§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research in categories appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers ~~designated by the chairperson~~ from among members of the IRB. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Introduction

Research that (1) presents no more than minimal risk to human subjects and (2) involves 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 criteria for IRB approval of research as stipulated in 45 CFR 46.111 and 21 CFR 56.111, including but not limited to requirements for informed consent, apply regardless of the type of review procedure used by the IRB.

Evaluating Minimal Risk

In evaluating the harms and discomforts introduced by the research, an IRB should consider the nature of the study procedures, other study characteristics, and steps taken to minimize risk.

In assessing eligibility for expedited review, the IRB should consider the characteristics of the subject population, including but not limited to their age, health conditions, social or economic vulnerabilities and experience in relation to the anticipated harms and discomforts. The expedited review procedure may not be used, for example, when 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.

The categories and their examples, described below, should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list means only that research falling within one or more of the categories is eligible for review through the expedited review procedure when it is determined that the proposed research involves no more than minimal risk to human subjects.

Applicability

A. This list of categories applies only to non-exempt human subjects research. Research that does not meet the definition of research involving human subjects (45 CFR 46.102) or clinical investigation involving human subjects (21 CFR 50.1), or is exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101), does not require IRB review.

B. The expedited review procedure may not be used for classified research involving human subjects.

C. Categories one (1) through ten (10) apply to both initial and continuing IRB review of research. Category eleven (11) applies to continuing review of previously approved research.

D. The categories in this list apply regardless of the age of subjects, except as noted.

E. Research that may be eligible for expedited review includes, but is not limited to, the examples in the categories provided below.

Research Categories

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 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 where an investigational device exemption (IDE) application or an abbreviated IDE application for a non-significant risk (NSR) device (21 CFR 812) is not required.[1]

2. The collection of blood specimens using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits for volume: (a) from non-pregnant adults who weigh at least 110 pounds, the amounts collected should not exceed 550 ml in an 8-week period; or (b) from children[2] and pregnant adults, the amount of blood to be collected should not exceed the lesser of 150 ml or 3 ml per kg (5% of blood volume) in an 8-week period.

   Examples:

   a. Finger stick, heel stick, or ear stick with reasonable limits on frequency and with volumes consistent with clinical practice employing these methods.

   b. Venipuncture with reasonable limits on frequency and with the total volume of clinical and research specimens limited as defined above.

   c. Collection of blood from an in-dwelling peripheral venous catheter placed for research purposes with volume limits as defined above.

   d. Collection of blood from an in-dwelling catheter already in place for clinical purposes, with the total volume of clinical and research samples limited as defined above.

3. Prospective collection of biological specimens, excluding blood, for research purposes by noninvasive or minimally invasive means.

   Examples:

   a. Tissues and fluids that the body produces continuously or sheds as a normal process, which are collected in a non-disfiguring manner.

b. Tissues and fluids if routine patient care indicates a need for removal or extraction.

c. Dental plaque and calculus.

d. Tissues from non-facial skin punch biopsies that do not require sutures.

e. Specimens collected by curettage, urethral, vaginal or rectal swabs.

f. Tissues collected from pap smears.

g. Specimens collected from the external auditory canal or nares.

4. Collection of additional data and biological specimens, excluding blood specimens, for research purposes during procedures already being performed for clinical purposes, provided the additional collection does not increase risk, pain or discomfort beyond minimal.

   Examples:

   a. Collection of additional bodily fluids (e.g., peritoneal fluid, bone marrow or cerebrospinal fluid)

   b. Reasonable extension of anesthesia, sedation or operating room time to allow collection of additional data or specimens.

5. Collection of data and biological specimens through noninvasive or minimally invasive procedures (not requiring the addition of general anesthesia or sedation for research purposes) routinely employed in clinical practice.

   Examples:

   a. Physical sensors that are applied either to the surface of the body or at a distance.

   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.

   f. Allergy skin-testing.

   g. Procedures involving a single exposure to ionizing radiation with an effective dose not exceeding 0.1 mSv (the amount typically associated with a chest x-ray).

6. Secondary use of materials (data, documents, records, or biological specimens) that have been or will be collected for purposes other than the currently proposed research project.

   Examples:

   a. Secondary use of data collected from another research study.

   b. Secondary use of clinical or educational records.

   c. Use of banked specimens in biorepositories.

7. Activities at statistical and data coordinating centers or biospecimen repositories that are not involved in the primary collection of data or specimens, which may be ongoing at other sites.

   a. Multicenter clinical trial where data are gathered under separate IRB approval(s) for the performance sites, but received and managed by a central coordinating center that does not otherwise participate in the clinical intervention or interact directly with subjects.

8. Collection of data from voice, video, digital, or image recordings made for research purposes.

9. Surveys, interviews, self-reports, direct and indirect observations of individual and group behavior, other verbal or computer-assisted interactions or assessments, non-invasive physical or behavioral tasks, manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health, and epidemiologic research.

   Examples:

   a. Measures of performance on cognitive, perceptual, neuropsychological, behavioral and other related tasks employing non-invasive technologies (e.g., paper and pencil assessment, computerized tasks, remote data collection using mobile devices).

   b. Interviews, questionnaires, surveys, focus groups, and internet-based data collection on personal experience, identity, language, relationships, attitudes, beliefs and practices.

   c. Psychiatric diagnostic or symptom assessments in healthy or mentally ill populations conducted by clinicians or trained interviewers (with appropriate mechanisms for clinical back-up or referral).

   d. Measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers).

   e. Methods used in ergonomics and human factors research including cognitive, human-computer, physiological and bio-mechanical measures in consumer, industrial, and biomedical settings.

   f. Qualitative and quantitative data collection through observation, participant observation and interaction with groups in naturalistic settings (including the internet).

   g. Surveys on personal and family finances, consumer preferences and decision-making.

   h. Assessments of compliance with medication or treatment regimens.

   i. Surveys to establish effectiveness of public health interventions.

10. Establishment of subject recruitment databases.

    Examples:

    a. Collection of identifiable information for the purpose of establishing subject pools.

    b. Disease-specific patient registries.

c. Screening protocols including interviews, questionnaires and physical assessments that could be expedited under one of the categories listed above.

Continuing Review of Previously Approved Research

11. Research previously approved by the convened IRB and now subject to continuing review where one of the following conditions apply:

a. (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. no subjects have been enrolled and no additional risks have been identified; or

c. the remaining research activities are limited to data analysis; or

d. a non-significant risk (NSR) determination was initially made by a convened IRB for research involving medical devices and the research was determined to present no greater than minimal risk to the subject; or

e. 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.

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[1] Circumstances where an investigation device exemption (IDE) application would not be required include those where (i) a non-significant risk (NSR) device is being reviewed by an IRB under 21 CFR 812.2(b); or (ii) the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling; or (iii) the research is exempt from the IDE submission requirements under 21 CFR 812.2(c).

[2] Children are defined in the HHS [45 CFR 46.402(a)] and FDA [21 CFR 50.3(o)] 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."