



WORKSHEET: Eligibility for Review Using the Expedited Procedure

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The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. This worksheet is to be used. It does not need to be completed or retained.

☐ **Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedureⁱ**

Initial or continuing review must meet criteria set 2. Modifications can meet either criteria set 1 or 2.

1 Minor Modifications (Check if "Yes" or "N/A". All must be checked)

- ☐ The modifications do not affect the design of the research.
- ☐ The modifications add no more than Minimal Risk to subjects.
- ☐ All added procedures fall into categories (1)-(7) below. ("N/A" if no added procedures)

2 Initial Review, Continuing Review, or Modifications (Check if "Yes" or "N/A". All must be checked)

- ☐ The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. ("N/A" if the research falls into category (8)(b))
- ☐ Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to the their 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 Risk. ("N/A" if the research falls into category (8)(b))
- ☐ The research is **NOT** classifiedⁱ
- ☐ The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)**
 - ☐ (1)(a) Clinical studies of drugs when an IND is not required.
 - ☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
 - ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipunctureⁱⁱⁱ 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^{iv}.
 - ☐ (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture^v 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^{vi}.)
 - ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive^{vii} means.^{viii}
 - ☐ (4) Collection of data through noninvasive procedures^{ix} (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.^x
 - ☐ (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 on individual or group characteristics or behavior^{xi} or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
 - ☐ (8)(a) 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^{xii}. (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.)
 - ☐ (8)(b) 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.
 - ☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (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, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (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.

ⁱ Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers Document issued on: July 8, 2010 states "46. What types of review functions are IRBs responsible for with respect to HUDs? IRBs are responsible for initial as well as continuing review of the HUD. For initial review of a HUD, IRBs are required to perform their review at a convened meeting (21 CFR 56.108). For continuing review, IRBs may use the expedited review procedures (21 CFR 56.110)."



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- ⁱⁱ Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, "Classified National Security Information," December 29, 2009
- ⁱⁱⁱ Withdrawal of blood from an indwelling venous line is a "venipuncture."
- ^{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 Withdrawal of blood from an indwelling venous line is a "venipuncture."
- ^{vi} 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.
- ^{vii} 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.
- ^{viii} 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.
- ^{ix} 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.
- ^x 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.
- ^{xi} Examples: 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.
- ^{xii} 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.