1. PURPOSE

To provide the framework to ensure that IRB meetings are conducted and documented in a consistent manner in order to meet both federal and Avera requirements.

2. PROCEDURE

Except when an expedited or exempt review is acceptable, the IRB will review proposed research at convened meetings at which a quorum and appropriate expertise is present. The IRB will meet monthly, or at some other frequency determined by the Chair, Co-Chair(s) and the IRB Staff.

3. DEFINITIONS

Quorum: A quorum is defined as one half the number of regular members plus one, including at least one member whose primary concerns are in a nonscientific area and at least one member whose primary concerns are in a scientific area. If the IRB has an odd number of members, then the majority should be calculated by taking half of the total number of IRB members, and rounding up to the next whole number. For example, if the IRB membership is 15, then majority is 8 (half of 15 is 7.5, and rounding up to the next whole number is 8).

Licensed medical professional: An individual who has successfully completed a prescribed program of study in a variety of health fields and who has obtained a license or certificate indicating his or her competence to practice in that field. Examples of a licensed medical professional include, but are not limited to: physician, pharmacist (Pharm. D.), Physician's Assistant (PA), Doctor of Nursing Practice (DNP), and Certified nurse practitioner (CNP)

Majority of vote: A vote where more than half of the IRB members present cast their vote in favor of a motion to be carried.

Members (or consultants) considered present at the meeting: Determined by members being physically present, or attending via video or teleconference, or any other media that allows them to be a participant in the discussion by listening and being able to speak about any concerns or additions that they may have.

4. SPECIFIC PROCEDURES

4.1 Quorum

- An alternate member may attend in the place of an absent regular member.
- IRB members who leave the room due to a conflict of interest (COI) cannot be counted towards quorum and the IRB vote will reflect that IRB member as being recused.
- When the IRB reviews research that involves human subjects vulnerable to coercion or undue influence, at least one person (member or consultant) who is knowledgeable about, or experienced in working with such participants, must be present at the convened meeting. As noted above, attendance by video or teleconference, or other media, is acceptable.
- When FDA-regulated research is reviewed at a convened meeting, at least one IRB member who is a licensed medical professional must be present. (see definition above for 'members present')
- For research to be approved, it must receive the approval of a majority of the members present at the meeting. (see definition above for 'members present')
- If quorum is lost during a meeting, due to a required member (e.g. non-scientific) leaving the room, the IRB will not vote until quorum is restored, even if that means deferring the vote to the next meeting.

- Consultants will not be used to establish a quorum and may not vote with the IRB.

4.2 Recusal

IRB members with an identified COI on an IRB agenda item may be asked to leave the IRB meeting before the vote on the item with which they have a conflict. If they remain in the room, they can serve only as an informational resource for questions on the study. When this occurs, the member does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

4.3 Primary and Secondary Reviewers

Prior to the convened meeting, IRB staff will designate Primary and Secondary Reviewers for each research proposal needing to go to the full board, including continuations and amendments, according to their scientific or scholarly expertise. For all other reviews, such as expedited or exempt reviews, a single reviewer may complete the review.

If there are no IRB members with the appropriate expertise, an expert consultation will be arranged.
If a secondary reviewer is assigned for a full board review and is unexpectedly not able to attend the IRB meeting, the primary review is sufficient for review and approval, as long as quorum is met for the board and there is majority vote.
If there is not an appropriate scientific or scholarly reviewer (member or consultant) to conduct an in-depth review of the protocol, the protocol will be deferred to the next IRB meeting.

4.4 Meeting Materials Sent Prior to IRB Meetings

Every effort will be made to give all IRB members, including those attending by conference call, and alternates access to all required meeting materials within seven (7) days in advance of the meeting to allow time for adequate review. Refer to SOP 300-Submission Requirements for IRB Review for the list of materials to be submitted.

All members will have access to all the submission documents via the secured website the IRB is using. Each member is assigned a unique username and password to access specific meeting materials. All members may bring printed materials from the website or a laptop to the meeting.

Each member will receive an agenda, the agenda will list which members are assigned to be the Primary and Secondary Reviewers for each study that is to be reviewed.

4.5 Minutes

4.5.1. The IRB Staff or designee will record minutes of each meeting. This designee is required to have the following additional training before they can be delegated to record meeting minutes:

a. Read this SOP 301
b. Read OHRP & FDA Guidance document titled "Minutes of Institutional Review Board (IRB) Meetings"
c. Attend an IRB meeting and observe someone recording meeting minutes who has already been trained

d. Document the above training by completing Appendix A titled, "Training Documentation for staff taking minutes of an IRB meeting"

