1. PURPOSE

This procedure describes the training and educational requirements for IRB members and IRB staff.

2. PROCEDURE

Training of IRB staff and IRB members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of human research subjects in a consistent manner throughout the Avera research community. IRB members, IRB staff and others charged with responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics, and policies applicable to human subject research.

3. SPECIFIC PROCEDURES

3.1 Training

3.1.1 IRB staff and IRB members who are overseeing human subject research, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an entity under the jurisdiction of Avera will receive initial and ongoing training regarding the responsible review and oversight of research. They will also have access to the full list of IRB procedures.

3.1.2 The IRB Manager and Executive Director of Research Compliance establish the educational and training requirements for IRB members and IRB staff.

3.1.3 IRB members will participate in initial and continued training in clinical research, and regulations specific to IRBs and research. The Chair will receive additional training in the duties required of a chair.

3.1.4 CITI training with affiliation thru Avera Research Institute will be required of all IRB staff and IRB members at least every three years. The minimum required modules which must be completed prior to serving on the IRB include:

- *IRB Human Subjects Research (HSR)*, and
- *Good Clinical Practice (GCP).*
- *Responsible Conduct of Research (RCR)* is encouraged to be completed, but not required.
- Chairs will also need to complete *IRB Chair, Manager, & Coordinator* training within CITI.

3.1.5 IRB staff will receive initial and continuing training in the areas specific to their responsibilities.

3.1.6 IRB members and IRB staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. Avera will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

3.2 Documentation

Training and continuing education will be documented and added to the IRB member personnel files. A database will be maintained by the IRB staff of CITI training and expiration dates.

3.3 Community Outreach

The Avera IRB provides information to the research community regarding the rights of a human research subject as a volunteer. The IRB encourages and promotes community outreach efforts through presentations and lectures whenever possible.

3.3.1 Procedure for Maintaining Community Outreach Efforts Offered

The IRB members or staff conduct trainings or make presentations upon request, with the assistance of the Executive Director of Research Compliance as needed.

4. RESPONSIBILITY

The IRB Manager is responsible for establishing, conducting and/or supervising all relevant training programs for IRB members and IRB staff. All training and education for staff, IRB members and outreach activities will be evaluated on an annual basis.

IRB Manager and Executive Director of Research Compliance are responsible for guiding the development of IRB member training programs.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107
45 CFR 46.107

Revision Number	Version Date	Approved By	Date Approved
2.0	10/2/2019	Avera Institutional Official	10/10/2019
• Changed all reference to the DHSP to instead be the IRB. • Added that the Executive Director of Research Compliance will work with the IRB Manager to determine the required training all IRB staff and IRB members must complete. • Specifically listed the CITI training that IRB members and IRB staff must complete. • Removed the information about researchers, as that part does not belong on this SOP, and is addressed in SOP 300.			
1.0	August 2016	Director HSRP / August 2016	