determination of exemption will be considered noncompliant, and subject to procedures described in SOP 12.3 Complaints or Allegations of Noncompliance.

3.3 Project closure.

A termination/project closure report is required to the IRB when a project is completed or terminated.

3.4 Unanticipated events.

A report is required to the IRB in the event of unanticipated problems involving risks to participants or others, or serious adverse events. A research-related injury or a loss of confidential research data would be examples of unanticipated events that would place participants at risk. Refer to SOP 7.7 *Unanticipated Problems and Serious Adverse Events* for more information.

3.5 Quality assurance and research compliance.

Research eligible for expedited review is subject to random (not-for-cause) or directed (for-cause) audits to ensure compliance with federal regulations and institutional policies. Refer to *Section 12 Quality Assurance and Research Compliance* for more information.

DEFINITIONS:

Investigator: anyone involved in conducting the research; i.e., study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining coded private information or specimens, analyzing data (note that this would *not* include someone whose sole role is providing coded private information or specimens to an investigator).

Minimal risk: 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.

Principal investigator (PI): an NDSU faculty or staff member who has primary responsibility for the research. When graduate students conduct research, their faculty advisor serves as the PI.

Classified research: research that is specifically authorized by an Executive order to be kept secret in the interest of national defense or foreign policy.

REFERENCES:

FederalWide Assurance Terms
45 CFR 46.102 and 21CFR56.102 Definitions
45 CFR 46.107(d) and 21CFR56.107(e) Conflict of interest
45 CFR 46.107(e) and 21CFR56.107(f) Special representation
45 CFR 46.109 and 21CFR56.109 IRB review of research
45 CFR 46.110 and 21CFR56.110 Expedited review procedures
45 CFR 46.111 and 21CFR56.111 Criteria for IRB approval of Research
45 CFR 46.112 and 21CFR56.112 Review by institution
Expedited Review Categories (Federal Register, Vol 63, No. 216, Nov. 9, 1998)
OHRP guidance on Expedited Review Procedures
OHRP guidance on Written IRB Procedures
OHRP Guidance on IRB Approval of Research with Conditions

RELATED FORMS:

IRB Protocol Form
Expedited Categories Attachment
Expedited Review Guide

RELATED HRPP SECTIONS:

2 Applicability
6 Conflicts of Interest
7.2 Criteria for IRB Approval

7.4	Full Board Review
7.5	Protocol Amendments
7.7	Reports of Unanticipated Problems and Serious Adverse Events
12	Quality Assurance and Research Compliance