

**EXPEDITED REVIEW**

<b>SOP #:</b>	<b>402</b>	<b>VERSION #:</b>	<b>1</b>	<b>EFFECTIVE DATE:</b>	<b>11/01/14</b>	<b>SUPERSEDES DOCUMENT:</b>	<b>/ /</b>
<b>THIS POLICY PERTAINS TO:</b>			<b>ALL RESEARCH SUBMITTED TO THE IRB</b>				
<b>RESPONSIBILITY FOR EXECUTING POLICY:</b>		<b>IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB COORDINATOR, INVESTIGATORS, IRB MEMBERS</b>					
<b>LAST REVIEWED ON:</b>		<b>/ /</b>		<b>RESULTS:</b>	<b>REVISED</b>		
<b>APPROVAL AUTHORITY:</b>		<b>Associate Vice President for Research and Economic Development</b>					
<b>APPROVED BY:</b>					<b>DATE:</b>	<b>10/23/14</b>	

**1. POLICY**

An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson or his or her designee. A designee is an IRB member recognized by the IRB Chairperson, who has a minimum of 3 months experience on the Board. The IRB Chairperson will provide a list of designee's to the IRB office. A designee or experienced member is one who has demonstrated a consistent and comprehensive pattern of review of assigned protocols as an IRB member and has demonstrated a dedication to the protection of human subjects with their actions and comments. These designees (reviewers) may conduct reviews using the exempt process and the expedited processes. This policy pertains to initial reviews and protocol changes to previously approved research.

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, (2) do not involve identification of subjects and/or responses that 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, (3) are classified, and (4) involve only procedures listed in one or more of the specific categories listed below. The categories in this list apply regardless of the age of subjects, except as noted. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or by the Full Board, utilized by the IRB. Categories one (1) through seven (7) pertain to both initial and continuing IRB review. (Federal Register Volume 63, No 216).

**2. SPECIFIC POLICY****2.1 Expedited Research Categories ([45 CFR 46.110](#))**

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. For example:
  - 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; and/or
  - 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 include:
  - 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 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.)
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.)

The expedited review procedure may not be used with human subjects research involving prisoners.

#### 2.1.1 Minor Modifications.

For modifications to previously approved research to qualify for review by the expedited procedure, the research must represent a minor modification.

**Minor Modifications.** A change is considered minor when it does not materially affect an assessment of the risks and benefits of the study, does not substantially change the aims or design of the study, and is not directly relevant to the determinations required for approval. Examples of items that generally might be considered appropriate for expedited review and approval: changes in research personnel or contact information, minor changes to the protocol or consent document in order to clarify or correct earlier information provided there is no change in the evaluated risks or potential for benefit.

Minor modifications do not include the addition of procedures that involve more than minimal risk or do not fall into categories (1)-(7) of research than can be reviewed using the expedited procedure.

Minor modifications made to the research must continue to meet the applicability criteria and fit under the categories of research that may be reviewed by the IRB through and expedited review procedure.

#### 2.1.2 Continuing Reviews

Continuing review of research previously approved by the convened IRB can be approved as expedited category 8 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.

Continuing review of research can be approved as expedited category 9 when the research was 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.

## 2.2 Minimal Risk

According to the definition in [45 CFR 46.102](#), 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.

The activities listed should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure 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.

## 2.3 Initial Review of Expedited Research

In reviewing the research, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in [§46.108\(b\)](#). However, the reviewer may refer the application to the Full IRB for a standard review as warranted.

2.3.1 The initial reviewer will receive the following documents (if applicable), but not limited to:

- The Human Subjects Review Form, signed by the Investigator (and their adviser if the Investigator is a student).
- Key Personnel Listing
- Questionnaires & assessment instruments
- Proposed informed consent document/Assent and permission documents (if applicable)
- Proposed subject instructions
- Letters of Cooperation
- Supporting material, such as examples of recruitment advertising, etc.
- Investigator Brochure, or device specifications
- DHHS-approved sample consent document (when one exists)
- The complete DHHS-approved protocol (when one exists)
- Financial Interests Disclosure Document (if applicable)
- Documentation of completion of required training (if not already in the IRB database)
- FDA Form 1572 (drug study) or signed investigator agreement (device study)

- Privacy Board documentation (HIPAA), if applicable
- If additional IRB review is being sought at another institution: Name, Address and telephone number of IRB
- If additional review is being sought at another UND committee, the approval if it is completed.
- Contract of funding agency minus the budgetary pages
- Grant Application
- Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board plan (DSMB)

2.3.2 If modifications are requested by the reviewer and the investigator does not want to make the requested modifications, or modifications have been made that were not requested, the reviewer may refer the study to the Full IRB.

## **2.4 Notification of the IRB**

When the expedited review procedure is used, all regular members shall be informed of actions taken by the IRB at the next convened meeting.

## **2.5 Additional Items That May be Reviewed by the IRB Chairperson or Designee (Reviewer)**

2.5.1 Specific revisions stipulated by the convened IRB requiring simple concurrence by the Investigator may be reviewed by the reviewer. All other changes will be referred to the convened IRB unless they are minor modifications as defined in 2.5.2.

2.5.2 Minor Changes to previously approved research:

1. The IRB Chairperson or designee may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Protocol revisions that entail no more than minimal risk to participants are considered “minor” changes.
2. Changes to informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk, or significant changes in the study procedures, are considered minor changes and may be reviewed by the reviewer.
3. The IRB Chairperson or reviewer may approve new or revised recruitment advertisements or scripts.

## **2.6 Documentation of Expedited Review**

If the study qualifies for expedited review, the IRB Chairperson or designee will document the review and category, period of approval, determination of risk, and any other protocol specific findings on the Report of Action Form along with his/her signature and the date.

## **3. RESPONSIBILITY**

The IRB Chairperson or designee is responsible for identifying submissions that qualify for expedited review.

The IRB Chairperson, IRB Vice-Chairperson, or IRB Coordinator is responsible for providing guidance to the reviewer as needed.

The IRB Chairperson or designee is responsible for conducting and documenting expedited review.

The IRB Secretary is responsible for providing a listing of expedited reviews performed to IRB members at convened meetings.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.101

21 CFR 56. 104, 105

**5. ATTACHMENTS**

RR 402-A Expedited Review Categories

Human Subjects Review Form

IRB Checklist

**6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

<b>Who</b>	<b>Task</b>
<i>IRB Secretary</i>	Maintain and make available submission information regarding expedited research. If study qualifies for expedited review, assemble reviewer’s materials and assign IRB member to review
<i>IRB Chairperson, IRB Coordinator, IRB Members</i>	Make determination regarding qualification for expedited review. The Reviewers may: <ul style="list-style-type: none"> <li>• Approve the request.</li> <li>• Request revisions and/or additional documentation from PI.</li> <li>• Send the proposal to the Full Board for review.</li> <li>• Make a determination that the project is not human subjects research and does not require IRB review and approval.</li> </ul> Approval: Document expedited category on Report of Action Form and confirm by signature and date.
<i>IRB Secretary</i>	Upon completion of the review, add the study information to the IRB database. Confirm by approval letter and Report of Action Form to the Investigator within 3 weeks of receiving complete expedited submission. Upon completion of the review, add the study to the List of Projects Reviewed and provide the list to IRB members at the next IRB meeting.