DAKOTA COLLEGE AT BOTTINEAU

Policy

INSTITUTIONAL REVIEW BOARD (IRB) POLICY DCB.618
EFFECTIVE DATE: NOVEMBER 2017 REVIEWED: FEBRUARY 2025

Statement of Principles and Purpose**:** For the protection of human subjects in research procedures and internal policies.

Policy
Persons conducting research involving human subjects have an ethical and professional obligation to ensure the safety, protection, and rights of participants. Dakota College at Bottineau (DCB), through the Institutional Review Board (IRB), intends to assist those engaged in human subject research in conducting their research according to ethical guidelines reflecting professional and community standards. This institution recognizes its duty and obligation to protect the rights and welfare of human subjects of research regardless of research funding sources.

DCB has an obligation to ensure that all research involving human subjects meets regulations established by the **United States Codes of Federal Regulations (CFR).** It is not the intent of DCB or the IRB to interfere in any way with competent, ethical, and sound research involving human participants. However, DCB must ensure that its personnel act in compliance with regulations governing human subject research. It is important to observe these regulations because how research involving human subjects is conducted reflects on the institution's professional, personal, and community commitments to rigorous ethical and scientific standards of conduct.

It is likely that not all possible contingencies have been foreseen or considered in these guidelines and procedures. The IRB needs the cooperation of the research community of scholars at DCB in establishing the means to ensure adequate protection of human subjects. Therefore, the IRB invites input from investigators and interested parties regarding revisions and updates to these guidelines and procedures. Where possible and appropriate, the IRB will incorporate these recommendations.

The Institutional Review Board of Dakota College at Bottineau is a faculty board, under the aegis of Academic Affairs.

I. IRB MEMBERSHIP

IRB membership shall be consistent with regulation §46.107 of the Code of Federal Regulations 45 CFR 46.

(a) DCB's IRB shall have at least five members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to

such issues as community attitudes, in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall ascertain the acceptability of proposed research in terms of institutional commitments and practice. The IRB shall, therefore include persons knowledgeable in these areas. When the IRB reviews research that involves a vulnerable category of subjects such as children, prisoners, pregnant women, or persons with physical handicaps or mental disabilities, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that DCB's IRB does not consist entirely of men or entirely of women. The IRB will consider including qualified persons of both sexes, so long as no selection is made for membership in the IRB based on gender. DCB's IRB may not consist entirely of members of one academic discipline.

(c) DCB's IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

(d) DCB's IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No member of DCB's IRB may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) DCB's IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

(g) IRB members are required to take the CITI online course, or a similar nationally recognized IRB training course, on the protection of human subjects in research.

II. THE IRB CHAIR AND VICE CHAIR

The IRB Chair shall be a DCB faculty member of the IRB with an appropriate terminal degree, usually at the doctoral level. The duties of the Chair are described throughout the remainder of this document.

The IRB Vice Chair shall be a DCB faculty member with an appropriate terminal degree. This person has all associated responsibilities and obligations of the Chair, whenever the Chair is incapable of serving in that capacity and when the Chair is an investigator on a research project

being reviewed or considered by the IRB. The duties and responsibilities of the Vice Chair are the same as for any IRB member, except when in the authorized capacity of acting Chair.

In the event that both the Chair and the Vice Chair are not able to chair a meeting of the IRB, the IRB members present shall appoint a member to act as Chair for that meeting. This person shall have all responsibilities and duties associated with the office of Chair for that meeting.

Nominations of candidates for Chair and Vice Chair can come from any member of the IRB. Self-nomination is allowed. Nominations are taken from the floor during the first regular IRB meeting in the fall term of each year. Election shall stem from a majority vote of those IRB members present and voting at this meeting. The Chair shall be elected first. Those nominated for Chair, but not elected may be nominated for Vice Chair. Both Chair and Vice Chair shall serve in their respective capacities for one year and may be considered for re-election at the end of each term of office.

III. REMOVAL OF IRB MEMBERS BEFORE EXPIRATION OF APPOINTED TERM

In the unlikely event that a member of the IRB should conduct him/herself in a manner inviting consideration for a request for removal from the IRB, such a member can be removed from the board with a vote of two-thirds of the membership of the IRB.

The IRB Chair and Vice Chair can only be removed from office by a two-thirds vote of the membership of the IRB. Anyone removed as Chair or Vice Chair may retain regular IRB membership for the duration of his/her term unless the person is removed from the IRB by the procedure outlined in the above paragraph.

