HUMAN RESEARCH PROTECTION

Criteria for expedited IRB review

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Resource type GUIDANCE

This document may be used by researchers to consider expedited human research categories and criteria prior to IRB submissions.

The IRB, not the researcher, is responsible for determining whether research qualifies for expedited review. The Human Research Protection Office (HRPO) staff assess eligibility for expedited review as part of the IRB pre-review process. (Research that is not eligible for exemption or expedited review must be reviewed by the convened IRB.)

All requests for expedited IRB review must be submitted via the online IRB submission system, Cayuse HE.

Visit the HRPO website for additional information: https://www.hhrinstitute.org/researcher-resources/ohsr/

A. Basic eligibility criteria

ALL of the following must be met

1 The research activities present no more than minimal risk to human subjects.

2 Identification of human subjects or their responses will NOT reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing; reasonable and appropriate protections must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

3 The research is not classified.

4 The research fits within in one or more of the federally-defined expedited categories in Section B.

B. Expedited review categories **OHRP Expedited Review Categories (1998)**

The research is categorized fully as one or more of the following:

1a Clinical studies of drugs for which an IND is not required.

1b Clinical studies of medical devices for which an IDE is not required, or in which medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2a Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture[i] from healthy, non-pregnant adults who weigh >110 pounds, where the amount drawn is <550 ml/8-week period and collection occurs at most 2 times/week[ii].

2b Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture[iii] from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (at most 50 ml or 3 ml/kg/8 week period), and the frequency with which it will be collected (at most 2 times/week[iv].)

3 Prospective collection of biological specimens for research purposes by noninvasive[v] means.[vi]

Examples: tissues and fluids that the body produces continuously or sheds as a normal process, which are collected in a non-disfiguring manner, tissues and fluids if routine patient care indicates a need for removal or extraction, dental plaque and calculus, tissues from non-facial, non-genital skin punch biopsies in adults that do not require sutures, specimens collected in adults by curettage, urethral, vaginal or rectal swabs, and specimens collected from the external auditory canal or nares.[vii]

4 Collection of data through noninvasive[v] 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.

Examples: physical sensors that are applied either to the surface of the body or at a distance and do not involves input of significant amounts of energy into the subject or an invasion of the subject's privacy; weight or testing sensory acuity; magnetic resonance imaging, excluding MRI with contrast dye; electrocardiography, electroencephalography, thermograph, detection of naturally occurring radioactivity; electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; moderate exercise, muscle 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 for any purpose, or will be collected solely for non-research purposes.

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

7	Research or individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. **Examples:** Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
8a	Continuing review of research previously approved by the convened IRB 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[viii]. Note: For a multi-center protocol, an expedited review procedure may be used by the IRB for a particular site whenever these conditions are satisfied for that site.
8b	Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source[ix]. Note: Studies under the 2018 Rule that meet this criteria still require continuing review. [x]
8c	Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. Note: For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.
9	Continuing review of research that meets all of the following criteria: 1) is NOT conducted under an investigational new drug application or investigational device exemption; 2) does NOT fit into expedited categories 2-8; 3) is NO GREATER than minimal risk as documented and determined by the IRB at a convened meeting; and 4) for which the IRB has not identified any additional risks.[xi] NOTE: Studies under the 2018 Rule that meet this criteria still require continuing review.[x]
	For Humanitarian Use Device (HUD) submissions ONLY: Continuing review of the use of an HUD when the device is used solely for clinical purposes. FDA guidance: HDE Program

[i] Withdrawal of blood from an indwelling venous line is a "venipuncture."

[ii] Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure. Blood draw amount is based on the blood drawn for research purposes and is separate from the standard of care draws.

[iii] Withdrawal of blood from an indwelling venous line is a "venipuncture." Blood draw amount is based on the blood drawn for research purposes and is separate from the standard of care draws.

[iv] Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

[v] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

[vi] 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.

[vii] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2013-may-20-letter-attachment-a/index.html

[viii] Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

[ix] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). *Per correspondence with OHRP dated December 2018.*

[x] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html

[xi] Ibid. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html