Wayne State University
Institutional Review Board (IRB)

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Expedited Research Categories

Category One (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.

Category Two (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 participants, 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 participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

Category Three (3)

Prospective collection of biological specimens for research purposes by noninvasive means.
Examples:

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 gum base 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.

Category Four (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.

Category Five (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 participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category Six (6)

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

Category Seven (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 participants 45 CFR 46.l0l (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Category Eight (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 participants;
    ii. all participants have completed all research-related interventions; and
    iii. the research remains active only for long-term follow-up of participants; or
b) where no participants have been enrolled and no additional risks have been identified; or
c) where the remaining research activities are limited to data analysis.

Category Nine (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.

Investigator Responsibilities and Ongoing IRB Reporting:

Investigators conducting minimal risk research are required to provide a Status Update of the research project. Investigators are also responsible for updating the IRB of any changes to the study by submitting the Medical/Behavioral Amendment Form. The amendment must have IRB approval prior to implementing any proposed changes. Investigators conducting research determined to be minimal risk are responsible for ensuring that the rights and welfare of human participants is protected. Expedited status does not lessen the ethical obligations to participants and therefore, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

To Submit for Expedited Review

1. Complete a Medical/Behavioral Protocol Summary Form located at www.irb.wayne.edu
2. Complete all associated appendices as directed in the Protocol Summary Form.
3. Complete a HIPAA Summary Form; if accessing or using medical records found at www.irb.wayne.edu
4. Submit a Research Protocol with a list of scientific references
5. Provide a list of the kind of data to be collected and/or any data collection tools or instruments, flyers, advertisements and other documents to be used in the research
6. Carefully follow all submission directions provided with the form