

## **IRB Policy 8: Expedited Review**

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### **I. Pertinent Definitions:**

- A. **Continuing Review:** Periodic IRB review of ongoing research activities to ensure that the rights and welfare of human subjects are protected. Includes analysis of risk/benefit ratio, with special attention to whether new information or unanticipated risks have been discovered since the previous IRB review, and whether any new information regarding the risks and benefits should be provided to participants.
- B. **Expedited Review:** Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.
- C. **Children:** Per regulations, children are “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.” Per Tennessee state law, 18 years of age is the legal age of consent.
- D. **Minimal Risk:** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

### **II. Summary Policy**

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA IRB) is to conduct expedited review of eligible protocols in a manner that meets and/or exceeds all applicable guidelines. Research receiving initial expedited review are those meeting the criteria for expedited review as detailed in 45 CFR 46.110, 38 CFR 16.110 and, for the ETSU/VA IRB, the VHA Handbook 1200.5.

### **III. Expedited Reviewers**

An expedited review is a plenary review conducted by the IRB Chair, or designated IRB members who have been selected based on their expertise and

experience. Expedited reviewers are empowered with similar authority extended to the IRB, except that they cannot disapprove the research.

Expedited reviewers are selected for each individual protocol by the IRB Chair or Vice Chair. Consideration for selection is based on areas of expertise, research experience, time served on the IRB, dedication to continuing education and availability to accept new and continuing research proposals. An experienced IRB member means a voting member or alternate voting member who has served on an IRB for at least six months, and possesses the scientific expertise and professional competence needed to review the proposed research.

The Chair (or Vice Chair) reviews each expedited initial submission to determine which IRB members have the appropriate expertise and experience to conduct an in-depth evaluation of the protocol. The Chair is responsible for evaluation of the proposal for recommendation of any special representation needed among the reviewers, i.e., pediatric expertise for a study involving children. The Chair determines that at least one reviewer has the appropriate scientific and disciplinary expertise and determines which IRB members will serve as expedited reviewers.

Neither the Chair nor the Vice Chair may review for approval research studies submitted for exempt or expedited review from their respective departments or divisions (for larger departments). Members who have a conflict of interest may not participate in the expedited review process of any involved study. If a study is assigned to a reviewer who has a conflict of interest, he/she must indicate that conflict by reporting it to the IRB Coordinator. The IRB Coordinator will notify the IRB Chair, who will reassign the review.

#### **IV. Procedures for Expedited Review**

1. Documentation for both initial and continuing reviews conducted under expedited procedure includes the specific review categories justifying the expedited review and documentation of the review and action taken by the IRB chair or designated reviewer and any findings required under the HHS regulations.
2. If the Chair or the expedited reviewers cannot approve the study consistent with expedited review procedures, the proposal will be recommended for review by the convened IRB.
3. In conducting expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB

in accordance with the full board review procedure set forth in 45 CFR 46.108(b) and described in Policy 9.

4. IRB members are informed of research proposals approved at time of initial or continuing review under an expedited review procedure and minor changes in research protocols approved under an expedited review procedure via the approved IRB minutes. (45 CFR 46.110(c)).

## **V. Review Categories**

HHS Regulations at 45 CFR 46.110(b)(1) limit the use of expedited review procedures to specific research categories published in the Federal Register. The following categories of research may be reviewed by the IRB through an expedited review procedure:

(b)(1) An IRB may use the expedited review procedure to review the following:

- (i) Some or all of the research appearing on the list described below, unless the reviewer determines that the study involves more than minimal risk;
- (ii) Minor changes in previously approved research during the period for which approval is authorized; or
- (iii) Research for which limited IRB review is a condition of exemption under § \_\_.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

At initial review, only those 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 expedited categories defined by the federal regulations.

