Office/Contact: Office of Research Assurance and Sponsored Programs
Source: Federal Policy for the Protection of Human Subjects (also referred to as the Common Rule) – codified at 45 CFR 46, Protection of Human Subjects, Subparts A-D; SDBOR Policy 4.8.1
Link: https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html; https://public.powerdms.com/SDRegents/documents/1726703
Associated Forms: University Human Subjects Approval Request; Research Misconduct Allegation Steps

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SOUTH DAKOTA STATE UNIVERSITY
Policy and Procedure Manual

SUBJECT: Protection of Human Subjects
NUMBER: 8:7

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1. Purpose

   This policy sets forth the guidelines for research involving human subjects at the University, as overseen by the University Human Subjects Committee ("the Committee") and University experts.

2. Definitions

   The following definitions, taken from the Common Rule (45 CFR § 46.102), shall apply to this policy:

   a. Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following are not research: scholarly and journalistic activities, authorized public health surveillance activities, authorized collection and analysis of information or biospecimens for a criminal justice agency, and authorized operational activities in support of intelligence or other national security missions.

   b. Human Subject: a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

   c. Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3. Policy

a. At the University, the guiding principles for the protection of human research participants will be based on the Belmont Report. The Belmont Report establishes three basic principles essential when conducting any human research:

i. Respect for persons: individual autonomy through informed consent, and protection for those with reduced autonomy;

ii. Beneficence: through the maximization of benefits and the minimization of harm; and

iii. Justice: through an equal selection of subjects and a sharing of risks and benefits.

b. In accordance with National Institutes of Health (NIH) policy, all University personnel listed on an application as investigators (key personnel) conducting human subjects research that is supported by NIH funds are required to complete required education in the protection of human research participants. Although the scope of the policy is limited to research supported by the NIH, to adequately protect all human subjects in research, the University extends the NIH mandate to all research. The training module chosen by the University is an on-line training program for researchers developed by the Collaborative Institutional Training Initiative (CITI), found at the following website: https://www.citiprogram.org.

c. All University personnel are required to submit the *University Human Subjects Approval Request* when conducting research involving human subjects, and must have successfully completed the required education in the protection of human research participants.

d. To ensure equal and adequate protection of human research participants and to apply this policy uniformly, all research conducted at the University regardless of funding source shall fall under this policy. In general, the University will apply 45 CFR 46, Subpart A (the Common Rule) as well as Subparts B, C and D to all research, with the following exception:

i. Class activities/classes designed to teach research methods, where the purpose is research training, the results will not be disseminated outside of class, and the participants are clearly informed that the activities are an instructional exercise only. For in-class research methods/training and research projects excluded from review, faculty are strongly encouraged to incorporate materials found at the University Human Subjects website into their classroom activities. Instructors should consult with the Research Integrity and Compliance Officer (RICO) or Committee Chair if any research may be considered greater than minimal risk.

e. Activity that does not meet the Common Rule definition of research, or research deemed not to be using human subjects, will be approved as not human subjects research and is excluded from this policy. It is strongly recommended that all activities that may include human subjects research be brought to the Chair of the Committee or RICO for initial review.

f. Research involving human subjects that falls under the categories of research enumerated in 45 CFR § 46.104 will be deemed to be exempt from the Common Rule. Principal

investigators (PIs) may not make a unilateral determination of a project's exempt status and must submit a protocol or research materials for review. A single trained individual—either the Chair of the Committee or a designee will make the determination as to exempt status. This individual may call on others to provide additional guidance, as needed. If a proposal is determined to be exempt from the Common Rule, no continuing review will be required, except that the PI must report any proposed changes to the protocol (such as those that may change the activity so it is no longer exempt) and report any unanticipated or anticipated but serious adverse events.