4.5.2. Minutes will be written in sufficient detail to show the following:

a. Meeting attendance including:
   i. Members or alternate members attending through teleconferencing; Documenting that those members have received all IRB materials in order for them to actively and equally participate in the discussion
   ii. Status of each attendee (regular member, alternate, consultant, etc.)
   iii. If applicable, alternate members and whom they are voting for
   iv. Names of members who recuse themselves due to conflicts of interest along with a notation if the member left due to a conflict
   v. Names of members abstaining to vote
   vi. Documentation of members leaving and re-entering
b. Actions taken by the IRB on each agenda item requiring full IRB action
c. Separate deliberations for each action
d. Voting results, including the number for, against, abstaining, and recusal due to a COI
e. The basis for requiring changes in research
f. The basis for disapproving of the research
g. Written summary of the discussion of controverted issues and their resolution
h. Justification of any deletion of substantive modification of information concerning risks or alternative procedures contained in the informed consent document
i. Determination of level of risk for the individual submission
j. For continuing reviews, determine the frequency of review for the approval period; whether protocols need to be reviewed more than annually for FDA regulated studies or studies that are more than minimal risk. Note: Studies that meet the criteria of expedited review and are not FDA regulated that were approved under the Revised Common Rule effective 1/21/19, no longer need annual continuing review.
k. Determinations required by the regulations, and protocol-specific findings justifying those determinations, for:
   i. Waiver of alteration of informed consent
   ii. Waiver of documentation of informed consent
   iii. Waiver of HIPAA authorization
   iv. Research involving pregnant women, human fetuses, and neonates
   v. Research involving prisoners
   vi. Research involving children as participants
   vii. The determination of significant risk/non-significant risk (SR or NSR) for device studies

4.5 Distribution of Minutes:

- Minutes must be written and available for review in a timely manner.
- Draft minutes will be distributed to IRB Chairs, Co-Chairs prior to the next IRB meeting for review. A quality check (QC) of the meeting minutes will also occur.

- Corrections requested by the IRB Chairs, Co-Chairs will be made by IRB Staff and the minutes will be made available to members. IRB Staff will maintain filed copies of the minutes, agenda and pertinent materials.
- Once approved by the IRB Chairs, Co-Chairs, meeting minutes will be distributed to members.
- If corrections are later determined to be needed to the minutes, the edited minutes will be sent to the IRB Chairs, Co-Chairs for approval. Once approved, the corrected minutes will be distributed to IRB members and filed.

4.6 Meeting Conducted Via Conference Calls

Meetings may be convened via a telephone conference call. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call to take place -- "telephone polling" (where members are contacted individually) will not be accepted as a conference call.

Members not present at the convened meeting, nor participating in the conference call may not vote on an issue discussed during a convened meeting (no voting by proxy).

4.7 Voting

After presentation of primary and/or secondary reviewers, and discussion among the IRB members, a motion is made, with a second, regarding the submission. Members of the IRB vote on the motion(s) made. IRB members also will determine level of risk, the frequency of review for each protocol, and that the criteria for approval have been met. A majority of IRB members must approve in order for the motion to be carried.

5. RESPONSIBILITY

Chair, Co–Chairs, and IRB Staff are responsible for IRB meeting procedural conduct and documentation. Chair, Co-Chairs, or Chair-designees are responsible for conduct and leadership of IRB meeting convened for review.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR Part 46
45 CFR Part 94
21 CFR Part 56
42 CFR Part 50 Subpart F
OHRP & FDA Guidance for Institutions and IRBS: Minutes of Institutional Review board (IRB) Meetings
Avera IRB Conflict of Interest Policy
NIH Guide – Objectivity in Research
OHRP COI Policy Draft

7. REFERENCED DOCUMENTS

SOP 300
Waiver of Documentation or alteration of informed consent and HIPAA
Waiver of Assent, Parental Permission and HIPAA
Waiver of Informed Consent and HIPAA

REVISION HISTORY

Revision Number	Version Date	Approved By Date Approved
03.1	7/17/2019	Avera Institutional Official 7/23/19
• Studies reviewed at the full board will have a Primary and Secondary reviewer assigned for each review. For all other reviews, such as expedited or exempt reviews, a single Primary reviewer may do the review instead of a Primary and Secondary reviewer. • Removed that 'rationale' be needed for determining whether device studies are Significant Risk (SR) or Non-Significant Risk (NSR). Just need to document SR or NSR for device studies. • Defined what a 'member present' entailed; can include telephone, video conference or other media.		
03	6/27/2019	Avera Institutional Official 7/9/19
• Added in language about how we handle revising minutes after they had already been approved and sent out to board.		
02	3/12/2019	Avera Institutional Official 3/19/19
• Added definitions of a Quorum, Licensed Medical Professional, and Majority. • The IRB members will receive required meeting materials 7 days in advance of the meeting, instead of 10 days. • Removed what will be reviewed at Original, Amendment, and Continuation submissions, because that is addressed in SOP 300. • Added in a section about the training the minute recorder must complete. • IRB Chairs or Co-Chairs will approve the minutes, instead of the whole board. • Updated applicable regulations		
01	August 2016	Director HSRP / August 2016