Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) (Policy)

Purpose
Oglala Lakota College recognizes that the Oglala people, and many other peoples in North America and on other continents who have been subject to colonization, have been subjected to research practices that are ethically and morally reprehensible. The review process at Oglala Lakota College is informed by an appreciation for that historical background in addition to federal law and generally acceptable ethical principles.

In order to comply with ethical principles and with federal guidelines concerning the protection of human and animal subjects, research conducted under the auspices of Oglala Lakota College is subject to a review process in order to insure that it meets required legal and ethical standards. Oglala Lakota College’s Institutional Review Board must review all clinical and behavioral research involving human subjects conducted at or through Oglala Lakota College in order to assure that the research complies with ethical standards and federal law.

Oglala Lakota College’s Institutional Animal Care and Use Committee (IACUC) must review all research involving animal subjects in order to comply with ethical standards and federal law. The IACUC’s overall task is to determine whether a project’s societal benefit justifies any animal pain and suffering that it might cause, and whether whatever animal pain or suffering occurs will be kept to a minimum.

Nothing in this Policy or statement of Purpose should be construed as creating an impediment to research. Oglala Lakota College encourages research. This policy is designed to support research and to insure that research is conducted with due regard for protection of human and animal subjects.


A. Definition of Research
Oglala Lakota College adopts, for the purposes of human subjects protection, the federal definition of 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.” 45 CFR 46.102

B. Covering Regulations:
45CFR46 Protection of Human Subjects
C. Ethical principles:
Ethical principles reflect cultural and social bases for the goal of protecting human subjects. The Lakota values of respect and generosity are foundation stones and they overlap substantially with the internationally recognized principles that formed a basis for legal regulation of research. Those include 1, respect for persons: individuals are autonomous agents, and persons of diminished autonomy are entitled to protection; 2, Beneficence: Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being (do no harm, maximize benefits, minimize potential harm); 3, Justice: Who ought to receive the benefits of research and bear its burdens? An injustice occurs when some benefit is denied without good reason or when some burden is imposed unduly (cf. Belmont Report, 1979 US Dept. H.E.W.)

D. Scope: What is subject to IRB Review
1. Generally, any Oglala Lakota College research that uses humans, human tissue, surveys of human subjects, or human subjects’ records requires IRB review, irrespective of its funding source. The IRB’s charge extends to research in the social and behavioral sciences as well as research in the health and biological sciences.

2. Specifically, IRB review and approval is required for any research involving human subjects that meets any of the following criteria:
   a) research is conducted by University faculty, adjunct faculty, staff, students;
   b) research is performed on the premises of the Oglala Lakota College, including Piya Wiconi, college centers, and He Sapa Learning center;
   c) research is performed with or involves the use of facilities or equipment belonging to Oglala Lakota College;
   d) research involves Oglala Lakota College students, staff, or faculty
   e) research satisfies a requirement imposed by Oglala Lakota College for a degree program or for completion of a course of study
   f) research is certified by a college administrator to satisfy an obligation of a faculty or consultant appointment at Oglala Lakota College, including clinical or adjunct appointments
   g) research is conducted by or under the direction of any employee or agent of Oglala Lakota College, in connection with his or her institutional responsibilities;
   h) research using data on human subjects gathered in earlier projects require IRB review.

E. IRB Membership and Articulation within Oglala Lakota College
1. Composition and selection of members: IRB committee membership will be comprised of no less than seven persons, at least five of whom represent a minimum of five of the departments at OLC that conduct research or that may conduct research, and at least two of whom are chosen from the community on Pine Ridge Indian Reservation. The departments including those listed in the catalog or organizational chart of the College, as well as other programs which do not fall under a specific department, can select delegates. Each department and program is encouraged to select a delegate. It will be the responsibility of the Vice President for Instruction to insure that the departments and programs select sufficient representatives for the IRB and to insure that the IRB delegates chosen by the departments and programs reflect diversity in gender and ethnicity (this diversity requirement is per 45CFR46). The OLC representatives will collectively select the
community delegates to the IRB. Community delegates must not be employees or otherwise affiliated with Oglala Lakota College, nor can they be spouses or OLC employees or Board members. At least one of the community delegates must not be related in the degree of immediate family to any employee or Board member of the college.

