

## **KEY DEFINITIONS (See 45 CFR 46.102.)**

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

**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.

**IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

## **KEY CRITERIA FOR IRB APPROVAL (See 45 CFR 46.111.)**

The IRB shall determine that all of the following requirements are satisfied in order to approve the research application.

- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (ii) whenever appropriate, by using procedures already performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to the subjects must be reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result.
- (3) Selection of subjects must be "equitable."
- (4) Informed consent must be obtained from each prospective subject or a legally authorized representative, (except in specified limited circumstances where waivers may be granted).
- (5) Informed consent must be appropriately documented.
- (6) Where appropriate, there must be adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.
- (7) Where subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards must be included to protect the rights and welfare of subjects. Such subjects include children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

In addition, the IRB has an institutional responsibility to flag institutional administrative issues and to coordinate its review process with other necessary administrative or legal reviews, where institutional interests are involved.

## **GENERAL REQUIREMENTS FOR INFORMED CONSENT (See 45 CFR 46.116.)**

The following information shall be provided to each subject in seeking informed consent. Information should be presented in a language understandable to the subject. The form must be on Boston University letterhead, numbered, with the title of the study, the P.I.'s name, telephone number, and date at the top of each page. A statement should be included indicating the subject will receive a copy of the form. Please note this represents the minimum information to be given a potential subject; the Board may request that additional information be provided. The IRB may waive the requirements to obtain informed consent in some circumstances. If a waiver of any requirement for informed consent is requested, please consult with the Coordinator for the Board.

- (1) A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. (See 45 CFR 46.116 [a] [1].)
- (2) A description of any reasonably foreseeable risks or discomforts to the subject. (See 45 CFR 46.116 [a] [2].)
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research. (See 45 CFR 46.116 [a] [3].)
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. (See 45 CFR 46.116 [a] [4].)
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. (See 45 CFR 46.116 [a] [5].)

The subject should be made aware of who is expected to have access to information which can identify the subject. If assurances are made that research information will be treated confidentially, it is advisable to indicate that confidential information will not be disclosed "unless required by law or regulation." This is advisable because, under many circumstances, the disclosure of research data can be lawfully compelled by subpoena, and it is important not to promise confidential protection where it cannot be guaranteed. The foregoing exception is particularly important to include in consent forms where the disclosure of the research information could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

### Sample Paragraphs

All information will be held in strict confidence and may not be disclosed unless required by law or regulation. Any reports or publications will not identify individual participants by name or initials. Because this study is using an investigational device, the study records may be examined, in confidence, by representatives of the Food and Drug Administration and the device manufacturer.

The interview and questionnaire data will be treated confidentially and may not be disclosed, unless required by law or regulation. Interview and questionnaire data will be stored in locked files and destroyed at the end of the research. Results will be published only in aggregated form (for example, tables of information).

- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. (See 45 CFR 46.116 [a] [6].) The following is a standard paragraph developed by the IRB in consultation with University legal counsel:

## General Requirements for Informed Consent (continued)

### Standard Paragraph

I understand that in the event injury occurs resulting from the research procedures, medical treatment will be available at area hospitals. [For Boston University students who are research subjects, treatment will be available at the Boston University Student Health Service (881 Commonwealth Avenue).] However, no special provision will be made for compensation or for payment for treatment solely because of my participation in this experiment. I understand that this paragraph is a statement of Boston University's policy and does not waive any of my legal rights.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject. (See 45 CFR 46.116 [a] [7].) The following is a standard paragraph developed by the IRB in consultation with University legal counsel:

### Standard Paragraph

If you have any questions regarding the research or your participation in it, either now or any time in the future, please feel free to ask them. The research team, particularly \_\_\_\_\_, who may be reached at \_\_\_\_\_, will be happy to answer any questions you may have. You may obtain further information about your rights as a research subject by calling \_\_\_\_\_, who is the Coordinator of the Institutional Review Board for Human Subject Research of the Boston University Charles River Campus, at 617/353-4365. If any problems arise as a result of your participation in this study, including research-related injuries, please call the Principal Investigator, \_\_\_\_\_, at \_\_\_\_\_, immediately.

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (See 45 CFR 46.116 [a] [8].)

## APPENDIX A

### Categories of Research Exempt From Further Institutional Review Board Review (See 45 CFR 46.101 [b].)

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and
  - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (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) if:
  - i) the human subjects are elected or appointed public officials or candidates for public office; or,
  - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (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.
- (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:
  - (i) public benefit or service programs;
  - (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.

**N.B. Exemption number 2 for research involving survey or interview procedures or observations of public behavior does not apply to research involving minors, except for research involving observation of public behavior when the investigator(s) does not participate in the activities being observed.**

**Research activities involving fetuses, pregnant women, human in vitro fertilization, prisoners, or children as subjects are subject to special regulations. Please contact the Coordinator for the Board for additional information.**

## APPENDIX B

### Categories of Research That May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure<sup>1</sup>. (See 45 CFR 46.110 and 63 FR 60364.)

#### Applicability

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this 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 categories in this list apply regardless of the age of subjects, except as noted.
- (C) 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 are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (F) Research Categories Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
  - (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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    - (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.
  - (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    - (a) 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
    - (b) from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the

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<sup>1</sup> An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

<sup>2</sup> Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

## Appendix B: Expedited Review Categories (continued)

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.

- (3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
  - (a) where (i) the research is permanently closed to the enrollment of new subjects;
  - (ii) all subjects have completed all research-related interventions;

## **Appendix B: Expedited Review Categories (continued)**

- and (iii) the research remains active only for long-term follow-up of subjects; or
  - (b) where no subjects have been enrolled and no additional risks have been identified; or
  - (c) where the remaining research activities are limited to data analysis.
- (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.