Categories of Review

Exempt Research

Exempt Category 1
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

1. Research on regular and special education instructional strategies.
2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

*Note: This category may be applied to research involving children*

Exempt Category 2
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
2. Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

*Note: Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review.*

Exempt Category 3
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

1. The human subjects are elected or appointed public officials or candidates for public office.
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exempt Category 4
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

*Examples: Existing Data Records Review, Pathological Specimens*

Exempt Category 5
Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

1. Public benefit or service programs.
2. Procedures for obtaining benefits or services under those programs.
3. Possible changes in or alternatives to those programs or procedures.
4. Possible changes in methods or levels of payment for benefits or services under those programs.

Exempt Category 6
Taste and food quality evaluation and consumer acceptance studies:

1. If wholesome foods without additives are consumed.
2. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level fund 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 US Department of Agriculture.

*Note: This category may be applied to research involving children.*
Categories of Review, continued

**Expedited Review**

**Expedited Category 1**
Clinical studies of drugs and medical devices only when
- Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required; or
- Research on medical devices for which (i) an investigational device exemption application (21 CR 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.

**Expedited Category 2**
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture 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
- Other adults considering the age, weight, and health of the subjects, the collection procedures, the amount of blood to be collected, and 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.

**Expedited Category 3**
Prospective collection of biological specimens for research purposes by noninvasive means.

**Expedited Category 4**
Collection of data on subjects 18 years of age or older through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves as well as procedures involving general anesthesia or sedation. Where medical devices are employed, they must be cleared/approved for marketing.

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

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

**Expedited Category 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.

**Expedited Category 8**
Continuing review of research previously approved by the entire IRB as follows:
- 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; or
- Where no subjects have been enrolled and no additional risks have been identified; or
- Where the remaining research activities are limited to data analysis.

**Expedited Category 9**
Continuing review of research in which 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 Committee Review**
Projects that involve more than minimal risk, prisoners, or those that do not fit into one or more of the categories for expedited review or exempt status must be reviewed by the full board at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific.