

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.
- expedited review may *not* be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- expedited review may *not* be used for classified research involving human subjects.
- standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened review.
- categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Eligible categories of research:

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 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.

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.

Investigators complete the protocol form and any relevant attachments, utilizing the most recent version of forms from the IRB web site. Protocol applications must be completed thoroughly, containing sufficient detail regarding procedures involving human subjects so that a thorough IRB review may be performed. Investigators may utilize guidance and/or checklist available on the IRB website to assist them in preparing a complete application for submission to the IRB office.

Upon receipt of the signed and completed application in 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 will process the protocol application, verify training documentation and ensure the application is complete, utilizing the submission checklist for documentation.

2.2.1 Incomplete application.

If the application is incomplete, a qualified HRPP staff member will communicate with the investigator (and co-investigator, as applicable) to obtain the necessary forms, attachments, signatures, or additional information. All communication will be documented in the protocol file.

2.2.2 Project not eligible for expedited review.

HRPP staff may consult with the IRB Chair or 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 (if received prior to the submission deadline). The IRB retains the final authority to determine the eligibility for expedited review, and may err on the side of caution to ensure protection for subjects, and compliance with the terms of NDSU's assurance.

2.2.3 Complete application.

HRPP staff forward completed applications, including a copy of the pre-review submission checklist, for review. 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.

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 or designee will determine the need for any special representation.

2.3 IRB review procedures.

2.3.1 Selection of reviewers.

The IRB Chair or 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 he/she has completed orientation and training, attended at least 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 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 (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 own department if the reviewer/researcher relationship does not have a perceived power differential (chair/faculty). Those members with a conflict of interest not readily apparent to HRPP staff are to notify the IRB office so a re-assignment may be made. Refer to *Section 6 Conflicts of Interest* for more information.

2.3.2 Review process and criteria.

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

2.4 Possible IRB actions and notification.

2.4.1 Approval.

The IRB may determine that the protocol materials and consent form(s) are satisfactory as presented, and meet all required criteria for approval. 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 of approval. The approval is documented in the protocol file and database record.

2.4.2 Requires modifications for approval.

The IRB may determine that the criteria for approval can only be met if certain revisions are made to the protocol. Qualified HRPP staff compile reviewer(s) determinations and comments, and may consult with reviewers or IRB chair or designee in cases of conflicting determinations. HRPP staff communicate the determination in writing to the investigator; all documentation is retained in the protocol file. The investigator is expected to respond with revisions or additional information within 90 days, otherwise the IRB will withdraw the protocol from consideration.

An assigned reviewer, IRB Chair or designee, or other experienced member reviews the revised protocol materials upon receipt. If acceptable, HRPP staff draft and 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 of approval. Documentation is retained in the protocol file and database record. Should an investigator disagree with the determination, their written appeal may be considered at the next available convened meeting.

2.4.3 Not eligible for expedited 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 *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).

2.4.4 Deferral.

The IRB may determine that the protocol materials contain insufficient information to make the required findings 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 forwarded for the applicable review.

2.5 Approval period.

The IRB determines the approval period, appropriate to the degree of risk, but not less than once/yr. The typical approval period is 364 days; however, the IRB may determine that some research projects require more frequent review; such as:

- any research involving fetuses;
- any research involving significant risk, and/or a high risk:potential benefit ratio
- any research for which there have been reports of injury or unanticipated problems as a consequence of participating in the research
- any other research the IRB deems appropriate to review on a more frequent basis

The date of approval is the date that a reviewer has signified a determination of approval (or contingent approval) by signing the review checklist form. If this date is different for 2 or more reviewers, the earliest date is designated as the approval date. Note that if minor modifications are required, however, the *research may not begin* until these have been accepted by the IRB. The expiration of approval will then be set at no more than 364 days after the approval date.

2.6 Notification to IRB and institutional officials.

IRB members are provided with an attachment to each month's agenda listing the protocols that were certified as exempt, and the new and continuing protocols reviewed by the expedited method since the last meeting. 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) and/or the Associate VP for Sponsored Programs Administration by posting on a shared computer drive.

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 Continuing review.

If a project will continue beyond the initial approval period, continuing IRB review and approval of research must occur prior to the date of expiration of approval. The IRB office will typically send a notice to the principal investigator (PI) approximately 2 months prior to the expiration date; however, timely submission of the report is the responsibility of the investigator. Refer to *7.6 Continuing Review* for more information.

3.2 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 *7.5 Protocol Amendments* for more information.

3.3 Project closure.

A report is required to the IRB when a project is closed to accrual, completed, or abandoned. Refer to *7.6 Continuing Review* for more information.

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 are several examples of unanticipated events that would place participants at risk. Refer to *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; ie, 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 will conduct research, their faculty advisor is considered 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:

[FederalWideAssurance Terms](#)

[45CFR46.102](#) and 21CFR56.102 Definitions
[45CFR46.103\(b\)\(4\)](#) Written IRB procedures
[45CFR46.107\(e\)](#) and 21CFR56.107(e) Conflict of interest
[45CFR46.107\(f\)](#) and 21CFR56.107(f) Special representation
[45CFR46.109](#) and 21CFR56.109 IRB review of research
[45CFR46.110](#) and 21CFR56.110 Expedited review procedures
[45CFR46.111](#) and 21CFR56.111 Criteria for IRB approval of Research
[45CFR46.112](#) 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 Procedures](#)

RELATED [FORMS](#):

IRB Protocol Form
Participant informed consent/info sheet template and instructions
Expedited Categories Attachment Form
Protocol Submission Checklist
IRB Review Checklist

RELATED HRPP SECTIONS:

2 Applicability
6 Conflict of Interest
7.2 Criteria for IRB Approval
7.4 Full Board Review
7.5 Protocol Amendments
7.6 Continuing Review
7.7 Unanticipated Problems and Serious Adverse Events
12 Quality Assurance and Research Compliance