g. For research involving no more than minimal risk that appears on the Federal Register list of categories, or for minor changes to previously approved research, or research for which limited review is a condition of exemption, an expedited review process may be followed, in accordance with 45 CFR § 46.110. At the University, expedited review will consist of review by up to three members of the Committee for new protocols, for continuing review, modifications to a protocol, or to accept research approved by another institution's Institution Review Board. The level and scope of review will be equivalent to the level of review carried out during full Committee review. Under expedited review, the reviewers may agree to approve, approve with modifications, request a resubmission of the protocol, or refer the protocol to the Committee. A protocol may not be disapproved using expedited procedures. All actions approved using expedited review shall be presented at the following Committee meeting for information, discussion and/or further review.

h. The work of carrying out the review of non-exempt and non-expedited research falls to the Committee. In keeping with the Common Rule, the Committee shall consist of no fewer than five individuals, including one individual whose interests are primarily non-scientific and one individual not affiliated with the University, except for service on the Committee. The Committee shall choose an individual as Chair, and in the absence of the Chair, designate an individual to preside over a meeting on his or her behalf.

    i. The Chair shall convene and preside over meetings, arrange for initial review in order to rule protocols as exempt or arrange for using expedited procedures as outlined in the Common Rule. The chair may call upon other reviewers from within the Committee or non-voting, ad hoc reviewers (consultants) as necessary, to assist in initial and in expedited review.

    ii. The RICO shall serve as a member of the Committee, will provide overall administration, assist in initial and continuing review as directed by the Chair, assist in making determinations for exempt and expedited applications, and will coordinate Committee activities with other compliance activities and committees as needed. In addition, the RICO shall be responsible for overseeing the training of the Committee, will assist the Institutional Official (IO) (i.e. Vice President for Research and Economic Development or designee) in filing annual updates and other reports to the Department of Health and Human Services (HHS), and will monitor federal and state regulations and suggest revised policies and procedures to remain in compliance with those regulations.

    iii. The Administrative Assistant to the Committee shall assist in scheduling meetings and arranging for meeting space, take minutes in conformity with Office of Human Research Protections (OHRP)/Food and Drug Administration (FDA) guidance and Robert's Rules of Order, and assist in maintaining records.

1. These records shall include all information required by 45 CFR § 46.115, including a current roster of all Committee members with detailed information per 45 CFR § 46.108(a)(2), files of all projects, and records of all correspondence between the PI and Committee. Files of projects should contain, at a minimum, the date the application for approval was submitted, the application and any related correspondence (including revised applications), a description of the location of the research activity, and review and oversight action and determination documentation (recorded in addition to a reference to the action or determination in the meeting minutes). Files shall be destroyed three (3) years after the close or completion of the project.

2. The minutes should contain a list of all of the individuals attending the meeting, including non-members, and should be actively updated throughout the meeting to reflect that a quorum does or does not exist at any given time; the number of members voting for, against, or abstaining on all votes; a description of each action taken by the Committee and the date of approval and the approval period, if applicable; the basis given for suspension or termination of approval, or changes in the research, if any; and a summary of the discussion on each matter.

iv. Committee members will have varying backgrounds with respect to experience, gender, race, culture, and sensitivity to community attitudes. Committee composition shall also be structured to reflect the types of research generally conducted at the University. Should the Committee regularly review research involving human subjects that are vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making, individuals who are impoverished or lack education), consideration shall be given to appointing members with experience in working with these individuals.

v. Committee members shall generally be appointed to three year terms. Committee member terms will be staggered in order that continuity can be maintained. Committee members may be reappointed to additional terms, as needed, and if willing to continue service.

vi. The Committee, through the Chair or other designees, may seek the advice of experts in other disciplines or vulnerable populations to review protocols on an ad hoc basis as necessary. These individuals shall not have voting privileges.

