1. PURPOSE

This procedure describes and outlines the process to determine if the research meets criteria for expedited review.

2. PROCEDURE

An expedited review procedure consists of a review of research involving human subjects by the Chair or designee. A designee is an IRB member or IRB staff recognized by the IRB Chair who has sufficient experience to perform such a review. An experienced member is one who has demonstrated a consistent and comprehensive pattern of review of assigned protocols as an IRB member and has demonstrated a dedication to the protection of human subjects with his/her actions and comments. These designees (reviewers) may conduct reviews using the exempt process and the expedited review process.

This procedure pertains to both initial, continuing review, and amendments to previously-approved research.

The categories of research that may be reviewed by the IRB through an expedited review procedure at initial or continuing review include research activities that (1) present no more than minimal risk to human subjects (2) do not involve identification of human subjects and/or responses that 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 confidentially are no greater than minimal, and (3) are not classified. Classified research is generally defined as research subject to a security classification established by a United States government agency. In addition, minor changes to studies previously approved by the IRB (either via exempt, expedited or full board review) may undergo expedited review.

Examples of items that may be reviewed via expedited review include (but not limited to);

- Studies involving data collection
- Minor changes to studies previously reviewed and approved by the IRB (change in spelling of PI name, change in page numbering of consent, correction of address information, others at the discretion of the IRB Manager)
- Protocol changes that are minor and do not increase risk
- Administrative documents (revised Clinical Investigator's Brochure, and others at the discretion of the IRB Manager).

3. SPECIFIC PROCEDURES

3.1 Initial Review

In reviewing the research, the reviewer may exercise all of the authorities of the full IRB except that the reviewer may not disapprove the research. Disapproval is only determined by the convened IRB. The reviewer may refer the application to the full IRB for a standard review as warranted.

The reviewer(s) will have access to the entire study. The expedited reviewer(s) will use the "Expedited Review Checklist" to determine if the research meets the expedited review eligibility.

Reviewer(s) will use the "Criteria for Approval Checklist(s)" to determine if the study meets the regulatory criteria for approval, as well as any other applicable checklist to conduct the review.

If modifications are requested by the reviewer and the PI does not want to make the requested modifications, or modifications have been made that were not requested, the reviewer may refer the study to full IRB Board.

3.2 Continuing Review

Studies which have been approved as expedited may be reviewed via expedited review procedures as long as the study continues to involve only minimal risk.

A study that received full IRB review may be determined by the full IRB to be minimal risk and thus, if the IRB so determines, can be annually reviewed by the expedited procedure. This determination will be documented in the minutes. For studies that are not FDA-regulated and therefore fall under the OHRP regulations (commonly referred to as the 2018 Common Rule), if the full IRB determines a study can be expedited, the study will not need to be submitted to the IRB for annual continuation per the updated regulations.

The reviewer will use the Expedited Review Checklist(s) to determine if the research meets the expedited review eligibility.

The reviewer at continuation will have access to the entire study file.

To determine if the study continues to meet the regulatory criteria for approval, the reviewers will use the "Criteria for Approval Checklist(s)" as well as any other applicable checklist to conduct the review.

3.3 Amendments or Minor Modifications to Previously Approved Research

The Chairperson or designee may approve expeditable amendments or minor modifications of previously approved research during the period for which approval is authorized.

Minor modification is defined as a change that does not materially affect an assessment of the risk and benefits of the study, does not change the aims of the study design, and is not directly relevant to the determination required for approval.

Examples of amendments or minor modifications include, but are not limited to:

- Protocol revisions that entail no more than minimal risk.
- Changes to the informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk to subjects, or significant changes in the study procedures.
- Changes in research personnel or contact information.

The reviewer(s) will use IRB Checklists to determine if the amendment or minor modification qualifies for an expedited review. The reviewer(s) will have access to the entire study file.

3.4 Additional Items that May Be Reviewed by the Expedited Review Process

- **IRB Meeting Determination: Minor Modifications.** The IRB may stipulate specific revisions that would require simple changes, and concurrence or agreement by the PI in order to be approved. These stipulations must be clear enough so that the reviewer needs minimal judgment to determine whether the protocol, consent, advertisement, or other document was modified as requested by the IRB. (See SOP 406-IRB Determinations)

3.5 Documentation of Expedited Review

The Chair or designee may document the expedited review (initial, continuing review, modifications) by use of a checklist, and the checklist will become part of the IRB study file.

3.6 IRB Notification

When the expedited review procedure is used (initial, continuing review, amendment) all regular members of the IRB shall be informed of actions taken by the IRB at the next convened meeting. The expedited actions will be listed in the meeting agenda to notify members of actions taken.

4. RESPONSIBILITY

Chair or IRB Manager is responsible for identifying submissions that qualify for expedited review.

Chair, Manager or IRB designee is responsible for conducting and documenting expedited review on the appropriate checklists.
IRB Staff are responsible for providing a listing of expedited reviews performed to IRB members at convened meetings.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.110
45 CFR 46.102
21 CFR 56.110
FDA Information Sheets, 1998
OHRP IRB Guidebook

6. REFERENCED DOCUMENTS

HRP-313; Expedited Review Checklist
HRP-314, 314a, 314b; Criteria for Approval Checklist
HRP-312; Exempt and Limited IRB Review Checklist
HRP-315; Advertisements Checklist

Revision Number	Version Date	Approved By	Date Approved
02.0	4/03/2019	Avera Institutional Official	5/9/2019
• Changed the names of checklists used to be current • Updated applicable regulations			
01	August 2016	Director HSRP / August 2016	