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Use of Human Subjects in Research at DSU
(Institutional Review Board)

Policy

Federal policies for the protection of human subjects require that Dakota State University and its employees protect the rights and welfare of human participants in research. To comply with these regulations, all faculty, staff, and students who plan to use human participants in research must have prior approval from the Dakota State University Institutional Review Board (IRB). The IRB serves as the administrative and oversight body established to protect the rights of human beings in research endeavors as directed by the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm). Based on recommendations in the Belmont Report, federal rules require the development of an Institutional Review Board for the protection of research endeavors involving human subjects, and in particular, research for which institutions receive federal funding. The IRB at Dakota State University ensures that human subjects used in any research activity, in any capacity, are adequately protected, as is governed by federal law. The *Federal Policy for the Protection of Human Subjects*, also referred to as the Common Rule, has been codified at 45 CFR 46 Protection of Human Subjects, Subparts A-D and can be found on the Office of Human Research Protection (OHRP) website: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

Jurisdiction of the IRB at Dakota State

All research involving human participants conducted by Dakota State University (DSU or this institution) faculty, staff, or students requires the approval of the IRB. All projects must be fully approved before any use of human participants occurs.

A proposed activity will be considered under the jurisdiction of the IRB if any of the following are true:

1. The research is sponsored by this institution.
2. The research is conducted by or under the direction of any employee or agent of this institution:
    a. In connection with his or her institutional responsibilities, or
    b. Using any property or facilities of this institution.
3. The research involves the use of this institution's non-public information to identify or contact human research subjects or potential subjects.

What qualifies as research?

For this document the following definitions, taken from the Common Rule shall apply.

Research means 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.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information

Minimal risk means that 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 (Source: 45 CFR Part 46.102).

Guiding Principles

At DSU the guiding principles for the protection of human research participants will be based on the Belmont Report (http://ohsr.od.nih.gov/guidelines/belmont.html). The Belmont Report establishes three basic principles essential when conducting any human research:

1. **Respect for persons**: individual autonomy through informed consent, and protection for those with reduced autonomy
2. **Beneficence**: through the maximization of benefits and the minimization of harm
3. **Justice**: through an equal selection of subjects and a sharing of risks and benefits

Scope

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

Class Activities / Classes

The Institutional Review Board (IRB) for the Protection of Human Subjects provides flexibility in the level of review for class activities /student research projects.

Class Activities that Do Not Require Application for IRB Review

Student research projects that meet the definition of classroom research/student research may be conducted under the supervision of the faculty member without submitting a protocol to the IRB.

To be defined as classroom research/student research, a project must meet ALL of the following conditions; the project:

a. is a normal part of the student's coursework

b. is supervised by a faculty member

c. has as its primary purpose the development of the student's research skills

d. meets all the criteria for an Exempt or Expedited Review as defined in the IRB Guidelines

e. does not present more than minimal risk to participants or to the student investigator

f. does not include any persons as research subjects under the age of 18

g. does not include any persons as research subjects who are classified as protected populations or sensitive subjects according to Federal regulations

h. does not involve sensitive, personal, or incriminating topics

i. does not include any activity that is a clinical investigation or involves medical intervention or procedures, even when they are a part of a course curriculum, because this always constitutes human subjects research and requires prior IRB review and approval.

j. will not be presented at local, state, national or international conferences, published, used for thesis/dissertation projects, or otherwise disseminated beyond the classroom.

If a student believes they may wish to present or publish their work at a future point, the student must submit a regular IRB protocol and have it reviewed prior to beginning research. The IRB cannot approve projects after the fact.

If the faculty member has concerns or doubts, he/she should consult with the Compliance Coordinator or the chair of the IRB. The faculty member or student researcher may request a formal review by the IRB of any student research project prior to beginning the research project.

Faculty Responsibilities

1. Faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics, and practice of protecting human subjects in research; to adhere to these principles during the conduct and supervision of classroom research projects; and to teach these practices and principles to students. Faculty will be responsible for ensuring that all student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research.

2. Faculty who supervise classroom research projects must complete the CITI Computer-Based Training module located on the web at http://www.citiprogram.org.

3. Information about classroom research projects must be forwarded to the Compliance Coordinator before any research is conducted. Information should include the professor's name, the course name and number, the names of all the students completing a classroom project, the titles of all research projects that will be conducted as classroom research, and a two-three sentence description of each project. Additionally, the faculty member should attach their CITI completion certificate.

4. Educational programs and training sessions about the protection of human subjects in research are offered to faculty, staff and students. Members of the IRB are available to provide advice and consultation to university researchers as questions arise. Contact the IRB@dsu.edu for additional information.

