MAESTRO review system

Type of Reviews and Categories

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Types and Categories of IRB Review

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Types of IRB Review

Federal regulations have established the following three categories of IRB review of proposed research activities involving human subjects:

1. **Expedited Review** – An Expedited Review may be conducted by the IRB when the research activities involve no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories as defined by **45 CFR 46.110**. All categories are listed below.

2. **Exempt Review** – An Exempt Review may be conducted by the IRB when the research activities will be in one or more of the exempt categories as defined by **45 CFR 46.101(b)**. All categories are listed below.

3. **Full Board Review** – A Full Board Review must be conducted for studies that pose greater than minimal risk to human subjects. All Full Board Reviews must be conducted at convened meetings which are held at timely intervals. The principal investigator may be invited to attend a convened meeting at which their protocol is to be reviewed. In such cases, the IRB reserves the right not to review the research study if a representative of the research team knowledgeable about the study design is not present.

Please provide sufficient detail in the application to show how this research falls into the category/categories selected.
NOTE: The research project must qualify for an expedited review as authorized under **45 CFR 46.110** or an exempt review authorized under **45 CFR 46.101(b)**; otherwise, it will be reviewed by the full IRB.

Expedited Review

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be 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**. The activities listed should not be deemed to be of minimal risk simply because they are included on this list.

Classified research involving human subjects may not be reviewed using the expedited review procedure. 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 subjects 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.

Minor changes in previously approved research may be reviewed using the expedited review procedure during the period for which approval has been authorized. The IRB may also use the expedited review procedure to review modifications and amendments to an approved study that contain only insignificant changes from the approved protocol.

Categories of Expedited 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*, 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 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.

*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)**). In New Mexico, the legal age for consent to treatments or procedures involved in the research is 18 years of age.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

(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 membrance prior to or during labor;

(h) 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;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and

(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 include:

(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; and

(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)(4)**. 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; 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.

Exempt Review

Studies which fall under any exempt category as defined by **45 CFR 46.101(b)** may qualify for an exempt review. An exemption cannot be granted for research that uses prisoners and for research with children that involves survey or interview procedures or observation of public behavior, unless the research involves observations of public behavior when the investigator(s) does not participate in the activities being observed. If the IRB finds the study is not exempt, it must go through an expedited or full board review.

While research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the **45 CFR 46** regulations, they must still be submitted to the IRB for their review and approval.

Categories of Exempt Research Activities

1. Educational Practices

Research conducted in established or commonly accepted educational settings, involving 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.

2. Surveys, Questionnaires, Interviews, Observational Studies

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

a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

b. 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.

3. Educational Tests

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 or appointed public officials or candidates for public office; or

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

4. Existing Data or Specimens

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

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:

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 methods or levels of payment for benefits or services under those programs.

6. Taste and Food Quality and Consumer Acceptance

Taste and food quality evaluation and consumer acceptance studies,

a. if wholesome foods without additives are consumed, 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 and Inspection Service of the U.S. Department of Agriculture.

Full Board Review

All research which does not qualify for either exempt or expedited review must be reviewed by the Full IRB. The full IRB review is conducted for studies that pose greater than minimal risk to human subjects. All protocols requiring review by the full IRB shall be reviewed at convened meetings which will be held at timely intervals. If an emergency meeting is necessary in order to comply to any aspect of the federal regulations, such a meeting will be called by the IRB Chair. The principal investigator may be invited to attend a convened meeting at which their protocol is to be reviewed. In such cases, the IRB reserves the right not to review the research study if a representative of the research team knowledgeable about the study design is not present.