



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 504
Expedited Research

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe when the IRB may review new applications, modifications, and continuing review reports by an expedited procedures, as well as requirements for the expedited review process.

Scope

This SOP applies to all Investigators, IRB members and administrative staff.

Applicability

Use of expedited review by the IRB must be restricted to those IRB applications that fulfill one of the nine categories listed in the Procedures section below. This procedure may be used to review *minimal risk* studies or *minor changes* to approved studies.

Definitions

Expedited Review: A review mechanism that provides allowance for one or more IRB members to conduct the review.

Expedited Review Categories: The following nine categories are outlined by federal regulations as follows:

- **Category 1** Research on drugs for which an investigational new drug application (21 CFR 312) is not required or research on medical devices for which a) an investigational device exemption application (21 CFR 812) is not required or b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- **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, amounts drawn may not exceed 550 ml in an 8-week period and no more 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/kg in an 8-week period and collection may not occur more frequently than 2 times per week.
- **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 the 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.
- **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.
- **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).
- **Category 6** Collection of data from voice, video, digital, or image recordings made for research purposes.
- **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.

- **Category 8** Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new subjects, and all subjects have completed all research-related interventions, and 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 and report writing.
- **Category 9** Continuing review of research, not conducted under an investigational new drug application or an investigational device exemption where Category 2 through Category 7 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.

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.

Minor change: Minor changes may be reviewed by the expedited process rather than by a convened IRB meeting. A minor change:

- Neither meaningfully increases risk, nor meaningfully decreases benefit, when considered in light of any changes proposed to mitigate risk and improve benefit;
- Does not meaningfully decrease scientific merit; and
- Does not adversely affect the assessment of the research with respect to the criteria for approval described in 45 CFR 46.111.

Policy

Under expedited review procedures, the review may be carried out by a member of the IRB or at a scheduled convened meeting of the IRB. If the review is not carried out in a convened meeting, 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 at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary affiliation is in nonscientific areas.

Expedited research involves one or more of the following criteria:

- Presents no greater than minimal risks to subjects
- Includes reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, if the identification of the participants or their responses will reasonably place them at risk of criminal or civil liability or be damaging to their financial standing,

- employability, insurability, reputation, or be stigmatizing
- Is not classified
- Fits one (or more) of the expedited review categories

Procedures

- 1.0 The investigator submits all applicable IRB application materials for review. For guidance, see [IRB Getting Started Page](#) – Documentation Required for Project Submission.
- 2.0 For qualified expedited research:
 - 2.1 **Educational and Behavioral** (non-biomedical) studies will be reviewed at a scheduled convened meeting (every three weeks) for review of initial and continuing reviews. The IRB Committee designated as “Educational and Behavioral Research – IRB” will conduct the reviews. The purpose of conducting these reviews at a convened meeting is to facilitate and improve IRB timelines for review and approval.

The expedited review process may be exercised via a designated IRB member for review of amendments.
 - 2.2 **Biomedical Research** studies that qualify for expedited review will be conducted by a designated IRB member. Biomedical research studies may qualify for expedited review during or after initial approval, based on regulations or changes in the research project.
- 3.0 An [IRB review chart](#) is available to aid in identifying what type of research submissions are assigned to the appropriate reviewing IRB Committee.
- 4.0 IRB Office will assign, if applicable, the expedited research study to the appropriate reviewing IRB Committee as described in 2.0 above. See [USA IRB Committees](#) webpage for additional detail and scheduled meeting dates.
- 5.0 The Investigation must receive an IRB approval document before the research can proceed or for the continuation of the research.
- 6.0 Expedited Review of New Protocols, Continuing Review and Amendments
 - 6.1 The IRB Office is responsible for first confirming whether the new, continuing, or amendment submission is classified as expedited research. If IRB submission qualifies for expedited review, the study will be assigned a designated reviewer or approved at a convened meeting of the IRB.
 - 6.2 In reviewing the research, the designated reviewer may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by a fully convened IRB as described in [45 CFR 46.108\(b\)](#).

- 6.3 If the proposed new, continuing or amendment submission is not eligible for review through the expedited review procedure, the IRB Office and/or the designated reviewer will request that the protocol be added as an agenda item for a convened IRB meeting.
- 6.4 Research projects designated as expedited status may require continuing review (i.e., annual renewal). If research study is eligible for elimination of continuing review, the IRB Office will initiate an annual check-in to inquiry about the status of the study. Furthermore, for any change that is proposed or may need to be made while conducting the research, the Investigator must submit an amendment form.

History:

Effective:

Revisions: January, 2019

Responsible Office:

Office of Research Compliance and Assurance