

# Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure <sup>1</sup>

## *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 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 merely means that the activity is eligible for review through the expedited review procedure when the specific 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.

(C) The expedited review procedure may not be used where identification of the subjects and/or their response place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply to 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 for marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with 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 labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts of blood to be collected 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 children<sup>2</sup>, considering the age, weight, and health of the subjects, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount of blood to be collected 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.



- (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 investigation where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a continuing review that the research involves no greater than minimal risk and no additional risks have been identified.

<sup>1</sup> An expedited review procedure consists of a review of research involving human subjects by the IRB 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**.

<sup>2</sup> Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research is conducted." **CFR 46.402(a)**.

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