2. Delegates (members) of the IRB Committee, including the community delegates, will serve on the IRB for two years. Terms of delegates are renewable by their respective departments. Terms of the community delegate(s) are renewable at the discretion of the IRB committee members. When their terms expire, or when a member leaves or resigns, the vacancy will be filled by one of the academic departments or by a community member duly chosen in accord with No. 1 above. IRB committee members will select a chair from among the delegates representing the academic departments. The chair will serve for one year. The IRB Committee may choose other officers as it deems appropriate.

3. Quorum and voting: A simple majority of delegates to the IRB Committee constitutes a quorum, except that no decision can be made in the absence of a delegate from the community. Each delegate has one vote, including the Chair of the Committee.

4. Articulation within OLC: IRB Committee is a permanent committee of the college. It’s minutes and proceedings are available to college employees. IRB Committee is not a part of the Governance System (Piya Wiconi Okolakiciye) of Oglala Lakota College. IRB decisions can be reviewed by OLC administration. Decisions of an IRB to disapprove research cannot be overturned by OLC officials, nor can OLC officials approve of research that the IRB has not approved (cf. 45CFR46.112).

F. IRB Application Process
Applications for IRB review of proposed research will be made to the IRB Committee of OLC, and will be submitted in accordance with protocols set by the IRB Committee for the following three categories of research: 1, exempt (no disruption in the daily life of human subjects and no risk – still requires application to the IRB); 2, expedited (minimal risk to human subjects); and 3, full review (more than minimal risk potential).

G. IRB Review Process – IRB Committee responsibilities and duties
1. Temporal considerations – IRB committee will meet monthly to review applications. Applications shall be handled expeditiously and notifications to applicants will be made not later than one working day following the IRB committee consideration. IRB Committee will conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.

2. Record keeping – IRB committee will be responsible for maintaining records of all applications, minutes of meetings, decisions, and replies to applicants for IRB review. Specifically, and in accord with 45CFR46, it is the responsibility of the IRB Committee to maintain:

   (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

   (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these
actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103 (b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103 (b)(4) and §46.103 (b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116 (b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.

3. Notification – IRB committee is responsible for replying expeditiously to all requests for IRB reviews. Notification will include any suggestions, and specific reasons for disapproval, including recommendations to overcome problems. Notification will be made to applicants and will be reflected in the minutes of the IRB Committee. IRB Committee minutes will be posted electronically and will be made available in hard copy by the Chair of the IRB.

4. The IRB Committee will publish protocols for application for an IRB review, for each category of risk, and will post those protocols, and application forms, as a link to Oglala Lakota College’s website under the heading IRB. Those links will be available to the OLC community not later than 30 days after the effective date of this Policy. Elements of IRB Review will minimally include the following:
   a) Review the Informed Consent Form. Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied;
   b) Review the Application Form: does the abstract description agree with the description in the consent form? Do the rationale and experimental design suggest that useful information is likely to result? Are there risks to the subjects? Is there a realistic chance of benefit?
   c) If federally funded, does the abstract match the grant application?
Part II: Protection of Animal Subjects: The Institutional Animal Care and Use Committee (IACUC)

A. Regulations
9CFR1 subchapter A (Animal Welfare)

B. Scope: What is subject to review
The IACUC committee reviews any use of live animals in research, teaching, service or display by faculty, staff, or students affiliated with Oglala Lakota College, regardless of where the activity occurs and of the activity’s funding source.

Many of the animals covered in IACUC review are used in research, including agricultural research (such as the study of food and fiber production or diet manipulation) as well as medical, biological, and behavioral research. Some animals may be acquired and/or pastured by Oglala Lakota College, but some are free-ranging wildlife, or client-owned animals.

Animals used in educational settings are also protected by IACUC review. Examples include those used to teach agricultural techniques, animal husbandry, and medical and veterinary procedures.

In short, all animals used by College personnel for College purposes or owned by Oglala Lakota College come within the scope of the IACUC’s review. These animals are involved in a variety of uses and in a range of disciplines.

C. Membership and Articulation within Oglala Lakota College
1. The IACUC is a permanent committee of Oglala Lakota College. Federal regulations require that the IACUC have at least five members, although it typically has more in order to provide a suitable breadth of expertise. One of the IACUC members must be a veterinarian. It shall be the responsibility of the Vice-President for Instructional Division to convene a meeting of the faculty, who will select a minimum of three members of the IACUC. Members must include at least one community member who is not related, in the degree of immediate family, to any college employee or Board member and one veterinarian. The members of the IACUC selected by the faculty and program directors select the community delegate or delegates to the IACUC and will select the veterinarian delegate as well.

