Eligibility for Expedited Review of US Federally-funded Research — Pointers for Researchers

The HREC may use an expedited procedure for an initial review, a continuing review or a review of amendments if the request meets Common Rule criteria described below. All expedited protocols must be reviewed at least once annually.

1. Initial Review

Protocols may be reviewed using an expedited review process if they meet the following criteria [45 CFR 46.110(b)(1)]:

1. Research poses no more than minimal risk to subjects; AND
2. Research for which each of the procedures falls within one the following expedited review categories outlined by the Office for Human Research Protections (OHRP) [45 CFR 46.110] and the Food and Drug Administration (FDA) [21 CFR 56.110]:

**Expedited Categories 1-7**

* Category 1

Clinical studies of drugs and medical devices only under the following conditions:

1. Research on drugs for which an investigational new drug application (21 CFR 312) is not required, but only if the research does not significantly increase the risks, or decrease the acceptability of the risks, associated with the use of the product.
2. Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required, or (ii) the medical device is cleared or approved for marketing and the medical device will be used according to its cleared or approved labelling.

* Category 2

Collection of blood samples by finger prick, heel stick, ear stick or venipuncture as follows:

1. From healthy, non-pregnant adults who weigh at least 50 kg. Amounts drawn may not exceed 550 ml in an eight week period and collection may not occur more frequently than two times per week; or
2. From other adults and children, considering age, weight and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight-week period and may not occur more than two times per week.

* Category 3

Prospective collection of biological specimens for research purposes by non-invasive means. Examples:

* Hair and nail clippings in a non-disfiguring manner.
* Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.
* Excreta and external secretions, including sweat.
* Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue.
* Placenta removed at delivery.
* Amniotic fluid obtained at the time of rupture of the membrane prior to or during labour.
* 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 according to accepted prophylactic techniques.
* Mucosal or skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
* Sputum collected after saline mist nebulisation.
* Category 4

Collection of data through non-invasive procedures (that do not involve general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures that involve X-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing. Examples:

1. 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 participant or an invasion of the participant’s privacy.
2. Weighing or testing sensory acuity.
3. Magnetic resonance imaging.
4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given 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 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 behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research that employs survey, interview, oral history, focus group, programme evaluation, human factors evaluation, or quality assurance methodologies.

2. Continuing Review

Protocols may be reviewed using an expedited review process if they meet one of the following criteria:

1. Continuing research activities pose no more than minimal risk to subjects AND research met the criteria for initial expedited review AND all procedures continue to meet one of the expedited review categories 1-7 above.
2. Research which was previously reviewed by the convened HREC but meets one of the following categories for expedited review as defined by the OHRP and the FDA:

* Category 8

1. The research is (i) permanently closed to the enrolment of new participants, and (ii) all participants have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of participants; or
2. No subjects have been enrolled and no additional risks have been identified; or
3. The remaining research activities are limited to data analysis.

* Category 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 HREC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Amendments to an Approved Protocol

1. The HREC may use an expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized [45 CFR 46.110(b)92)].
2. Amendments (modifications) to protocols previously approved by a convened HREC may be reviewed using an expedited review process if they meet the following criteria:
   1. Amendments do not pose an increased risk to subjects; AND
   2. Amendments constitute a minor change to previously approved research.
   3. All added procedures fall within categories 1-7 of research that may be approved using an expedited procedure (see above).
3. Amendments to protocols previously approved by an expedited review procedure may be expedited if they meet the following criteria:
4. With the modifications, the research continues to pose no more than minimal risk to subjects.
5. The modifications do not involve any procedures that do not meet expedited categories 1-7 above.

4. Examples of minor and substantial modifications are provided below:

Minor modifications

* A change that would not materially affect the assessment of risks and benefits in the study.
* A change that does not substantially affect the study’s aims or design.
* An increase or decrease in sample size, supported by a statistical justification.
* Administrative changes such as contact details, addition or removal of key personnel and/ or study sites.
* Narrowing the range of inclusion criteria.
* Broadening the range of exclusion criteria.
* Alterations in oral forms of administration of a drug e.g. tablet to capsule or liquid, as long as the dose remains constant.
* Changing data collection points or amounts of data collected as long as it does not alter safety evaluations.
* An increase in safety monitoring resulting in more frequent visits or an increase in the length of hospitalisation.
* Changes in compensation with adequate justification.
* Editorial changes that clarify but do not alter the existing meaning of a document.
* Translations of materials already reviewed and approved by the HREC.

Substantial modifications

* Broadening the range of inclusion criteria
* Narrowing the range of exclusion criteria.
* Alterations in the dosage or route of administration of a study drug.
* Significantly extending the duration of a study.
* Removal of laboratory tests, monitoring procedures or study visits directed at gathering safety information.
* Appearance of new, serious unexpected adverse events or significant risks.
* New study documents to be distributed to or seen by participants that include information or questions substantively different from materials already approved by the HREC.