

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 005
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.110

SUBJECT: Expedited Review

1. Federal regulations have established a list of categories of research that may be reviewed by the IRB through an expedited review procedure.
2. At FSU, the expedited review procedure consists of a review of research involving human subjects by the IRB Committee Chairperson and two of the more experienced reviewers designated by the Chair or IRB Secretary from among the members of the IRB. In reviewing the research, the reviewer may exercise all of the authorities of the IRB, except that the reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedures set forth in 45 CFR 46.108(b). All expedited protocols must be continually reviewed at least annually by the IRB. The standard requirements for informed consent (or its waiver, alteration, or exception) apply to all IRB approvals regardless of the type of review utilized by the IRB. The reviewer may refer the application to the full committee for review as warranted.
3. Appropriate Use of Expedited Review Procedures. Use of expedited review by the IRB must be restricted to those applications that fulfill one of the following categories listed in paragraph numbered 4 below. The categories on the list apply regardless of the age of subjects, except as otherwise noted.
 - a) Minimal Risk. Research activities that present no more than minimal risk to human subjects AND involve only the procedures listed in one or more of the specific categories (see paragraph 4 below) may be reviewed by the IRB via the expedited review procedure.
 - 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.
 - An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

- The categories in paragraph 4 below should not be deemed to be of minimal risk simply because they are included on the list.
 - Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- b) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's 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 were no greater than minimal.
4. Categories of Research Eligible for Expedited Review. The following expedited categories pertain to both initial and continuing IRB review:
- a) Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.
 - b) 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.
 - c) Recording of data from subjects 18 years of age or older using noninvasive 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 (for example, x-rays, microwaves).
 - d) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
 - e) 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.
 - f) Voice recordings made for research purposes such as investigations of speech defects.
 - g) Moderate exercise by healthy volunteers.

- h) The study of existing data, documents, records, pathological or diagnostic specimens.
 - i) Research on individual or group behavior or characteristics of individuals, such as studies on perception, cognition, game theory, or test development, where the research investigator does not manipulate subject's behavior and the research will not involve stress to subjects.
 - j) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
 - k) Any other category specifically added to this list by DHHS and published in the Federal Register.
5. In conducting the expedited review, the designated reviewers must examine materials in sufficient detail to make the following determinations required under federal regulation and IRB Policy.
- a) Risks to subjects must be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b) Risks to subjects shall be reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the reviewers should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research. The reviewers should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c) The selection of subjects must be equitable. In making this assessment, the reviewers should consider the purposes of the research and the setting in which the research will be conducted, and be cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - d) Informed consent must be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulation and institutional policies.
 - e) Informed consent shall be appropriately documented pursuant to federal regulation and institutional policies.
 - f) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - g) When appropriate, there are adequate controls to protect the privacy of subjects and to maintain the confidentiality of data.
 - h) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally

disabled persons, the IRB reviewers must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6. The materials to be provided to the Chairperson and designated reviewers shall be as follows:
 - a) Completed IRB application with appropriate signatures.
 - b) Full investigator's or sponsor's protocol.
 - c) Proposed informed consent document(s) and /or script as appropriate.
 - d) Copies of surveys, questionnaires, or videotapes.
 - e) Copies of letter of assurance or cooperation with research sites.
 - f) Relevant grant applications.
 - g) Investigator's brochure.
 - h) Advertising/recruitment flyers intended to be seen or heard by potential subjects, including email solicitations.
7. The primary reviewers and the Chairperson reviewing the application shall determine a review interval for the research as appropriate to the degree of risk but not more than annually. The primary reviewers and/or Chairperson may decide to request full Committee review of a project.
8. A detailed listing of all projects reviewed and approved by Expedited Review must be provided to all committee members at the next convened full committee meeting. The documentation must include a citation to the specific permissible category or categories justifying the expedited review.