Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure [1]

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 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 merely means that the activity is eligible for review through the expedited review procedure when the specif 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 respor place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employabili or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exce the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

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 Part 312) is not req on marketed drugs that significantly increases the risks or decreases the acceptability of the risks asso 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 i 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 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[2], considering the age, weight, and health of the subjects, the collect amount of blood to be collected, and the frequency with which it will be collected. For these subjects, not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more 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 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 subgingival dental plaque and calculus, provided the collection procedure is not more i prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophy

(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) routine practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not genera 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 involv 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 radi electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiograp

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will b nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research th

(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 pe motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance met research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 (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 investiga where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a cc research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of a review of research involving human subjects by the IRE or more experienced reviewers designated by the chairperson from among members of the IRB in acc requirements set forth in **45 CFR 46.110**.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for cons procedures involved in the research, under the applicable law of the jurisdiction in which the research **CFR 46.402(a)**.

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