Required education in the protection of human research participants:

All DSU personnel listed on an application as investigators conducting human subjects research are required to complete education in the protection of human research participants – prior to beginning the study. Moreover, all members of the DSU IRB are required to complete such training. The training module chosen by DSU is an on-line training program for researchers developed by the Collaborative Institutional Training Initiative (CITI), found at http://www.citiprogram.org.

Roles and Responsibilities

Principal Investigator:

The principal investigator (PI) is the "first line of defense" in all research. On behalf of the institution, the Principal Investigator is responsible for full compliance with the Common Rule and these DSU policies and procedures. These responsibilities include:

- Submitting a human subjects protocol and application for approval;
- Ensuring that all key personnel are trained and have completed required education in the protection of human research participants;
- Following approved protocols and notifying the IRB of any changes to the research or informed consent prior to making changes (the only changes that can be done without prior consent are those necessary to eliminate apparent immediate hazards to subjects);
- Immediately filing a report of any unanticipated problems or anticipated, serious adverse events; and
- Reporting on the progress of the research and filing all necessary project extensions.

All faculty and staff may serve as principal investigators. The IRB 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 principal investigators, but must name a faculty member as co-investigator/advisor on the application. The faculty member will be ultimately responsible for compliance with this and related policies.

Institutional Official:

The responsibility for seeing that an organization is in institutional compliance falls to the Institutional Official (IO). The IO shall maintain registration with HHS, help identify and upon consultation with others appoint individuals to the IRB, review, recommend and report any disciplinary actions taken as a result of non-compliance. Upon consultation with the chair and other individuals, the IO shall see that all members of the IRB 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 IRB's review and record keeping duties. The Dean of Graduate Studies and Research will serve as the Institutional Official.

Compliance Coordinator:

The Compliance Coordinator will provide overall administration, assist in initial and continuing review, assist in making determinations for exempt and expedited applications, and will coordinate IRB activities with other compliance activities and committees as needed. In addition, the Compliance Coordinator shall be responsible for overseeing the training of the IRB, will assist the IO in filing annual updates and other reports to HHS, and will monitor Federal and state regulations and suggest revised policies and procedures to remain in compliance with those regulations. The Compliance Coordinator will provide administrative support to the IO by scheduling meetings of the IRB, arranging for meeting space, taking minutes and maintaining records. The Director of the Office of Sponsored Programs shall serve as the Compliance Coordinator.

Chair of the IRB:

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 the initial and expedited review.

Institutional Review Board:

The work of carrying out the review of non-exempt research falls to the Institutional Review Board.

Composition of the Institutional Review Board

Size and Composition:

In keeping with the Common Rule, the DSU IRB shall consist of no fewer than five individuals, including one individual whose interests are primarily non-scientific and one individual not affiliated with DSU, except for service on the IRB. The Board shall choose an individual as chair, and in the absence of the chair, designate an individual to preside over the meeting on her/his behalf.

Board members will have varying backgrounds with respect to experience, gender, race, culture, and community experience. Board composition shall also be structured to reflect the types of research generally conducted at DSU.

Term of Service:

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

Consultants/ad hoc reviewers:

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

Meetings

The IRB shall meet as necessary to conduct business, generally once per month during the academic year and once over the summer term if schedules permit. Minutes of the previous meeting and materials for review will be made available to each member at least three full days prior to the meeting. If there is no business to discuss, the purpose of the meeting may be for training or review of policies and procedures. A quorum, which shall consist of a simple majority (over half of the IRB) will be required to conduct all business. The quorum must include one member whose interests are primarily scientific, and one member whose interests are primarily non-scientific. Non-voting members may not be counted toward a quorum. Members may participate via video or teleconferencing.

Minutes and Records:

A current roster of all IRB members will be kept on file. Members meeting specific requirements as required by the Common Rule will be identified in the roster.

Paper files of all projects shall be kept, as well as electronic backups. Records of all correspondence between PI and IRB or chair shall be kept. Files shall be destroyed three years following the close/completion of the project.

Minutes shall be kept and made available to the IO and HHS or other agency officials, upon request. Minutes shall generally conform to Roberts Rule of Order and include the following:

- Date, time and place of meeting
- Those in attendance
- Approval of previous meeting's minutes
- Movement from open to closed sessions
- Motions/including outcomes, and abstentions
- Other major points of order
- Adjournment

In addition, the level of discussion included in minutes shall include sufficient detail for others to ascertain the nature of discussion and conclusion reached.

Levels of Review

Excluded from the policy:

All research projects involving human subjects require the submission of a Human Subjects Application except where already exempted by OHRP ruling. Upon review of the application, activity that does not meet the Common Rule definition of research, or research deemed not to be using human subjects will be deemed as excluded from this policy.