IV. DUTIES OF THE IRB CHAIR

Research protocols involving human subjects shall be presented to the Chair of the IRB for evaluation and categorization as EXEMPT (from full board review), EXPEDITED REVIEW, or FULL REVIEW, according to procedures detailed in "DCB IRB Guidelines for the Protection of Human Subjects in Research."

The primary function of the IRB is to determine under which category a proposal falls, exempt, expedited, or full review categories, as described below, and to review research proposals. Duties of the IRB Chair include review of all research proposals as well as additional duties described below.

Meeting procedures:

A meeting of the IRB shall occur as needed. Members shall be informed at least five (5) working days in advance for regular meetings. Special meetings may be called with short notice, but such meetings must have **a majority of** IRB members in addition to the Chair present to be

considered an official meeting. The Chair shall prepare the agenda and direct the meeting according to the following format:

1. Call the meeting to order.
2. Announcements.
3. Approval of minutes from previous meeting.
4. Old business.
5. New business.
6. Adjournment.

V. INITIAL CATEGORIZATION AND REVIEW OF PROTOCOLS

The chair of the IRB shall review all protocols and requests for review to determine which of the following three categories of review is appropriate:

A. EXEMPT (from full board review): Research activities involving human subjects in which there is minimal or no risk and in which the only involvement of human subjects would be in normal educational settings, would involve the use of educational tests, would involve the study of existing data, would examine public service programs, or would involve taste and food quality evaluation qualify for an exempt review.

At DCB, the protocols meeting the above definition are required to include a level of informed consent (tacit or signed) and satisfy the requirements of any participating agency (such as a school). The protocol must be approved by the IRB Chair or by one of the IRB members within fourteen (14) days of submission.

A member of the IRB will review protocol submissions deemed to be exempt from either expedited or full board review. This member will have fourteen (14) days in which to review and return each protocol to the IRB Chair.

B. EXPEDITED REVIEW: Research activities involving no more than minimal risk and in which the only involvement of human subjects would involve clinical studies of drugs or medical devices, would entail collecting blood samples or similar biological specimens, would involve collection of data through noninvasive procedures, would examine materials or data from various recordings, or would work with research on individual or group characteristics or behavior qualify for an expedited review.

In the case of an expedited review, three members of the IRB will review the research protocol. A simple majority of the designated reviewers must vote for approval of an expedited review protocol. If there is no majority vote for approval, the protocol will automatically be considered by the full IRB at the next available meeting of the board. A protocol cannot be disapproved by expedited review procedures.

C. FULL REVIEW: All research projects involving human subjects that do not qualify for exempt or expedited review must be reviewed by the full IRB **and approved by a majority of the IRB** at an official meeting.

In order to effectively and legally review proposed research not in an exempt or expedited category, there shall be a majority of IRB members present, including at least one member whose primary concerns **are not in the academic discipline of the research**. Whenever possible and desirable, the Principal Investigator (or representative) shall be present at the portion of the meeting in which his/her proposal is under consideration, in order to clarify portions of the protocol and project. Members of the IRB are authorized to ask questions pertaining to the study in order to reach a conclusion regarding risks, benefits, safety, and protection of human subjects.

D. CRITERIA FOR FULL IRB APPROVAL OF RESEARCH:
In order to approve research a majority of the board must be present in addition to the Chair. The members shall determine that all the following requirements are satisfied:

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

2. Risks to subjects are reasonable in relation to anticipated benefits and to the importance of the knowledge that may reasonably be expected to result.

IRB members should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The members should not consider possible long-range effects of applying knowledge gained from the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

While it is not in the realm of IRB authority to evaluate the scientific, social, or political worthiness of any research project, issues of project design are an appropriate area of concern. IRB members must consider the design of the experiment in determining whether a protocol should be approved if such design either directly or indirectly places the subjects at risk. If the protocol introduces an element of risk that is not outweighed by direct benefit to participating subjects and the design is so flawed as to create a doubt as to its value as a research inquiry, then IRB members may consider design in arriving at a decision.

3. Selection of subjects is equitable given the purposes and setting of the research.

4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representative in accordance with Federal regulations (45 CFR 46.116).

5. Informed consent will be appropriately documented (in accordance with 45 CFR 46.117).

6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons who are economically or educationally disadvantaged, persons who are institutionalized, or persons who are minors, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects.

E. VOTING PROCEDURES AND OPTIONS FOR FULL BOARD REVIEWS:

After an adequate period of discussion of the research protocol, the Chair will call for a motion to consider at which point any IRB member may move for one of the following:

APPROVAL: Protocol and consent forms are satisfactory as presented and the investigator may begin research immediately.

