A. Governing Principles

Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research"). These principles are defined in the Belmont Report as summarized below:

- **Respect for Persons** - Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. Respect for persons is manifested in the informed consent process in which potential subjects are provided information about the study in a manner understandable to them and then allowed to choose whether or not they wish to participate.

- **Beneficence** - Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. Beneficence requires that investigators and IRB members engage in an analysis of the risks and benefits to the subjects, making sure that the anticipated risks are relative to the potential benefits. Risk should be minimized as much as possible.

- **Justice** - Justice requires that the benefits and burdens of research be distributed without bias. The principle of justice directs us that subjects should not be chosen simply because they are available and easy to influence. In addition, it requires that subjects who are likely to benefit from a study should not be excluded.

B. Authority

Jurisdiction of the Avera Institutional Review Board applies to all biomedical or behavioral research, development or related activities or projects involving human subjects and carried out or conducted by individuals affiliated with Avera facilities.

The IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. Specifically, the IRB:

- Will review all research projects involving human subjects before the involvement of human subjects may begin;
- May disapprove, modify or approve studies based upon consideration of human subject protection aspects;
- Reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
- Has a mechanism in place for prompt reporting of any planned changes in approved projects prior to the implementation of those changes;
• Has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the investigators and auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
• May suspect or terminate approval of a study;
• May place restrictions on a study for the purpose of subject protection.

The IRB is established to review biomedical and behavioral research involving human subjects regardless of the source of funding and location of the study. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46 Section 101(b)(1-6) or 101(i), all research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, are subject to these policies and procedures if one or more of the following apply:

• The research is sponsored by institutional authorities and/or;
• The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the Institution in connection with his or her institutional responsibilities and/or;
• The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the Institution using any property or facility of the Institution and/or;
• The research involves the use of the Institution's nonpublic information to identify or contact human research subjects.

C. Responsibility

1. IRB Review of Research

All research involving human subjects (as defined below), and all other activities, which even in part involve such research, regardless of sponsorship, must be reviewed and approved by the Institution's IRB(s). No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of "research" or "human subjects," and their implications for the jurisdiction of the IRB under Institutional policy are determined by the IRB.

It is the IRB's purpose and responsibility to protect the rights and welfare of research subjects. The IRB reviews and oversees such research to ensure that it meets well-established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonisation.

According to federal regulations, the activities that require IRB review include any activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual must be reviewed by the IRB. Specific activities that require IRB review include, but are not necessarily limited to, the following:

• Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (FDA)
under relevant investigational drug or medical device provisions of the Food, Drug, and Cosmetic Act, or experiments that need not meet the requirements for prior submission to the FDA, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

- Collection of data about a series of standard procedures or treatments for dissemination or generalization.
- A patient’s care of assignment to intervention is altered for research purposes in any way.
- A diagnostic procedure for research purposes that is added to a standard treatment.
- Systematic investigation involving innovative procedures or treatments; for example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to the standard treatment.
- Emergency use of an investigational drug or medical device. Note that when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject, and data generated from such care cannot be included in any report of a research activity.
- Human cell or tissue (genetic tissue) research that typically involves repositories that collect, store and distribute human tissue materials for research purposes. However, human cell and tissue repositories activities do not require IRB review if material submitted to the repository satisfies both of the following conditions: (1) The material, in its entirety, was collected for purposes other than submission to the repository (e.g., the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no “extra” material collected for submission to the repository); and (2) The material is submitted to the repository without any identifiable private data or information about the living individual (i.e., no codes or links of any sort may be maintained, either by the submitter or the repository) that would permit access to identifiable private data or information about the living individual from whom the material was obtained.
- Investigator-initiated research, where an investigator both initiates and conducts, alone or with others, a clinical trial. In the case of investigator-initiated studies, it is the investigator’s responsibility to keep the IRB informed of unanticipated non-serious research-related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the Institution’s IRB is not the IRB of record. The IRB recommends that an independent data safety monitoring board (DSMB) review all reportable adverse events and the DSMB reports are forwarded to the IRB in addition to individual reports.
- Student-conducted research, which includes all activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree, must be reviewed by the IRB. These activities include: (1) All master’s theses and doctoral dissertations that involve human subjects; and (2) All projects that involve human subjects and, for which, findings may be published or otherwise disseminated.
- Case studies, such as when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases. Such activity constitutes research that must be reviewed by the IRB. Additionally, this type of activity must always be reviewed by the IRB when there is intent to publish or disseminate the data or findings.
2. Failure to Submit a Project for IRB Review

The consequences 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 had been obtained prior to collecting the data. To do so is in violation of Institutional policy. It is also against Institutional policy to use those data to satisfy thesis or dissertation requirements. If an investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the investigator should submit a proposal to the IRB for review as soon as possible. If the IRB does not approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be published. Furthermore, the FDA may reject such data if it is submitted in support of a marketing application.

3. Confidentiality

The IRB members understand and agree that information disclosed orally or in written form, or discussed at the meeting may include confidential information that is proprietary to commercial entities sponsoring the proposed research and/or involves the privacy rights of individuals.