Expedited review may not be used if:

- research is minimal risk but does not appear in one of the listed categories
- research has been determined by reviewer to involve more than minimal risk
- research 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 subject's 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
- research is classified and involves human subjects

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. If a

reviewer finds that research appearing on the expedited review list is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB. If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

The categories in this list apply regardless of the age of subjects, except as noted. Categories one (1) through seven (7) pertain to both initial and continuing IRB review. The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§ .110(a)].

### Expedited 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 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<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 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.

(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 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 membrane prior to or during labor; (h) supra- and sub-gingival 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; (j) sputum collected after saline mist nebulization; and consistent with OHRP and FDA correspondence (k) vaginal swabs that do not go beyond the cervical os; (l) rectal swabs that do not go beyond the rectum; and (m) nasal swabs that do not go beyond the nares (9/22/11 OHRP correspondence).

(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: (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.

(5) 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). (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.

<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."

## **VI. Material Reviewed:**

The following materials are provided to the reviewer and the Chair for initial expedited review applications:

1. Completed new protocol submission xform, which includes narrative section(VA or non-VA) with required signatory attestations,
2. Full protocol, if applicable
3. Proposed informed consent document(s)\*
4. Copies of scripts, surveys, questionnaires, or videotapes, if applicable
5. Relevant grant applications
6. Investigator's brochure (if one exists);
7. Advertising intended to be seen or heard by potential subjects, including email solicitations.
8. Investigator CV
9. Consultant's written report (if applicable)
10. For HHS supported multicenter clinical trials, a copy of the HHS approved sample informed consent document\*
11. For HHS supported multicenter clinical trials, a copy of the complete HHS approved protocol
12. For studies that have an associated contract, verification from Sponsored Programs of the consistency for provisions of medical care

or other care and services for research-related injury between the consent document and the contract

\*Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria. (See informed consent policy.)

## **VII. Expedited Review Approvals**

Expedited reviews should be conducted with the same depth as reviews conducted by the convened board. Research materials submitted must include sufficient detail for the Reviewer(s) to determine the study meets criteria 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111, if applicable, for approval.

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized by: (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § \_\_.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § \_\_.117.

(6) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

In addition, for VA studies, the IRB determines if the patient's medical record (electronic or paper) must be flagged to protect the subject's safety by indicating the subject's participation in the study, and the source of more information on the study. The patient's medical record must be flagged if the study has been determined to be more than minimal risk.

If the IRB determines and documents that the patient health record must be flagged in Computerized Patient Record System (CPRS) as participating in a research study then the health record must identify the Researcher, as well as contact information for a member of the research team that would be available at all times, and contain information on the research study or identify where this information is available. The duration of flagging is the length of the duration of the individual's participation in the study

The instructions above apply to studies that **do not** have a Certificate of Confidentiality. Refer to Policy 13, Section VIII.C for instructions regarding studies that have a Certificate of Confidentiality.

Investigators are notified in writing of expedited review determinations. For VA studies only, investigators are informed of the review decision and expedited category(ies) in the approval letter.

Initial approval letters for expedited studies will contain notice of the requirement to report changes and unanticipated problems in research to the IRB. Information about continuing review interval, if continuing review is required, is also included in the initial approval letter.

## **VIII. Committee Notification**

The full Committee is informed of research proposals/activities that have been approved through the expedited review procedure. The IRB Coordinator enters proposals/activities that have been approved through the expedited review process into the database and compiles an expedited review list for the first meeting after the approval date. The IRB Coordinator ensures that the expedited review list is available in IRB Manager to all IRB members as part of the minutes.



For VA studies only, the expedited review eligibility category(ies) for expedited approvals will be documented in the minutes; and the VA Administrative Officer (AO) distributes the ETSU/VA IRB minutes to the members of the VA R&D Committee.

## **IX. Other Expedited Review Procedures**

See continuing review policy and modification policy for details on other appropriate uses of the expedited review procedure.

References:

[45 CFR 46.402\(a\)](#).

[Source: 63 FR 60364-60367, November 9, 1998.](#)

45 CFR 46.110

21 CFR 56.110

38 CFR 16.110