Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 402: EXPEDITED REVIEW

POLICY
The DMH IRB permits the use of expedited review procedures for eligible human subject research activities as defined by Federal regulations.

PROCEDURES

1. Eligibility for Expedited Review

1.1 Some or all of the research appearing on the list under Research Categories (below), unless the reviewer determines that the study involves more than minimal risk; or

1.2 Minor changes in previously approved research during the period for which approval is authorized; or

2. The Reviewer

2.1 The expedited review procedure shall be carried out by an IRB Co-Chair.

3. Authority

3.1 The reviewer (IRB Co-Chair) may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research.

4. Committee Notification

4.1 Completed expedited reviews will be posted to the IRB agenda, and the submission forms and attachments can be viewed at any time by all IRB members.

5. Applicability

5.1 The activities listed should not be deemed to be minimal risk simply because they are included on this list. Inclusion of 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.

5.2 The categories in this list apply regardless of the age of subjects, except as noted.

5.3 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.

5.4 The expedited review procedure may not be used for classified research involving human subjects.

5.5 The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of IRB review (expedited or convened).

5.6 Categories 1 through 7 pertain to initial, modifications (amendments) and continuing review.

5.7 Categories 8 and 9 pertain to continuing review only.

6. Research Categories

6.1 **Category 1**: Clinical studies of drugs and medical devices only when (a) or (b) is met.

(a) Research on drugs for which an investigational new drug (IND) application is not required. (NOTE: Research on marketed drugs that significant 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 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.

6.2 **Category 2**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant 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.

6.3 **Category 3**: Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

(a) Hair and nail clippings in a non-disfiguring 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 member 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; also includes nasal swabs that do not go beyond the nares.

(j) Sputum collected after saline mist nebulization.

6.4 **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. (NOTE: 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 indicates.). 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.

6.5 **Category 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. § 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

6.6 **Category 6**: Collection of data from voice, video, digital, or image recordings made for research purposes.

6.7 **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. § 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

6.8 **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.

6.9 **Category 9**: Continuing review of research, not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) where categories 2 through 8 above 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.

7. Review of Protected Populations (45 CFR 46, Subpart C)

7.1 Subpart C: Research Involving Prisoners as Subjects

7.1.1 Research involving prisoners as subjects shall be reviewed at a convened meeting. **EXCEPTION**: Research aimed at involving a broader subject population that only incidentally includes prisoners may be reviewed by the expedited review procedure for purposes of determining exemption from 45 CFR 46.

8. Definitions

8.1 Expedited Review: An IRB review procedure through which certain kinds of research activities may be reviewed and approved by an IRB Co-Chair and not at a convened meeting.

8.2 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.

8.3 Minor Changes: Any modification that does not materially affect the assessment of risks and benefits.

SCOPE

This SOP applies to all IRB members, the IRB administrator, and members of the research community.