Expedited Review Categories

Expedited review procedures may be used when ALL of the following criteria are true:

- The research activities present no more than minimal risk to human subjects
- Identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' 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.
- The research is not classified.
- The research falls into one or more of the following 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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of 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 drawn 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, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn 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.

(3) **Prospective collection of biological specimens** for research purposes by noninvasive means.

(4) **Collection of data through noninvasive 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

(5) **Research involving** materials (**data, documents, records, or specimens**) that have been collected or will be collected **solely for nonresearch purposes** (such as medical treatment or diagnosis).

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

(7) **Research on individual or group characteristics** or behavior (including, but not limited to, 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**

(8) **Continuing review** of research previously approved by the convened IRB as follows:

(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 investigational device exemption where categories two (2) through eight (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.