EXPEDITED REVIEW PROCESS

1. POLICY

The Birmingham VA Medical Center (BVAMC) 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 BVAMC. In addition, the BVAMC 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 BVAMC 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 BVAMC HRPP and Federal regulations.

The Expedited review process may not be used for “classified” research involving human subjects as “classified” research involving human subjects cannot be approved by a VA IRB or R&D Committee or performed at a VA facility, including space leased to, and used by VA.

2. RESPONSIBILITIES

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

**Associate Chief of Staff, Research and Development (ACOS/R&D):** The ACOS/R&D maintains responsibility for procedures, policies, and execution of the research program conducted at the BVAMC.

**Chair of the IRB:** The IRB Chairperson or a designated IRB member is responsible for conducting reviews using expedited procedures and is responsible for the thorough review and approval, approval with stipulations/modifications, or referral to the full IRB board for review.
**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.

**DEFINITIONS AND CRITERIA**

See additional definitions under SOP# 24 – HRPP Definitions

a. **Expedited Review Process** is an alternative to review by a convened IRB for a limited class of research. The expedited review process may be utilized for review of research studies if the following apply:
   - The research meets the Applicable Criteria listed below.
   - Modifications to previously approved research protocols meet the definition listed below.
   - Reports of protocol deviations, adverse events, safety reports, participant outreach/recruitment materials, and other correspondence or updates on previously approved research that meet the definitions listed below.

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 does not involve more than minimal risk to subjects and meets the applicable criteria (1-7) listed below under categories of applicable criteria for expedited review. The following are examples of modifications that can be approved using the Expedited Review process to previously approved research. The change or modification is minor (minimum risk to research participants) and/or is listed below under applicable criteria categories. Some examples of expedited modifications to previously approved research are the 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 is not on the list of applicable criteria, then the modification must be reviewed and approved at a full IRB convened meeting.

c. **IRB May Use Expedited Review for the Following:**

1. Any of the categories of research appearing on the list found at www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-researchexpedited-review-procedure-1998/index.html. Unless the reviewer(s) determines and documents that the study involves more than minimal risk;
2. Minor changes in previously approved research during the period for which approval is authorized; or
3. Research for which limited IRB review is a condition of exemption. In the expedited review process, the IRB Chair may carry out the review or delegate the review to one or more experienced reviewers from among voting IRB members. The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in this section. The IRB Chair or designee will provide copies of the approved Expedited Protocol to the Investigator and to the IRB members at the next IRB meeting for all members to review. These minutes or activities memos will then be forwarded to the R&D Committee highlighting the decision and the expedited review eligibility category for any expedited review actions.
   a. These criteria require the research proposal, report or modification present no more than minimal risk human participants.
   b. 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.
   c. The categories in this list apply regardless of the age of subjects except as noted.
   d. 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.
   e. 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 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 BVAMC 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 (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 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.

3. PROCEDURES

**Expedited Reviewer and Allowed Actions**: The expedited review is determined by and conducted by the IRB Chairperson or another voting experienced IRB member. A voting experienced member is IRB members with some experience on the IRB and who has reviewed and read in-depth the HRPP SOP # 4 Expedited Review. To review and conduct expedited reviews the Chair or experienced member must not have a conflict of interest in regard to the research project or item under consideration. All IRB members reviewing research activities are expected to disclose any conflicts of interest prior to determining and/or reviewing research activities using the expedited review process. The IRB Chairperson or designated IRB member 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. Note: All studies deemed appropriate for expedited review must be reviewed by the Privacy Officer and the Information Security Officer, prior to beginning study activities. In reviewing the research by the expedited procedure, the Chair (or alternate) may exercise all of the authorities of the IRB except that he/she 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. All actions are communicated in writing to the investigator and available for discussion at the next IRB meeting for IRB members.

a. **Initial Review:** The IRB Chairperson or designee will determine if an initial review may be approved utilizing expedited review procedures. The investigator submits the initial application using the identical initial requirements and providing the information needed to judge eligibility for expedited review (i.e. naming the Applicable Criteria listed above that defines the research study) to the IRB Chair or designee. 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. Note studies involving Investigational drugs and devices may not be approved by expedited review. All studies must be submitted to the R&D Committee for final review and approval.

**Research subject to the pre-2018 Requirements and FDA Regulated Research**

For both FDA regulated research and research that is subject to the pre-2018 Requirements, the assigned reviewer must first determine that all proposed research activities meet the definition of minimal risk. Once that determination has been made, the assigned reviewer must confirm that all proposed activities fit into one or more of the categories on the expedited review list.

