

RESEARCH CONSIDERED FOR EXPEDITED REVIEW

All Principal Investigators who wish to apply for IRB expedited review for their research proposals must complete the Social, Behavioural & Educational Research Application Form (IRB-Form-001).

Both the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) have designated categories of studies that can be expedited by the Chair or IRB member designated by the Chair.

In general, a research study falls under the expedited review if it involves no more than minimal risk and must fit into one of the specified categories. [See [Federal Register, Volume 63, No 216, November 9, 1998](#)].

All applications that are eligible for expedited review do not require a full board review and approval. However, expedited approvals will be reported to the full board for the board members' information. There will be some documentation of the expedited approval indicating, in particular, the category on the expedited review list that permitted the research to be approved in this fashion. Remember that even in an expedited review, all other provisions of 45 CFR 46 apply, meaning that if consent is going to be waived, there needs to be documentation demonstrating that all elements justifying a waiver have been satisfied. Each IRB that uses an expedited review procedure shall adopt a method for keeping all members informed of research proposals, which have been approved under this procedure ([section 45 CFR 46 §46.110c](#)).

Preliminary expedited review can be conducted for grant funded studies, prior to the release of funds by the funding agency.

Expedited review can result in full approval and non-approval.

Categories of Research That May be Reviewed by the IRB through an Expedited Review Procedure¹

(Cited from Office for [Human Research Protections \(OHRP\)](#) – Categories of Research)

Applicability

- A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. 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.

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

¹An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

- C. 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 in terms of 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.
- D. The expedited review procedure may not be used for government-designated classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review --expedited or convened-- utilized by the IRB.
- F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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 labelling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venepuncture as follows:
 - a) From healthy, non-pregnant adults who weigh at least 110 pounds (50kg). 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 children², 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.

Note: Blood samples in excess of 50 ml should be collected in the presence of a physician, nurse or a First Aider in a clinical setting. Blood samples in excess of 200 ml should be drawn only after a prior haemoglobin estimation. Sample in excess of 200 ml should not be drawn if the haemoglobin is less than 13.0gm/dL in males and less than 12.0gm/dL in females.

²Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

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 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.

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.

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. 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.)

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.
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.

The following examples fairly illustrate common forms of research activities that would qualify for expedited review under one or more of these categories:

- A study in which undergraduate students view a video about economic theory and then respond to computer-simulated scenarios about individual spending decisions.
- A field study using interview and participant observation to study the interrelationship between family life and involvement in religious activities.
- A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers.
- A longitudinal study involving surveys of people's background characteristics, political beliefs, and voting behavior.
- A study of people's ability to identify accurately the perpetrators of staged thefts.
- A study of prison administration records to study the relationship between inmates' individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development (GED) credential.
- A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group.

Reference:

OHRP 45 CFR 46.110

63 FR 60364-60367, November 9, 1998

<http://www.hhs.gov/ohrp/policy/63fr60364.html>