i. The Committee shall meet as necessary to conduct business. Minutes of the previous meeting and materials for review will be made available to each member at least three (3) full days prior to the meeting. A quorum, which shall consist of a simple majority (over half of the Committee) will be required to be present to review research. The quorum must include one member whose interests are primarily scientific, and one member whose interests are primarily non-scientific. Members with a conflict of interest (recusing themselves from the committee's discussion, vote and subsequent action) and non-voting members may not be counted toward a quorum. Specifically, members with a conflict of interest in a project must disclose the nature of the conflict on the record prior to any conduct of Committee business on the project, and thereafter may not participate in the Committee's initial or continuing review of the project, including any discussion by the Committee on the project, except to provide information requested by the other

members of the Committee. Members may participate via video or teleconferencing. The minutes of the meeting shall be made available to authorized representatives of the FDA and OHRP upon request.

j. At a minimum, Committee review (per the Common Rule) will ensure that:

   i. Risks to subjects are minimized by: (1) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and (2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

   ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result;

   iii. Selection of human subjects is equitable;

   iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR § 46.116;

   v. Informed consent will be appropriately documented or appropriately waived, with the rationale for the waiver properly recorded in accordance with and to the extent required by 45 CFR §§ 46.115 and 46.117;

   vi. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

   vii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

   viii. Additional considerations for vulnerable populations (e.g., those likely to be vulnerable to coercion or undue influence) are evident, as needed; and

   ix. The researcher is adequately trained and qualified.

k. A protocol under review shall be deemed approved by the Committee if accepted by a majority of those voting members present. The Committee may condition approval subject to modifications to the protocol. These modifications may be provided electronically or in writing; the Chair or a designee shall determine if the modifications follow Committee requirements. The Committee may require the resubmission of a protocol before action is taken, or may disapprove the research, with detailed comments/reasons for disapproval provided to the PI. The PI may appeal the decision for disapproval to the committee.

l. Any changes in protocols shall be reported to the Committee electronically or in writing prior to initiation, using forms approved by the Committee. The Chair, or designee, will make a determination as to accept the change using expedited procedures or through Committee review, in accordance with the Common Rule. The only exception to this requirement shall be when an investigator initiates a change to eliminate apparent immediate hazards to the subject. Unexpected or serious adverse events shall be reported

to the Committee by the PI.

m. Projects that require full Committee review and/or are FDA-regulated will be approved for up to one (1) year, unless the Committee determines that the level of risk necessitates more frequent review. PIs shall request an extension using the form approved by the Committee that provides information on the status of the project (including information such as percent complete, not yet started, ongoing, temporarily stopped) and certifying that no changes have been made. Continuing review will use full Committee review or expedited procedures, in accordance with the Common Rule and any appropriate guidance documents. Continuing review is not required for research that has progressed to the point that it involves only one or both of the following:

    i. Data analysis, including analysis of identifiable private information or identifiable biospecimens; or

    ii. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

n. The Committee may conduct or direct others to conduct random audits of any approved project or laboratory facilities for the purposes of post-approval project monitoring or continuing review.

o. The Committee is authorized to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the Committee's action and shall be reported promptly to the PI, IO, and the Federal sponsor. Such adverse events and all issues of noncompliance with the Committee's requirements, Common Rule or any other federal, state or local law or SDBOR/University policy must be reported to the IO by the Committee within two (2) working days of the Committee's knowledge of the issue.

p. During the process of initial or continuing review of an activity, material provided to the Committee shall be considered privileged information and the Committee shall assure the confidentiality of the data contained therein.

q. The IO is responsible for seeing that an organization maintains institutional compliance. The IO shall maintain registration with HHS; help identify and, upon consultation with others, appoint individuals to the Committee; review allegations of research non-compliance; recommend disciplinary action to the University President; and report, as the University President's designee under SDBOR Policy 4.8.1, any disciplinary actions to be taken as a result of non-compliance. Upon consultation with the Chair and other individuals, the IO shall see that all members of the Committee are properly trained and knowledgeable in administrative and substantive issues that would come before the Committee. The IO will also ensure that sufficient resources, space, and staff are available to support the Committee's review and record keeping duties. The IO may review Committee decisions, impose additional modifications or disapprove research activity approved by the Committee. The IO or any other official may not approve research that the Committee has disapproved.

