Expedited and Exempt Review Categories

Expedited Review Categories (Federal Policy 46.110)

RESEARCH IN THE FOLLOWING (MINIMAL RISK) CATEGORIES ARE ELIGIBLE FOR APPROVAL ON THE BASIS OF A REVIEW BY THE IRB CHAIR AND SELECTED IRB MEMBERS.

If applicable, mark this category description for which your research project qualifies on page 1 of the IRB application form.

1. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., X-rays and microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8-week period and no more than two times a week, from subjects 18 years of age or older and who are not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigation of speech defects.

7. Moderate exercise by health volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens (e.g. where identifiers could link data to particular subjects).

9. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Exempt Review Categories (Federal Policy 46.101b)

THE FOLLOWING CATEGORIES ARE EXEMPT FROM FULL IRB REVIEW, BUT MUST BE REVIEWED BY THE CHAIR OF THE IRB.

If applicable, mark this category description for which your research project qualifies on page 1 of the IRB application form.

1. INSTRUCTIONAL STRATEGIES IN EDUCATIONAL SETTINGS

Research conducted in established or commonly accepted educational settings are exempt from full IRB review if they involve normal educational practices such as:

a) Research on regular and special educational instructional strategies, or

b) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

[This category may be applied to research involving children. All other research on children requires full review.]

2. SURVEYS/INTERVIEWS; STANDARDIZED EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, are exempt from full IRB review if:

a) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, and

b) Disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

- Surveys or interviews on sensitive or personal topics, which may cause stress to study participants are not exempt from IRB review.
- Surveys or interviews with children are not exempt.

3. PUBLIC OFFICIALS; SURVEYS/INTERVIEWS; EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR

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

a) The human subjects are elected officials or candidates for public office; or

b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. EXISTING DATA; RECORDS REVIEW; PATHOLOGICAL SPECIMENS

Research involving the collection or study of existing data, documents, records, pathological specimens are exempt from full IRB review, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

- [Records considered private based on federal and state statute, including medical records and education records, require written release by the study subject or by the custodian of the record. Researchers are cautioned that review of private records involving access to and/or recording of identifiable information are not exempt from IRB review and requires written consent of the study subject. Existing public records do not require prior consent of subjects to review the records.]

- [Pathological or diagnostic specimens which are considered waste and are destined to be destroyed can be used in research and are considered exempt from IRB review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. (If either of these conditions applies, consent of the research subject is required, and a higher level of IRB review is required.) Specimens retrieved as extra during a clinical procedure require review at a higher level and require written consent from the subject.]

- [Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation.]

5. PUBLIC SERVICE PROGRAMS; DEMONSTRATION PROJECTS

Research and demonstration projects are exempt from full IRB review if they are conducted by, or subject to, the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine:

a) Public benefit or service programs;

b) Procedures for obtaining benefits or services under those programs;

c) Possible changes in, or alternatives to, those programs or procedures; or

d) Possible changes in the methods or levels of payment for benefits or services under those programs.

6. TASTE TESTING AND FOOD QUALITY EVALUATION

Taste and food quality evaluation and consumer acceptance studies:

a) If wholesome foods without additives are consumed (all food tested must be GRAS, or Generally Recognized As Safe); or

b) 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 Inspection Service or the U.S. Department of Agriculture.

[This category may be applied to research involving children; however, written parental consent to include children in taste testing studies is required.]