1. PURPOSE

This procedure describes the actions the IRB may take resulting from its review of research.

2. PROCEDURE

As a result of its review, the IRB may decide to approve, approve pending minor clarifications and/or modifications back to the IRB office, or approve pending major clarifications and/or modifications back to the full (convened) board, disapprove or table the proposed research activity. Except when the expedited review procedure is used, these actions will be taken by a vote of a majority of the regular and alternate members present. When reviewed via expedited review, the Chair, or designee can take any of the following actions except to disapprove a study.

Approval Timeframe: Approval is generally one year, but may be given for a lesser period of time (less than one year) based on the relative perceived high level of risk to the subject population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study subject population.

3. SPECIFIC PROCEDURES

3.1 Determinations

The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

Approve: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Chair, or designee of the IRB and expire within one (1) year of the approval date, but not later than the day preceding the date of review.

Approvals are always conditional on conditions being met by the PI. The conditions for continued approval and the time frame (if any) within which they must be met will be clearly stated in the approval letter sent out through the IRB software system. If the conditions of the approval are not met, approval may be withdrawn.

Approve with conditions, Minor Clarifications and/or Modifications back to the IRB Office: Before the approval will be granted, the IRB will stipulate specific revisions that require simple clarifications, modifications, or agreement by the PI. 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.

Clarifications and/or modifications will be discussed and voted upon during the IRB meeting, as well as terms of approval, duration of approval, any other determinations that need to be discussed, and level of risk.

The IRB Manager, Chair or designee will review the information then re-submitted by the PI. If the designated IRB reviewer determines that the PI has not made the appropriate responses to the IRB's

request, the reviewer may request additional information from the PI, or send the response back for full IRB review at a convened meeting. Upon satisfactory review, approval will be issued.

Approval Periods**:**

- Approval Date: The approval date is issued as of the date that the requested information or materials are reviewed and found to be fully satisfied.
- Expiration Date: The expiration date will be maximum one year (minus one day) from the date the study submission materials were fully satisfied, e.g. May 2, 2019 to May 1, 2020.
- Human Subjects must not be recruited into the study until final approval has been issued.

Approve with Conditions, Major Clarifications and/or Modifications back to the full (convened) IRB Meeting: The IRB requests any additional information, any clarifications, or any modifications that *cannot* be described as specific revisions that require simple concurrence by the PI. The convened IRB must review the responsive materials. If the convened IRB approves the research based on the responsive materials, the following apply:

Approval period:

- The approval date is issued as of the date of the IRB meeting in which the study was fully approved.
- Expiration date: The expiration will be one year (minus one day) from the approval date, but may be given for a lesser period of time (less than one year) based on the relative perceived high level of risk to the subject population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study subject population.
- Human Subjects will not be recruited into the study until final approval has been issued.

Table**:** A study may be tabled when significant questions are raised by the proposal requiring its reconsideration after additional information is received from the PI and/or sponsor. A study may also be tabled if there is a loss of quorum during a convened meeting, or if the appropriate expertise is not available at the meeting. Study will be then reviewed at the next full (convened) IRB Meeting. Tabling cannot be given through the expedited review mechanism.

Disapprove: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB. Disapprovals should be rare and may occur in instances such as:

- The study is disapproved outright because the full board determines that the science is clearly inadequate, the resources to conduct the study are not available, or that the research is inappropriate. In the first case, the IRB may ask the PI to seek scientific review and redesign the project and submit a revised application for the project.

4. RESPONSIBILITY

IRB Staff are responsible for ensuring that all IRB decisions and actions are based on Avera and regulatory requirements.

Chair or co-chair are responsible for ensuring the appropriateness of all IRB decisions and actions.

The IRB Manager, or designee, will sign all approval letters as the official designee for the IRB.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111
45 CFR 46.109

6. REFERENCED DOCUMENTS

None

REVISION HISTORY

Revision Number	Version Date	Approved By, Date Approved
02.0	5/7/2019	Avera Institutional Official, 5/9/2019
• Changed wording from "Approval Withheld Pending . . ." to "Approved with Conditions . . ."		
• Approved with Conditions, Minor Clarifications or Modifications will only need to come back to the IRB Office for review.		
• Approved with Conditions, Major Clarifications or Modifications will need to come back to the full (convened) IRB meeting for review.		
• Further explained when a study may be tabled.		
• Further explained when a study may be disapproved.		
01	August 2016	Director HSRP / August 2016