

**Department of Veterans Affairs  
Tuscaloosa VA Medical Center**

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**Human Research Protection Program SOP #4**

**October 17, 2007**

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**EXPEDITED REVIEW PROCESS**

**1. POLICY**

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to the mission of fostering a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the TVAMC. In addition, the TVAMC HRPP is committed to providing an efficient, ethical and safe mechanism for review of research protocols and their amendments, including the use of an expedited review process for a limited class of research.

It is the policy of the TVAMC HRPP to ensure that the applicable Federal, state, and local regulations are carried out in protecting the rights and welfare of subjects who voluntarily participate in investigational studies within this Medical Center, including when research is reviewed through an expedited review process. This Standard Operating Procedures (SOP) is a written documentation of the plan for conducting reviews by the expedited review process. This policy establishes procedures for an expedited review process that is conducted in accordance with the requirements of the TVAMC HRPP and Federal regulations.

**2. RESPONSIBILITIES**

**TVAMC Medical Center Director:** The Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the TVAMC.

**Coordinator for Research and Development (C/R&D) and R&D Administrative Officer (R&D AO):** The C/R&D & R&D AO maintains responsibility for procedures, policies, and execution of the research program (including expedited review process) conducted at the TVAMC.

**Experienced IRB members:** Experienced IRB members are those IRB members who have at least 6 months of experience working on the IRB. Experienced IRB members are designated by the IRB Chairperson to conduct reviews using expedited procedures and are responsible for the thorough review and recommendation to the Chairperson for approval, approval with stipulations/modifications, or referral to the full IRB board.

**Principal Investigators (PI):** The PI must abide by this HRPP SOP when applying for expedited review of research that meets the appropriate definitions and limits described in this SOP.

### **3. DEFINITIONS OR CRITERIA**

- a. **Expedited Review Process** is an alternative to review by a convened IRB for a limited class of research. The regulatory requirements for review by the expedited procedures are otherwise identical to review by a convened IRB. This expedited review process is used to provide timely reviews for investigators and to reduce the workload of a convened IRB, thereby providing a more efficient IRB review process. The expedited review process may be utilized for review of the following:
- Research meeting the Applicable Criteria list below
  - Modifications to previously approved research protocols that meet the definition in section 6.
  - Contingencies or stipulations required to secure approval that were identified at a convened IRB meeting
  - Reports of protocol deviations, adverse events, safety reports, participant outreach/recruitment materials, and other correspondence or updates on previously approved research.
- b. **Modifications to Previously Approved Research Eligible for Expedited Review Process:** Modifications or amendments to previously approved research are eligible for the expedited review process if the modification or amendment presents no more than minimal risk to human subjects. Criteria for determining that changes in previously approved research during the period for which the approval is authorized are minor, include but are not limited to, addition or deletion of investigators, consultants, or other members of the research team, minor grammar and format changes, deletion of procedures that decrease the risks or burden to subjects, protocol clarifications that do not result in change to the actual procedures or risk to subject, changes that do not exceed or increase the risks of the study identified at the initial or continuing review, study closure, and completion of a study. When a proposed change in a research study is not minor (e.g. procedures involving increased risk or discomfort are to be added), the IRB must review the change at a convened meeting.
- c. **Applicable Criteria Eligible for Expedited Review Process:** Criteria listed in VHA handbook 1200.5 Appendix B and “Categories of Research that may be reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure – FDA & DHHS” are eligible for expedited review. Applicable criteria involve only procedures listed in one or more of the below categories authorized by 45 CFR 46.110 and 21 CFR 56.110, with the following stipulations.
- These criteria require the research proposal, report or modification present no more than minimal risk human participants.
  - The activities listed 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

where 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.
- The expedited review process 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 is no greater than minimal.
- The expedited review process may not be used for classified research involving human subjects.
- IRBs are reminded that the standard requirements for Informed Consent or its waiver, alteration, or exception apply regardless of the type of review expedited or convened utilized by the IRB.
- Categories one (I) through seven (VII) pertain to both initial and continuing IRB review.

#### **CATEGORIES OF APPLICABLE CRITERIA**

- I. Clinical studies of drugs when the following condition is met: 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 risk or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
- II. 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 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.
  - 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, the frequency with which it will be collected. For those subjects the amount drawn may not exceed the lesser of 500 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. (*However, the TVAMC does not conduct research with children.*)
- III. Prospective collection of biological specimens for research purposes by noninvasive means, examples are:
  - 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 un-stimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
  - G. 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
  - H. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
  - I. Sputum collected after saline mist nebulization
- IV. Collection of data through non-invasive 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 (*not applicable at the TVAMC since the TVAMC does not conduct research with devices*). (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 are:
- 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
- V. 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 non-exempt.
- VI. Collection of data from voice, video, digital, or image recordings made for research purposes.
- VII. 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 a 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 non-exempt.

- VIII. Continuing review of research that is not classified research and that involves only procedures listed in one or more of Category I through VII above OR the one of the following:
  - A. Where:
    - (i) the research is permanently closed to the enrollment of new subjects
    - (ii) all subjects have completed all research related interventions
    - (iii) the research remains active only for long-term follow-up of subjects
  - B. Where no subjects have been enrolled and no additional risks have been identified
  - C. Where the remaining research activities are limited to data analysis
- IX. Continuing review of research, not conducted under an investigational new drug application exemption where categories (2) through (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.