r. The PI is responsible for full compliance with the Common Rule and this policy. Some of these responsibilities include:

   i. Consulting with the Chair of the Committee or RICO to determine if a project falls under this policy;

   ii. Submitting a human subjects protocol and application for approval;

   iii. Ensuring that all other key personnel are trained and have completed required education in the protection of human research participants;

   iv. Following approved protocols and notifying the Committee of any changes to the research or informed consent prior to making changes;

      1. The only changes that can be made without prior consent are those necessary to eliminate apparent immediate hazards to the subjects);

   v. If conducting a Federally-sponsored clinical trial, posting one Committee-approved informed consent form used to enroll subjects on ClinicalTrials.gov, or other designated publicly available Federal Web site, as required by 45 CFR § 46.116(h)(3).

   vi. Immediately filing a report of any unanticipated problems or anticipated, serious adverse events; and

   vii. Reporting on the progress of the research and filing all necessary project extension requests.

s. All faculty and staff may serve as PIs. The Committee may consider the experience and training of the individual as part of its review, and if deemed necessary, may recommend training above and beyond the required education in the protection of human research participants. Students may serve as PIs, but all must name a faculty member as co-investigator/advisor on the application.

t. The Committee, through the RICO or the Chair, shall promptly report actions taken at meetings to PIs. The reporting shall be done electronically or in writing, and shall consist of either an approval document, request for minor changes to a protocol followed by an approval document, request for major changes and/or resubmission of a protocol in order to secure approval at a subsequent meeting, or notification that a protocol has been disapproved, with reasons for disapproval. This information will be communicated to the PI in a timely manner, generally within five (5) working days following a meeting.

u. The University will be kept informed of Committee actions through periodic reports to the IO. Issues necessitating immediate notification to the IO, such as adverse events or noncompliance, will be provided to the IO generally within two (2) working days. Written Committee minutes will be provided to the IO at the same time they are provided to the Committee. The Committee website will be used to provide additional information to the University regarding human subjects protection issues. Other informational items will be provided to the University community using University means of communications, electronic mail, InsideState or MyState Online.

v. In accordance with the Common Rule and federal policy and guidance, the University, through the IO, will promptly report to the appropriate federal agency officials any of the following when the activity involves the use of federal funds:

i. Unanticipated problems involving risks to subjects or others;

ii. Serious or continuing noncompliance with federal regulations or the requirements or determinations of the Committee; and

iii. Suspension or termination of Committee approval.

w. The University may serve as a point of review of human subjects research for other organizations. These organizations must first sign a memorandum of understanding agreeing to abide by the decisions of the University Human Subjects Committee. A fee may apply. Cooperative research projects will rely upon a single Institutional Review Board designated by the Federal sponsor.

x. When a researcher is alleged to be in noncompliance with the Common Rule or any other federal, state or University regulations, the RICO will review the allegation and recommend action to be taken if noncompliance is found. Such action may include verbal or written warnings, the suspension of research activities until all appropriate administrative activities have been corrected or completed; re-inspection to substantiate the facility/laboratory is subsequently in compliance; and the referral of the noncompliance issues to the Department Chair, Dean, and the IO. Allegations of conduct rising to the level of academic misconduct per SDBOR Policy 4.8.1 shall be reported and processed in compliance with SDBOR Policy 4.8.1 and the *Research Misconduct Allegation Steps.* In either case, the University President, upon consultation with other officials as necessary, shall have decisional authority as to disciplinary action.

4. Responsible Administrator

The Vice President for Research and Economic Development, successor, or designee is responsible for the annual and ad hoc review of this policy. The University President is responsible for approval of modifications to this policy.

SOURCE: Approved by President on 09/16/2014. Revised; Approved by President on 02/13/2019. Revised 01/31/2024 (clerical).