Expedited Definitions

IRB EXPEDITED REVIEW – The policy and provisions are closely based on DHHS regulations (45 CFR 46.110).

Federal and state guidelines dictate that in order for research to be considered eligible for expedited review, certain criteria must be met and maintained. In order to approve research designated as expedited, the IRB must determine that all of the following requirements are satisfied:

1. The proposed procedures must be consistent with sound research design, and when possible, procedures already being performed on subjects should be used.

   → For example, obtaining additional blood at time of routine venipuncture is preferred rather than doing an extra needle stick to obtain the research sample.

2. The risks of the research must be reasonable in relationship to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may be gained.

3. Subject selection must be equitable, with all subjects having an equal opportunity to accept or decline participation.

4. Informed consent should be sought and documented unless a waiver of consent and/or documentation of consent has met the waiver criteria specified by the DHHS (45 CFR 46).

   DHHS mandates that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

   1. That the only document linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subjects wishes will govern

   or

   2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

5. Where appropriate, there is a plan to collect and monitor data to ensure subject safety

6. The privacy of subjects and maintenance of confidentiality of data are protected.

7. Where necessary, additional safeguards have been included to protect vulnerable subjects.

8. Research that is being conducted does not ask questions of a sensitive nature (e.g. questions or inquiries about sexual preferences, sexual behaviors, substance use or abuse, or illegal conduct.) Research does not allow for subjects to offer responses that could reasonably place them at risk for criminal or civil liability, be damaging to their financial standing, insurability, reputation, or be stigmatizing.

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

Expedited reviews may be conducted for initial as well as continuing IRB applications.

There are 8 categories of research that are eligible for expedited status. The activities described within these categories 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.

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

EXP1- Clinical studies of drugs and medical devices only when one of the following 2 conditions are met:

1. Research on drugs for which an investigational new drug application is not required.

or

2. Research on medical devices for which an investigational medical device exemption application is not required, or the medical devise is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

EXP2- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 150 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.

EXP3- Collection of biological specimens for research purposes by noninvasive means.

Examples:

(a) Hair and nail clippings in a non-disfiguring 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 by applying a dilute citric solution to the tongue
(f) Placenta removal at delivery
(g) Aminotic fluid obtained at time of rupture of the membrane before or during labor
(h) Supragingival 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 swap, or mouth washings
(j) Sputum collected after saline mist nebulization

EXP4 - 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.

→ PLEASE NOTE: That these examples assume the research is being conducted with a subject population for whom these tasks would pose no more than a minimal risk. If the tasks are performed on a subject population for whom the tasks would be considered risky, then this research is no longer eligible for expedited review.

EXP5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

→ PLEASE NOTE: Research using retrospectively of prospectively collected routine medical record information or leftover specimens collected at the time of clinical care would qualify in this category of expedited review, if the information is not considered sensitive and any potential breach of confidentiality would not be damaging to the subject. Research using the medical records of HIV-positive patients is an example of a study that should not be reviewed by the expedited method.

EXP6 - Collection of data from voice, video, digital, or image recordings made for research purposes.

→ PLEASE NOTE: If information included in the recordings is considered sensitive or potentially damaging to the subject's financial standing, employability, insurability, reputation, or if the subject's voice or (still or moving) image could be identified then this research is not eligible for expedited review.

EXP7 - 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.

→ PLEASE NOTE: Research studies on intelligence or other traits involving specific populations require careful analysis because this type of research, depending on the nature of the survey questions, could result in stigmatization of a segment of society.

EXP8 - 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.

EXP9 - 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.