



Determining Eligibility for Expedited Review for Initial Approval

This worksheet is intended to provide support for individuals in determining whether a proposed research protocol is eligible for initial approval using expedited review. This worksheet is not meant to be completed or retained on record.

Categories for Expedited Review

In order to be eligible for initial approval by expedited review procedures **all** proposed activities must fit into one or more of the following [Expedited Review Categories](#).

1. Research is a clinical study of drugs or devices that meets the following criteria (answer "Yes" if either a) or b) is "Yes") Yes No

a) Research is on a drug or drugs for which an investigational new drug application is **not** required (see: [21 CFR 312](#)) **and** research does not significantly increase the risks or decrease the acceptability of the risks associated with the use of the drug(s) Yes No

OR

b) Research is on medical devices for which an investigational device exemption application is **not** required (see: [21 CFR 812](#)) **or** the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling. Yes No

2. Research involves collection of blood samples by finger stick, heel stick, ear stick, or venipuncture and the conditions under either a) or b) are met: Yes No

a) Blood will be drawn from adults who meet ALL the following criteria: Yes No
i) Patient is healthy
ii) Patient is non-pregnant
iii) Patients are over 110 lbs
iv) Blood drawn will not exceed 550 ml in an 8 week period
v) Collection will not occur more than 2 times per week

OR

b) Blood will be drawn from children or adults who do not meet the above criteria but meet ALL the following criteria: Yes No
i) Collection procedure, amount drawn and frequency, take into account the age, weight, and health of the subjects
ii) The amount drawn will not exceed the lesser of 50 ml or 3 ml blood/kg patient weight in an 8 week period
iii) Collection may not occur more frequently than 2 times per week

3. Collection of biological specimens for research purposes is prospective and by noninvasive means*. Yes No

*Examples include but are not limited to: collecting hair and nail clippings; collecting external secretions (including sweat); uncannulated saliva stimulated by chewing wax; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; mucosal and skin cells collected by cheek scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

4. Collection of data is through noninvasive procedures** which meet all the following criteria (to answer "Yes" to item 4, a "Yes" answer is required for **all** the following): Yes No

a. Procedures are routinely employed in medical practice Yes No

b. Procedures do NOT involve the use of X-rays or Microwaves Yes No

c. Any medical devices used are approved for marketing Yes No

** 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



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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 only involves materials (i.e. data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) and research is not otherwise exempt under [45 CFR 46.101\(b\)\(4\)](#). ([Expedited Review Categories](#)) Yes No
- 6. Study involves collection of data from voice, video, digital, or image recordings made for research purposes. ([Expedited Review Categories](#)) Yes No
- 7. Research is on individual or group characteristics (e.g. perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or employs survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies and is not otherwise exempt under [45 CFR 46.101\(b\)\(2\)](#) or [\(b\)\(3\)](#). ([Expedited Review Categories](#)) Yes No

- 8. Do **all** the proposed activities fit into one or more of the previous categories? (*If answered "Yes" proceed to next section. If No, project must be reviewed by full board.*) Yes No

Conditions that make research ineligible from being considered for Expedited review

- 9. Are any research activities **greater than minimal risk**?* ([45 CFR 46.110b](#)) Yes No
 - a. *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 ([45 CFR 46.102\(i\)](#)).

* Note that the final determination of minimal risk must be made by the reviewer during the expedited review process ([45 CFR 46.110b](#)). This question serves as a prescreening only, not an official determination of minimal risk.

- 10. Is research classified? ([Expedited Review Categories](#)) Yes No
- 11. Could identification of subjects put subjects at risk of criminal or civil liability or be socially or economically damaging? ([Expedited Review Categories](#)) Yes No
 - a. If Yes, have measures been put in place to make this risk minimal? Yes No
- 12. Is this a clinical study involving randomization? Yes No

If answered Yes to questions 9, 10, or 12 then research cannot be approved under expedited procedures regardless of above categorization. A Yes on Question 11 means research can only be approved using expedited procedures if 11a is also answered Yes.

- 13. Is research ineligible for Expedited Review based on above conditions? (*If answered Yes, project must be reviewed by full board.*) Yes No

If answered "Yes" to item #8 and "No" to item #13, the new protocol can be reviewed under expedited review procedures. Otherwise, the protocol should be reviewed by the fully convened board.