

# IRB Categories of Review

## Exempt Categories:

### **Category 1: Educational Research**

45 CFR 46.104(d)(1): Research involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction:

- i. Most research on regular and special education instructional strategies
- ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.

### **Category 2: Educational Tests, Surveys, Interviews, or Observations**

45 CFR 46.104 (d)(2): Research that only includes interaction involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording):

- i. Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects
- ii. Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation or;
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

### **Category 3: Benign Behavioral Interventions**

45 CFR 46.104(d)(3): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

#### **Category 4: Secondary Research of Identifiable Private Information or Biospecimens**

45 CFR 46.104(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens:

- i. The identifiable private information or identifiable biospecimens are publically available
- ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects
- iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 164, Subparts A and E (HIPAA), for the purposes of "health care operations" or "research" as those terms are defined under HIPAA or for "public health activities and purposes" under HIPAA
- iv. The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities

#### **Category 5: Federally Supported Research for Public Benefit or Service Programs**

45 CFR 46.104(d)(5): Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- i. Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs:" ◊ The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act); ◊ The research or demonstration project must be conducted pursuant to specific Federal statutory authority; ◊ There must be no statutory requirements that the project be reviewed by an IRB; and ◊ The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- ii. Procedures for obtaining benefits or services under those programs;
- iii. Possible changes in or alternatives to those programs or procedures; or
- iv. Possible changes in methods or levels of payment for benefits or services under those programs.
- v. This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

## **Category 6: Taste and Food Quality Evaluations**

45 CFR 46.104(d)(6): Taste and food quality evaluation and consumer acceptance studies:

- i. Wholesome foods without additives are consumed
- ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

## **Expedited Categories:**

**Category 1:** 45 CFR 46.110 (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.
- 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.

**Category 2:** 45 CFR 46.110 (2): Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

**Category 3:** 45 CFR 46.110 (3): Prospective collection of biological specimens for research purposes by noninvasive means.

**Category 4:** 45 CFR 46.110 (4): Collection of data through noninvasive procedures (not involving general anesthesia or sedation)

**Category 5:** 45 CFR 46.110 (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).

**Category 6:** 45 CFR 46.110 (6): Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 7:** 45 CFR 46.110 (7): Research on individual or group characteristics or behavior

**Category 8:** 45 CFR 46.110 (8a): Continuing review of research previously approved by the convened IRB as follows: Where (a) 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

45 CFR 46.110 (8b): Where no subjects have been enrolled and no additional risks have been identified

45 CFR 46.110 (8c): Where the remaining research activities are limited to data analysis.

**Category 9:** 45 CFR 46.110 (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.

## **Full Board:**

Proposed human subject's research which does not fall into either the exempt or expedited categories must be submitted for full committee review.