

## **Institutional Review Categories**

### **Exempt Review Categories (45 CFR 46.101 (b))**

Projects can be approved by a single authorized reviewer. A copy of the review form along with consent forms, questionnaires, etc. and any supporting documentation for review by the chairperson or a designated member of the IRB

1. Conducted in established or commonly accepted educational settings that involve normal educational practices.
2. Involving the use of educational tests, survey or interview procedures or observation of public behavior. No exemption available if: 1) minors are involved in the survey or interview procedures; 2) minors are involved in observation of public behavior and the observers participate in the activities observed.
3. Involving use of educational tests, survey or interview procedures or observation of public behavior that is not exempt under paragraph 2.
4. Study of existing data, documents, records, or specimens.
5. Conducted by a subject to approval of HHS and involving certain public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

### **Expedited Review Categories**

1. Clinical study 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.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
  - From healthy, nonpregnant adults who weigh at 100 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;
  - 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 frequency with which it will be collected. For these subjects, the amount drawn may not exceed 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:

  - hair and nail clippings in a nondisfiguring manner;

- deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - permanent teeth if patient care indicates the need for extraction;
  - excreta and external secretions (including sweat);
  - uncannulated saliva collected either in an unstimulated fashion or stimulated fashion by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - placenta removed at delivery;
  - amniotic fluid obtained at the time of rupture of membrane prior to or during labor;
  - supra- and subgingival 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;
  - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
  - sputum collected after saline list nebulization.
4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Examples:
- 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;
  - Weighing or testing sensory acuity;
  - Magnetic resonance imaging;
  - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, dopple blood flow, and endocardiography.
  - 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, specimens) collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from HHS regulations for the protection of human subjects – 45 CFR 46.101(b)(4)
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.
8. Continuing review of research previously approved by the convened IRB.
- where (i) 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; or

- where no subjects have been enrolled and no additional risks have been identified; or
  - where the remaining research activities have been identified.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 do not apply but the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified.
- <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).  
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### **Full Review Category**

Projects with a physical risk or potential for injury or harm to the subject’s dignity or well being require a FULL review before the entire institutional Review Board.

## **Guidelines for Clinical-Research Protocols**

Many researchers are uncertain about how much information or what kinds of information they need to provide when they describe their protocols for clinical research. The following outline is offered as a guideline for clinical research proposals. The information you provide must address all the topics listed below that are relevant to your particular research design.

1. Introduction and background information: Why are you undertaking this research?
2. Objectives (specific aims) of the study: Explain the specific hypotheses you plan to test or the specific questions you hope to answer.
3. Selection of participants:
  - a) How many individuals will participate, of what ages?
  - b) What are your criteria for selecting participants and for excluding people from the study?
  - c) From where will the participants be recruited? If they will be patients, how will you find them?
  - d) How will participants be invited to participate in the study, and by whom?
  - e) How long will the participants be recruited? (Are there plans to replace or add participants after the study is underway?)
  - f) Are you taking any precautions so that participants will not feel coerced or pressured to participate in the study?
  - g) Will participants receive any inducements to participate, such as payments, services without charge, course credits, etc? If so, explain the amounts and reasons for inducements.
4. Procedures for obtaining informed consent or participants: Summarize your methods briefly and provide a copy of your consent statement with the Human Subjects Review form.
5. Procedures for treatment, examination, intervention or experimentation:
  - a) Where will the research procedures be carried out?
  - b) Who will carry out the research procedures, and what are their qualifications for doing so?
  - c) Briefly describe the procedures and techniques that will be used with the participants, in sequence.
    - Indicate how long and how frequently the procedures and techniques will be used, and any pretesting and posttesting.
    - Will procedures or techniques be randomized in any way?
    - Will the research require any use of deception? If so, be sure to explain why this is necessary and how participants will be debriefed.
    - Will materials with potential radiation risk be used, e.g., x-rays or exposure to radioisotopes?
    - Will medical, academic, or other confidential records be used?
    - Will the research involve making any visual or audio recordings of the participants (including still photographs)?

- If the research will involve administering drugs, explain:
  - The nature of the drugs and their most commonly observed effects, including unintended or “side” effects.
  - How the drugs will be obtained, prepared, and administered.
  - The dosages and schedules by which the drugs will be administered.
  - The status of the drugs according to the Food and Drug Administration.
  - Under what circumstances administration of the drugs will be modified or discontinued.
- d. What plans are there for responding to specific hazards, adverse effects, or toxicity of the research methods?
- 6. Criteria for outcomes: How will the results of the research be detected and measured?
  - a) What methods and criteria will be used to measure the major variables and effects in the research design?
  - b) What criteria will be used to determine when the research is completed or should no longer be continued?
  - c) What strategies of data analysis (such as statistical methods) do you plan to use?
  - d) Are there any plans for pathology review?
- 7. How will records of the research be maintained? In what form? Where?
- 8. References: What prior research provides the major context or procedures for this proposal?

## **Regulations Pertaining to Informed Consent (§46.116 General Requirements for Informed Consent)**

Except as provided elsewhere, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospect subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution or its agents from liability for negligence.

### a) Basic elements of informed consent:

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

### b. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

#### Documentation of Informed Consent

- a. The informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
  1. A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read to before it is signed; or
  2. A "short form" written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is signed by the subject or the representative.

However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."