Exempt:

Research involving human subjects that falls under the six categories of research enumerated in 45 CFR 46, 101(b) will be deemed to be exempt from the Common Rule. Principal investigators may not make a unilateral determination of a project's exempt status and must submit a protocol for review. A single trained individual – either the compliance officer, the chair, or his/her 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 ongoing review will be required, except that the investigator 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.

Expedited:

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, an expedited review process may be followed in accordance with 45 CFR 46.110. At DSU, expedited review will consist of review by three members of the IRB for new protocols, or by one to three members for continuing review, modifications to a protocol, or to accept research approved by another institution's IRB. The level and scope of review will be equivalent to the level of review carried out during full IRB 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 full IRB. A protocol may not be disapproved using expedited procedures. Instead, protocols that are not approvable using expedited procedures will be subject to full board review. All actions approved using expedited review shall be presented at the following IRB meeting for information and discussion.

Full IRB review:

Research involving human subjects that is not exempt from the policy and does not meet criteria for expedited review will be reviewed at a duly convened IRB meeting.

At a minimum, Board review (per the Common Rule) will ensure that:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 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.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, or waived when appropriate, in accordance with and to the extent required by 45 CFR 46.116.

- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Additional considerations for vulnerable populations are evident, as needed.
- The researcher is adequately trained and qualified.

A protocol shall be deemed approved if accepted by a majority of those voting members present. The Board may condition approval subject to modifications to the protocol. These modifications may be provided electronically or in writing; the chair or his/her designee shall determine if the modifications follow Board requirements. The Board 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 investigator. The investigator may appeal the decision for disapproval to the Board. The IO may review Board decisions, impose additional modifications or disapprove research activity approved by the IRB. The IO or any other official may not approve research that the Board has disapproved.

In accordance with the Common Rule, no member of the IRB may be counted towards a quorum or be involved (except to provide information requested by the Board) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Confidentiality:

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

Reporting on its Actions

The Board, through the Compliance Coordinator, shall promptly report actions taken at meetings to principal investigators. The reporting shall be done electronically or in writing, and shall consist of either an approval document, request for administrative 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 investigator in a timely manner, generally within five working days following a meeting.

The institution will be kept informed of IRB actions through periodic reports to the IO by the Compliance Coordinator. Issues necessitating immediate notification to the IO, such as adverse events or noncompliance, will be provided to the IO within two working days. Written IRB minutes will be provided to the IO at the same time they are provided to the Board, generally monthly. The IRB Web site will be used to provide additional information to the institution regarding human subjects' protection issues. Other informational items will be provided to the DSU community using DSU's official means of communications, electronic mail, etc.

Disciplinary Action

When a researcher is found to be in noncompliance with the Common Rule or other Federal, State, or DSU regulations, including this policy and procedures, the IRB may recommend disciplinary action to the Institutional Official. Such recommendations may include, but are not limited, to:

- Verbal warning from the Institutional Official or the College Dean.
- Written warnings from the Institutional Official or the College Dean that would become part of the investigator's permanent personnel file.

- Re-inspection to substantiate the facility/laboratory is subsequently in compliance
- The inability to use the results of the research in publications or other public dissemination.

Failure to comply with warnings will result in suspension of research activities and publications (planned or in-progress) until all appropriate activities have been corrected or completed. The Institutional Official will refer serious issues of noncompliance to the OHRP and the federal oversight agency, as appropriate. The University President, upon consultation with other officials as necessary, shall have final authority as to the IRB recommended or additional disciplinary action.

Ongoing Project Review and Protocol Changes

Non-exempt projects/protocols will be approved for up to one year. Four one-year project extensions may be granted (five years total duration). During initial or ongoing review, when the IRB discusses the level of risk associated with a protocol, it may also determine that more frequent review is appropriate. PIs shall be required to submit an extension using the forms provided by the Board 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. Ongoing review will use full Board review or expedited procedures, in accordance with the Common Rule and any appropriate OHRP guidance documents.

The IRB 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.

If a proposal was determined to be exempt from the Common Rule, no ongoing review will be required, except that the investigator 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.

Any changes in expedited or non-exempt protocols shall be reported to the IRB electronically or in writing prior to initiation, using correspondence approved by the IRB. The Chair or designee will make a determination as to accept the change using expedited procedures or through IRB 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 subjects. Unexpected or serious adverse events shall be reported to the IRB following its procedures.

Reporting to Federal Officials

In accordance with the Common Rule and Federal agency policy and guidance, DSU, through the Institutional Official, will promptly report to the OHRP and the appropriate agency officials any of the following.

1. Unanticipated problems involving risks to subjects or others;
2. Serious or continuing noncompliance with the federal regulations of the requirements or determinations of the IRB(s); and
3. Suspension or termination of IRB approval.