CONDITIONAL APPROVAL: The project is not satisfactory as submitted. Investigator must make modifications and/or alterations to protocol and/or consent form(s) as directed by the IRB. Revisions and modifications to the satisfaction of the IRB Chair (acting on behalf of the IRB) may then result in approval.

DEFERRAL: There is insufficient information to reach a definitive conclusion regarding the protocol. The investigator will be asked to revise and resubmit the protocol for full IRB review at a later meeting.

DISAPPROVAL: The Protocol places subjects at unacceptable risk relative to benefits. The research project as designed and described is not suitable for the involvement of human subjects.

Following the motion and second to consider, there will be an opportunity for further discussion and clarification. The motion can then be voted upon.

For full board reviews, IRB MEMBERS will vote by means of a secret ballot.

In order for the reviewed research to be approved, it must receive the approval of a majority of those members present. The Chair does not have voting privileges unless there is a tie vote. In this case the Chair has the power to cast a vote to break the tie.

VI. NOTIFICATION OF IRB FINDINGS

The IRB Chair shall notify investigators in writing of the findings and actions regarding their protocol within fourteen (14) calendar days of the review.

If approved, the investigator may begin the proposed research project.

If conditionally approved, the investigator shall be notified of the specific changes to the protocol and/or consent form necessary to proceed with IRB approval of the research protocol. The Chair of the IRB shall communicate in writing the findings of the IRB and the needed modifications. Until the investigator convincingly demonstrates in writing that all required changes have been made to the Chair's satisfaction, the research cannot begin.

If the investigator does not respond to the IRB Chair's notification of required changes within ninety (90) calendar days of receiving conditional approval, the proposed project must be resubmitted.

The letter of notification to the investigator will convey these stipulations and the time limit.

If deferred, the investigator will be notified in writing that the project as described provides insufficient information to reach a decision for approval or disapproval. The investigator will be asked to resubmit the protocol for consideration at a later regularly scheduled meeting. In addition, the findings of the IRB that resulted in such a decision will be conveyed to the investigator.

If disapproved, notification and the findings of the IRB resulting in such a decision will be conveyed in writing to the investigator.

In some cases, modifications or alterations to protocols and/or consent forms will be required for approval of a research project. Such details will be made in writing at the time of notification. It is the investigator's responsibility to comply with the requested changes to obtain approval. Every possible effort will be made to assist the investigator in bringing a non-approved project into compliance with IRB regulations to be approved. However, it is entirely the responsibility of investigators to meet deadlines and time demands when submitting proposals.

VII. MINUTES OF IRB MEETINGS

The minutes shall include, among other things:

(a) a record of those members present and voting, as well as an account of business conducted, and announcements made.

(b) an accounting of the votes cast for/against motions, the vote count on full board proposals, and relevant discussion regarding proposals being reviewed.

These minutes shall serve as IRB records of full review proceedings. All remarks, commentaries, opinions, and votes of board members are eligible to become part of the official record of the meeting.

A copy of the minutes and other official IRB records will be kept with the Chair.

VIII. ANNUAL REPORTS

All approved ongoing research projects involving human subjects shall undergo an annual review. Occasionally, selected projects will be reviewed more often than annually. Such projects are:

1. any research involving fetuses,

2. any research involving human subjects for which there have been reports of injury or unanticipated problems as a consequence of participating in the research,

3. any research for which the IRB had specifically required reports to be submitted more often than on an annual basis at the time approval was granted,

4. any research project the IRB deems appropriate to review more often than on an annual basis, including projects not in any of the above categories.

Reviews scheduled more often than annually shall follow the same reporting and reviewing procedures as indicated for annual reports, with the appropriate changes in reporting intervals and deadlines.

Reporting Procedure

Annual reports from investigators are due one year after the project approval date, or as specified by the IRB.

Investigators will be informed of impending Annual Review dates with a memorandum distributed ten (10) months after the approval date (or after the previous annual review for longer-term projects). At that time, reporting forms will be made available to relevant investigators.

Complete reports must be submitted to the IRB Chair within twelve (12) months following the approval date, or as designated by the IRB.

Failure to File an Annual Report

If no Annual Report is filed within a thirty (30) day grace period from the Annual Report due date, the investigator will be notified in writing that the approval for the indicated research project has expired. The investigator is prohibited from further experimentation involving human subjects in that research project.

