1. PURPOSE

This procedure describes the requirements for the reviews that occur after initial research approval and prior to review for renewal of IRB approval.

2. PROCEDURE

It is the procedure of the Avera IRB to review all requests for amendments to previously approved research to determine if a change in the risk benefit ratio of the study has occurred, and review claims for exemption to determine whether that change now makes the study non-exempt.

PI may not initiate any changes in research procedures or consent/assent form(s) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the human subjects. In such cases as described above, the PI must notify the IRB within 72 hours.

3. SPECIFIC PROCEDURES

3.1 Definitions

Amendment: An Amendment is considered a follow-on submission to the IRB. This may be a change to a protocol, a change to an informed consent, a change to the study team working on the research, or any change to the study, an Unanticipated Problem, or protocol deviation.

3.2 Amendments

PI or designated study team members must submit requests for changes to the IRB in the computer program utilized by the IRB. Each amendment will include:

- Description of the changes.
- Reason for the change.
- Whether or not changes are required to the informed consent document. Specify if study sponsor requested participants to be re-consented.
- The impact the changes will have on the study and/or the participants.
- All appropriate documents, (if applicable).
- Revised informed consent (changes underlined or tracked), (if applicable)
- Sponsor correspondence concerning the amendment, (if applicable).
- Amended protocol (if appropriate), (if applicable).

3.3 Determinations and Full Board Review

Upon receipt of the amendment, the IRB Manager will determine if the revision meets the criteria for an expedited review, or if it needs to go to full board. If the amendment that was submitted is found to involve no more than minimal risk, or if it's a minor change in previously approved research during the period of 1 year or less for which approval is authorized, the then IRB may use expedited review procedure. If the change represents more than a minimal risk to human subjects, it must be reviewed and approved at a convened IRB meeting.

For an amendment to be considered more than minimal risk, the proposed change would increase risk or discomfort or decrease the benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented, unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an

immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant's continued welfare.

The review of amendments will be done by the Primary and Secondary Reviewers system using the "Criteria for Approval Checklist". The Primary and Secondary Reviewers will review the amendment in depth and all other members attending the meeting should review enough to discuss the information.

If possible, the prior Primary and Secondary Reviewers of the initial IRB submission will be assigned as the reviewers. All other members will receive all the materials.

Expedited Review
If the amendment is a minor change, involving no more than minimal risk to the human subject, it will be reviewed by the expedited review process and will be reported to the IRB on the next month's agenda. See SOP 401 Expedited Review.

Changes to Exempt Studies
The PI must inform the IRB of any changes to the scope or design prior to implementation to ensure that the study continues to meet the exempt criteria.

3.4 PI Notification
All approvals for requested revisions will be reported to the PI via e-mail.

4. RESPONSIBILITY
IRB Manager is responsible for determining expedited review or review by the convened IRB of the amendment.

IRB staff are responsible for providing IRB members with adequate information to complete substantive and meaningful review of the protocol amendment, protocol change, modification or revision.

Primary and Secondary Reviewers are responsible for the review of the amendment.

All other IRB members are responsible to review materials in enough depth to be prepared to discuss information at the convened meeting.

IRB Manager is responsible for the correspondence back to the PI pertaining to the amendment.

5. APPLICABLE REGULATIONS AND GUIDELINES
21 CFR 56.108, 56.109, 56.113
45 CFR 46.103, 46.109, 46.115
FDA Information Sheets IRB Continuing Review after Clinical Investigation Approval – February 2012

6. REFERENCED DOCUMENTS
HRP-314, 314a, 314b; Criteria for Approval Checklist

Revision Number	Version Date	Approved By	Date Approved
02.0	4/03/2019	Avera Institutional Official	4/8/19
• Added in the definition of amendment • Minor administrative updates			
01	August 2016	Director HSRP / August 2016	