2. Delegates (members) of the IACUC Committee, including community delegates, will serve on the IRB for two years. Terms of delegates are renewable by their respective departments. Terms of the community delegate(s) are renewable at the discretion of the IACUC committee members. When their terms expire, or when a member leaves or resigns, the vacancy will be filled by one of the academic departments or by a community member duly chosen in accord with No. 1 above. IACUC committee members will select a chair from among the delegates representing the academic departments. The chair will serve for one year. The IACUC Committee may choose other officers as it deems appropriate.

3. Quorum and voting: A simple majority of delegates to the IACUC Committee constitutes a quorum, except that no decision can be made in the absence of a delegate from the community. Each delegate has one vote, including the Chair of the Committee.
4. Articulation within OLC: IACUC Committee is a permanent committee of the college. It’s minutes and proceedings are available to college employees. IACUC Committee is not a part of the Governance System (Piya Wiconi Okolakiciye) of Oglala Lakota College. IACUC decisions can be reviewed by OLC administration. Decisions of an IRB to disapprove research cannot be overturned by OLC officials, nor can OLC officials approve of research that the IACUC has not approved.

D. Application process
Researchers initiate IACUC review by submitting an application to the IACUC. The IACUC must approve a project before investigators can begin work on it. The IACUC will publish protocols for application for an IACUC review and will post those protocols, and application forms, as a link to Oglala Lakota College’s website under the heading IACUC. Those links will be available to the OLC community not later than 30 days after the effective date of this Policy.

E. Responsibilities of IACUC
1. Assess the project’s societal benefit and treatment of animals and communicate decisions and requests to the investigator in writing. The project must stand a reasonable chance of promoting human or animal health, contributing to the good of society, or advancing the boundaries of knowledge. Determine whether the investigator has designed the protocol so as to minimize any animal pain and suffering that occurs. The IACUC can withhold approval from projects in which pain and suffering are not minimized, even if the project’s benefits outweigh the pain and suffering.

2. Conduct semiannual inspections of all animal study areas and animal facilities. The importance of this requirement is underscored by the fact that the Chief Executive Officer of the institution must certify that the attending veterinarian and the animal care and use committee have the authority to enter any animal area at any reasonable time.

3. If a project involves a biohazard, the IACUC assesses the risk to humans and the need for precautions. (Investigators must list biohazards in the application form. Biohazards include diseases transmissible from animals to humans, infectious agents capable of causing disease in humans, biological toxins, radiation, and recombinant DNA. Investigators can obtain more information on biohazards from the Department of Environmental Health and Safety.)

4. Each project requires continuing review, typically annual review, although the IACUC may review projects at other times as well, if circumstances warrant. The IACUC may ask investigators to revise a project if it determines that animals may be suffering unnecessarily.

5. Federal regulations allow the IACUC to approve a project for a maximum of three years. If the research is to continue past this period, the IACUC must review the proposal prior to the expiration period. The IACUC will notify the investigator two months before the expiration date.

6. Records management and retention:
   a. a copy of the original application submitted to the IACUC,
b. an original of the IACUC’s response,  
c. a copy of responses to the IACUC’s stipulations or requests for additional information,  
d. the original notice of final approval,  
e. a copy of the Certification of Approval issued by the IACUC to any funding agencies,  
f. copies or originals of all other correspondence with the investigator,  
g. copies of completed continuing review forms and attachments,  
h. the original notice of renewal of approval and certification, where applicable, and  
i. copies of any inspection reports and follow-up action.  
j. Retain the above records for at least three years. These records are subject to inspection by federal authorities. Sanctions for incomplete or nonexistent records include suspension of funding, fines, exclusion from future funding.

7. Certification of IACUC approval  
Most federal and private funding agencies will not award a grant for a project involving animals until an IACUC has certified its approval. Federal agencies, for example, require certification of approval on the grant application’s face page. It shall be the responsibility of the IACUC to provide such certification as required by the funding agencies.

8. Reporting violations and other problems  
General concerns about the welfare of animals used by Oglala Lakota College should also be reported, even if the IACUC has approved the project in which the animals are used. Federal regulations require the IACUC to investigate all legitimate concerns.

9. Reporting health-related incidents  
If anyone suffers an injury (such as an animal bite or sustains injury from a kick, etc.) or is exposed to a hazardous biological or chemical agent during the course of a project, the supervisor and if necessary the Department of Environmental Health and Safety should be contacted immediately.