#### 4. **PROCEDURES**

- a. **Expedited Reviewer and Allowed Actions:** The expedited review is conducted by the IRB Chairperson or an experienced IRB member designated by the IRB Chairperson. The expedited reviewer must not have a conflict of interest in regard to the research project or item under consideration. Based on the recommendation of the designated experienced IRB member or the Chairperson's personal review, the IRB Chairperson makes the final determination of approval, approval with stipulations or modifications needed to secure IRB approval, or referral to the convened IRB for full review. In reviewing the research by the expedited procedure, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedures, i.e. by convened IRB.
- b. **Initial Review:** For initial review of new studies, the TVAMC HRPP currently requires full IRB review of all new studies. However, if future changes in this policy occur, in order to allow expedited review of eligible research (i.e. one of the Applicable Criteria), this HRPP SOP will be amended with details on the policies and procedures for expedited review of new studies.
- c. **Continuing Review:** For continuing review of previously approved studies, the investigator submits the application using the identical continuing review requirements along with a cover letter requesting expedited review and providing the information needed to judge eligibility for expedited review (i.e. naming the Applicable Criteria listed above that defines the research study). For approval through the expedited process, the research must meet one or more approvable Applicable Criteria listed above, as well as meet all other standards otherwise required by the IRB. The expedited reviewer will use the Continuing Review Checklist to conduct the review.

- d. **Modifications or Amendments to Previously Approved Research:** The investigator submits the modification or amendment in the form of a copy with tracked changes and a clean copy of the revised protocol, abstract, or consent form (if applicable) and the form entitled “Request for Amendment Approval.” The expedited reviewer receives and reviews the materials and modified documents in-depth (same materials that the convened IRB would have received). To document the review, the expedited reviewer will fill out the designated box indicating review and action on the form and complete the IRB Reviewer Amendment Checklist. If the modification or amendment to previously approved research does not meet criteria or eligibility for expedited review, the modification or amendment is referred for review and action by the convened IRB. The proposed changes in approved research may not be initiated without approval by the expedited review process or convened IRB, except when necessary to eliminate immediate hazards to the participant. Such changes to eliminate apparent immediate hazards to the participant must be promptly reported by the investigator to the IRB and the IRB (either expedited review or convened IRB) must determine that the change is consistent with ensuring the participants’ continued welfare and provide approval of the change or require stipulations for approval. See the HRPP SOP #7, regarding requirements for participants to sign approved revised informed consents. If modifications or amendments to previously approved research are approved through the expedited review procedures, the continuing review date does not change, but remains the same as determined at the most recent continuing review.
- e. **Contingencies or stipulations required to secure approval that were identified at a convened IRB meeting** are described in a memo from the IRB to the investigator. When the IRB requires modification to research to secure approval (i.e. contingent approval), verification of those modification by an IRB chair or experienced IRB reviewer without review by the convened IRB represents review by the expedited procedure, and should comply with regulations and guidance governing such review. The IRB should document the required modification so that an IRB chair or experienced IRB member can judge whether the revised protocol/consent form matches the one the IRB is was willing to approve. The investigator must address the contingencies or stipulations in written form and submit to the IRB office in a timely manner. The expedited reviewer will conduct the review and ensure that all contingencies, stipulations, and/or modifications have been made by the investigator. The expedited reviewer may grant approval or disapproval or she/he may require further clarification, modification, and/or stipulations in order to satisfy the intent of the IRB. Once all contingencies have been satisfied, the date of approval is the date the fully convened IRB approved the protocol rather than the date that the minor changes were approved by the IRB Chair or designee. The approval must be documented in the minutes of the first IRB meeting that takes place after the date of approval. Although the expedited review process is available for use by the IRB, the IRB may require that the research application return to the convened IRB for review prior to approval (such as for substantial modifications that require judgments by convened IRB).

- f. **Reports of protocol deviations, adverse events, safety reports, participant outreach/recruitment materials and other correspondence or updates on previously approved research** may be submitted by the investigator using the appropriate forms (i.e. protocol deviation or adverse events; see HRPP SOP #11) or a cover letter in the templated format provided by the IRB office with a signature block for the IRB Chair or designated experienced IRB member to indicate approve/disapprove/needs more information. The expedited reviewer will conduct the review and indicate the results by circling the action on the cover memo.
- g. **Communication to the convened IRB and all IRB members.** All actions taken through the expedited review process will be reported to the convened IRB for review and if necessary, further discussion or action. If the item submitted does not meet criteria or eligibility for expedited review, the item is referred for review and action by the convened IRB. All actions taken through the expedited review process are reported in the IRB minutes as communication to all IRB members. As further communication, the R&D Committee subsequently reviews and accepts the IRB minutes.

## 5. REFERENCES

- VHA Handbook 1200.5 Appendix B
- 26CFR 56.110(a)(b)
- 38 CFR 16.110
- 45 CFR 46.110
- 21 CFR 56.110

## 6. ATTACHMENTS

- Request for Amendment Approval Form
- Template for memo to IRB

## 7. RESCISSIONS

TVAMC HRPP SOP #4 Expedited Review dated May 7, 2007.

## 8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development