This termination notice/memorandum shall be signed by the Chair of the IRB and is effective from the date of the written notification.

In order to reestablish the research project, the investigator must file a new and complete request for review as indicated above.

IX. CHANGES IN PROTOCOL AND/OR CONSENT FORMS

Investigators shall file with the IRB Chair any substantive changes in protocol or consent forms. A copy of the revised protocol and/or consent form, along with a letter of clarification shall be forwarded to the IRB Chair no less than 14 days before the implementation of such change. If the proposed change requires full or expedited review, additional time may be required. In any case, the proposed changes cannot go into effect until IRB approval has been obtained.

EXCEPTION: A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subject. However, the IRB Chair must be notified in writing of such a change within 48 hours and a review is still required.

X. REPORT OF INJURY AND/OR UNANTICIPATED PROBLEMS

Investigators must report in writing to the IRB within 48 hours about an occurrence of any injury to a human subject or unanticipated problem involving risks to subjects or others as a consequence of the research project.

Investigators should use their best judgment regarding the nature and degree of a reportable injury or unanticipated problem. In general, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints from subjects in which they proclaim that participation in the research presents substantial discomfort, risk, and/or endangerment beyond that explained to them or as otherwise stated in the consent form.

Reports of injury and/or unanticipated problems must be filed with the following office:

Office for Protection of Research Risks
National Institutes of Health
Department of Health and Human Services
Bethesda, MD 20205

Such reports must be signed by the IRB Chair and filed as soon as possible from the date of occurrence.

XI. CONSEQUENCES OF NON-COMPLIANCE

All research involving human subjects conducted at DCB by faculty, staff, or students at DCB must have IRB review and approval before such research can be initiated. DCB's IRB requires that research protocols approved by IRBs from state, federal, or external funding agencies must also have approval by DCB's IRB before research may be undertaken.

Research that is conducted without IRB approval must be terminated immediately. Investigators associated with such research must apply for IRB review and approval prior to restarting the research project.

Investigators who continue non-approved research should note that such non-compliance will be reported to the appropriate administrators.

Failure to comply with IRB directives, regulations, and procedures, including the filing of annual reports, changes in protocol, consent forms, and other requests for information or compliance issued by the IRB Chair will result in the following:

Project Termination: Investigators and their staff and assistants are prohibited from involving human subjects in the research project until formal IRB approval/preinitiation is obtained. Such approval may be sought at the next regularly scheduled meeting of the IRB, or at a special meeting called at the discretion of the IRB Chair.

Suspension of Research Support: An additional consequence of non-compliance can be **a recommendation for** suspension of grant funds (internal or external in origin) allocated to that research project. Such freezing of funds will continue until the project and its investigators are in compliance with to regulations
determined by the IRB.

Report to Appropriate Federal Agencies: In some cases, the college is required to report to the Office for the Protection of Research Risks (OPRR) any termination of a project due to non-compliance with IRB regulations and directives. Further, such non-compliance is reportable to the federal agency supporting the non-compliant research project.

XII. INVESTIGATORY RIGHTS

In order to determine that all substantive and relevant changes in protocol and/or consent documents are being reported, and in order to verify compliance with IRB regulations, the IRB shall have the authority to inspect any research premises or review non-confidential research

documents relating to the protocol and procedures being used in human subject experimentation. Generally, the investigator will be asked to provide copies of relevant and necessary documents for IRB review. Such document inquiries are in addition to those generated in an annual review process. In most cases, this will only occur when there is an indication that a substantive change is in effect which has not been reported. Failure to comply with such IRB inquiries for information may result in suspension or termination of IRB approval of research.

XIII. SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

According to Federal Regulations 45 CFR 46.113:

"An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary of OPRR."

XIV. APPEAL PROCEDURES

There are no formal appeal procedures associated with IRB review. The IRB is not a judicial body, but a review board charged with the responsibility to consider and to uphold the rights, welfare, and protection of human subjects in research. IRB approval for research that has been suspended or terminated can be reinstated with a demonstration that the protocol/project can secure IRB approval. Similarly, a disapproved project need only be altered so that it can secure approval. An appeal process assumes that the decision of an IRB can be overturned by another group. An IRB ruling is not subject to appeal, nor can it be overturned by another group or person. Only the IRB can alter previous determinations.

XV. ENACTMENT

These procedures and policies are in effect immediately upon approval by Dakota College at Bottineau's Institutional Review Board and will remain in effect and enforceable until otherwise amended or repealed.