**Research subject to the 2018 Requirements**

For research that is subject to the 2018 Requirements, it is presumed that all activities included on the expedited review list are minimal risk activities and thus eligible for expedited review. If the assigned reviewer believes that a proposed study activity that is found on the expedited review list is greater than minimal risk and thus requires convened board review, the assigned reviewer must document the rationale for determining that the activity is greater than minimal risk on the reviewer form and then inform the IRB Administrator that the study needs to be scheduled for review at the next available convened board meeting.

b. **Continuing Review:** For continuing review of previously (full board review) approved studies, the investigator submits a cover letter requesting expedited review based on one of the following criteria:

1) the study is closed to enrollment
2) research in which no subjects have been enrolled and no additional risks have been identified or
3) research in which the remaining research activities are limited to data analysis

4) For Pre-2018 Requirements
to utilize the expedited procedure for continuing review an investigator must submit
documentation of the above with the Expedited letter of request. Other than what is
previously outlined above continuing reviews require full IRB review and approval
unless, determined during the Initial Submission review (by the convened IRB) that
subsequent continuing reviews could be completed using the expedited procedure.

For 2018 Requirements,

Continuing Review is no longer required for research eligible for expedited review.
Conducting Continuing Review on research that no longer requires Continuing
Review will require justification that is documented in the study files.

1. Continuing Review is no longer required for the following:
   a. Research eligible for expedited review
   b. Research reviewed by limited IRB review
   c. Research that has progressed to the point that it only involves one or
      both of the following:
         i. Data analysis, inclusive of analysis of identifiable private
            information or identifiable specimens, and/or
         ii. Access to follow-up clinical data obtained from procedures that
            subjects undergo as part of clinical care

c. Expedited Review of Modifications or Amendments to Previously Approved
   Research: The investigator submits the modification or amendment in the form of a
copy of the revised protocol, abstract, or consent form (if applicable) with tracked
changes and a clean copy of the revised protocol, abstract, or consent form (if
applicable) and the form entitled “Protocol Amendment” or “Miscellaneous Form”.
The IRB Chair or designee receives and reviews the materials and all modified
documents in-depth (same materials that the convened IRB would have received). To
document the review, the Chair or designee will fill out the revised checklist that lists
all applicable criteria for an expedited review. This checklist/form (once completed)
is then scanned and emailed back to the Investigator, copied for the file, and made
available at the next meeting for review by the full convened IRB. If the modification
or amendment to previously approved research involved more than minimal risk or if
the procedures in the modification did not fall in the categories (listed under
categories) 1-7 of the types of research the IRB is allowed to review using the
expedited process, then the change or modification must be reviewed by the convened
IRB. All of the IRB members present would then review all modified documents. All
Expedited reviews are available for review at the following full board meeting and
documented in the IRB minutes.

d. 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 convened IRB requires modifications to research not directly relevant to required federal determinations to secure approval (i.e. contingent approval), verification of those modifications by the IRB chair or Vice Chair without review by the convened IRB represents review by the expedited procedure, and should comply with regulations and guidance governing such review. If the IRB requested substantive modifications or clarifications that were directly relevant to the regulatory criteria for approval these modifications/clarifications must be reviewed and approved by the full convened IRB. The investigator must address the contingencies or stipulations in written form and submit to the IRB office within 60 days. If the modification/clarification has been determined (and met criteria for) expedited review the IRB Chair will conduct the review and ensure that all contingencies, stipulations, and/or modifications have been made by the investigator. The IRB will submit a letter to the investigator that states the investigator has met the stipulations of the convened IRB or 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 and available for the members to review.

e. **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). The Chair will conduct the review and indicate the results by checking the action on the form. Please note that the chair may determine full board review on these forms, and the review would need to be referred for full board review and action.

f. **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 to 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. Finally, all actions taken by the IRB or IRB Chair through either expedited review or full board review are communicated to the investigator in writing.

4. **REFERENCES**

- VHA Directive 1200.05
- VHA Directive 1200.05 Appendix B
- 26CFR 56.110(a)(b)
- 38 CFR 16.110
- 45 CFR 46.110
- 21 CFR 56.110
5. ATTACHMENTS

- Template for memo to IRB
- Decision Chart

6. RESCISSIONS


7. REVIEW DATE

January 1, 2020

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Louis Dell’Italia, MD
ACOS, Research and Development