

Research can be reviewed as ***EXPEDITED*** only if activities involving human subjects do not involve more than "minimal risk" and are in one of the following nine federally designated ***EXPEDITED*** categories. 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.*"

- (1) Clinical studies on drugs or medical devices for which an investigational new drug (IND) application or investigational device exemption (IDE) is not required.

Example: A study that uses a cleared medical device in accordance with its approved labeling.

- (2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Example: Hair and nail clippings in a non-disfiguring manner.

- (4) Collection of data through noninvasive procedures routinely employed in clinical practice provided where:
  - The procedure does not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves; or
  - The medical devices employed are cleared/approved for marketing.

Example: Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight, and health of the individual(s).

- (5) Research involving data, documents, records or specimens that have been collected or will be collected solely for non-research purposes.

Example: Medical treatment or diagnosis information.

- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

Example: Performing historical research of an event by bringing together people who were involved or have knowledge of the event to ask questions and record their responses for use.

#### **For continuing research projects only:**

- (8) Review of research previously approved by the full/convened IRB where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects; no subjects have been enrolled and no additional risks have been identified; or the remaining research activities are limited to data analysis.
- (9) Review of research not conducted under an IND application or IDE, and where categories two through eight do not apply, but the IRB has determined and documented that the research involves no greater than minimal risk and no additional risks have been identified.

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Research that will require ***FULL BOARD*** review involves "possible risk" to human subjects.

Example: Drug or medical device trials, surgical or other invasive procedures, surveys or questionnaires that involve children or impaired populations, and any population of subject not covered under either *Exempt* or *Expedited* categories.