 Avera Institutional Review Board	Standard Operating Procedure Number: 600	Title: Communication
	Version: 2.0	Effective Date: 9/22/2020

1. PURPOSE

The procedure describes the IRB actions that must be communicated to the PI and the importance of open communication among IRB, PI, research team, HRPP staff and officials.

2. PROCEDURE

It is important that staff, human subjects, and other interested parties have a means of communicating information about the conduct of a research project. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within Avera. The researcher and his/her research staff interact with human subjects; therefore, it is vital that open and frequent communication with the investigative team be maintained.

3. SPECIFIC PROCEDURE

3.1 PI Notifications

Initial submission (full IRB): The PI and/or designated study team will be notified by e-mail of the IRB decision after the meeting. If the study is approved with conditions, clarifications and/or modifications back to the IRB, the IRB must receive the response within 60 days of the date of notification. Responses received after 60 days will be reviewed as a new initial review.

Determination of Human Subjects Research: Since the Avera IRB is required to review and approve all research at Avera involving human subjects, there are still some proposed projects that are not “research”, and/or are not with “human subjects”. Researchers may submit a completed form to the IRB to make this determination, and inform the researcher if IRB review and approval is necessary. If a researcher makes a submission to the IRB with the “Determination of Human Subjects Research” form, or a similar form, the IRB will notify the researcher by email what the IRB determination was, no later than 10 business days after the submission.


Exempt and Expedited: The PI and/or designated study team will be notified by e-mail of the decision as soon as possible after review of the project. If the study is approved with conditions, clarifications and/or modifications back to the IRB, the IRB must receive the response within 60 days of the date of notification. Responses received after 60 days will be reviewed as a new initial review.

Renewals and Revisions: PI and/or designated study team will be notified by e-mail as soon as possible as to the action taken by the IRB for any continuing reviews or revisions.

Notification of Final Approval: PIs will be notified by e-mail of the final approval. The IRB-approved consent form(s) will be stamped with the approval and provided to the PI and/or designated study team with the final approval letter.

Disapproval: Correspondence will provide the reason(s) for disapproval and instructions to the PI and/or designated study team for appeal of this decision.

Table: Correspondence will provide reason(s) for tabling and instructions to the PI and/or designated study team to respond to this decision.

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Expiration: If a project expires and the PI does not respond to continuation notices, a warning letter of expiration will be sent to the PI, with a request to respond back to the IRB within five (5) business days. If the PI does not respond in five (5) business days, the IRB will administratively close the study, and may not accept future research proposals from the PI or from students for whom he/she serves as advisor until all submitted research is current. Refer to IRB SOP 404 for additional information on studies that expire.

3.2 Investigator Appeal of IRB Action

A PI may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing, signed by the PI, and submitted to the IRB within 60 days of the date of the IRB Letter.

PI may also appeal an IRB decision to disapprove a study. Any such appeal must be in writing, signed by the PI, submitted to the IRB within 60 days of the date of the IRB Letter, and must be reviewed by the full IRB at a convened meeting. The PI may request, or be asked to attend, the convened IRB meeting.

In response to an appeal, the IRB may reverse its decision, table consideration in order to obtain more information, or affirm its original decision. If the appeal is denied, the PI's institution cannot override the IRB's decision. A declined appeal is final.

3.3 PI and IRB Communications

The PI and/or designated study team can call or e-mail the IRB or HRPP at any time with questions, concerns, or suggestions. All attempts will be made to respond to messages or e-mails within 48 hours, or two (2) business days.

4. RESPONSIBILITY

IRB Manager or staff is responsible for overseeing all IRB communications.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109,
 21 CFR 56.113,
 45 CFR 46.109,
 45 CFR 46.113

6. REFERENCED DOCUMENTS

None

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	7/14/2020	Avera Institutional Official	9/22/2020
<ul style="list-style-type: none"> Changed the DHSP to HRPP. General administrative edits. PI may appeal an IRB decision up to 60 days after the IRB letter is sent to the PI. Updated regulations. Referenced SOP 404 for procedures on expiration of research studies. 			
1.0	August 2016	Director HSRP / August 2016	