1. PURPOSE

The purpose of this procedure is to describe specific activities that require IRB review and approval.

2. PROCEDURE

When an investigator is engaged human subject research (as defined in this procedure), the research must be reviewed and approved by the appropriate Avera IRB, or other designated IRB if applicable.

An institution becomes engaged in human subject research when its employees or agents:

(1) Intervene or interact with living persons for research purposes, or

(2) Obtain individually identifiable protected health information ("PHI") for research purposes.

No intervention or interaction with human subjects in research, including recruitment or data collection of PHI may begin until the IRB has reviewed and approved the research protocol.

3. SPECIFIC PROCEDURE

3.1 Applicable Regulations and Definitions

There are Institutional Review Board meetings each month at Avera focusing on Health Science and Oncology. The IRBs review research in accordance with:

- FDA regulations;
- DHHS regulations or other Common Rule Regulations; and
- Any other applicable state or local regulations.

3.1.1 Definitions:

Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research.

Intervention (DHHS): Includes both physical procedures by which information or biospecimens are gathered (such as a venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes.

Interaction (DHHS): Includes communication or interpersonal contact between investigator and subject.

Not Human Subject Research: Activities that do not meet the definition of human subject research.

Private Information (DHHS): Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving subjects. This may include identifiable private information obtained from a primary subject about a third party.

Research (DHHS): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)). Under FDA regulations, research (clinical investigation) means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects.

The following activities also require IRB review and approval under FDA regulations:

- Emergency use of an investigational drug, device, or biologic under 21 CFR §56.104(c) and 21 CFR §50.23(c). See SOP 413.
- Humanitarian device use under 21 CFR §814.3(n) and 814.124. See SOP 505.

3.2 Determining if an Activity Meets the Definition of Human Subject Research

When the IRB receives a submission, the IRB needs to determine if the activity is human subject research. The IRB staff, Chair or designee will review the submission and determine if the study meets the criteria for human subject research. If the submission meets the criteria of human subject research, the study will be reviewed according to the applicable SOPs. If the submission does not meet the criteria of human subject research, the investigator will be notified.

If an investigator calls the office seeking guidance on whether the project is human subject research, the PI will be asked to provide a written description of the project. The reviewer will make a determination if the project meets the criteria of human subject research. The investigator will receive written notification once the review is complete.

3.3 Activities Requiring Review

All research conducted at Avera that meets the definition of human subject research as defined by DHHS and FDA, regardless of sponsorship, must be reviewed and approved, or determined to be exempt by an IRB. The Avera IRB may designate another IRB to serve as the reviewing IRB.

An IRB must review all human subject research if one or more of the following apply:

1) The research is funded by Avera;
2) The research is conducted by or under the direction of any employee, staff, student, or representative of Avera in connection with his/her institutional responsibilities, without regard to the location of research;
3) The research is conducted by or under the direction of any employee of Avera using any of its property or facilities;
4) Avera receives a direct award and or contract to conduct human subject research by the federal government, even where all activities involving human subjects are carried out by a subcontractor or collaborator; and/or

5) The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (OHRP) in which the Avera IRB is designated as the IRB of record through an established IRB Authorization Agreement.
6) Student/Nursing/Resident research that is conducted using Avera PHI or resources, meets the definition of human subject research, and that are conducted by students for work toward a degree or a resident.

No human subject research, including intervention, interaction, collection of private identifiable information, administration of test articles, advertising, recruitment, or screening, may begin until the Avera IRB has reviewed and approved the research, issued an exempt determination, or accepted the oversight of an external IRB of Record.

3.4 Failure to Submit Human Subject Research for IRB Review

The implications of engaging in activities that qualify as research that is subject to IRB review without obtaining such review are significant. Results from such studies may not be published unless IRB approval was obtained prior to starting any study-related activities. To do so is in violation of Avera Policy and applicable regulations.

Failure to obtain IRB approval or an exempt determination from the IRB is considered non-compliance. Instances of non-compliance are taken seriously. IRB actions taken will be commensurate with the level of risk to human subjects. Please refer to SOP-407 for specific procedures dealing with non-compliance.

The IRB will not grant post-hoc approval for research conducted without prior IRB review and approval.

The IRB will not grant post-hoc exempt or not-human-subject-research determinations for research already conducted at the time of the determination request.

4. RESPONSIBILITY

IRB staff, IRB Chair or designee is responsible for determining whether research activities require IRB review.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102
21 CFR 50, 56, 312, 812

Revision Number	Version Date	Approved By	Date Approved
2.0	10/11/2019	Avera Institutional Official	11/1/19
• Cleaned up the definitions area to be true definitions. • Took out the listing of exact types of research that need IRB review, and made it more general. • Other administrative edits as needed.			
1.0	August 2016	Director HSRP / August 2016	