FORT PECK COMMUNITY COLLEGE RESEARCH CODE OF ETHICS

Sec.101. Philosophy and Relationship.

a. The Fort Peck Reservation is home to two separate American Indian nations, each composed of numerous bands and divisions. The Sioux divisions of Sisseton, Wahpeton, the Yanktonais, and the Teton Hunkpapa are all represented. The Assiniboine bands of Canoe Paddler, Rock Band and Red Bottom are represented. We are a sovereign people accepting the responsibilities to this land as given by the Creator. From this our people and ancestors derive the authority to enter into and maintain nation-to-nation treaties with the United States Government and to continue to live by the laws and ethics that guide us that are not made by us, but by the Creator. The Fort Peck Tribes are committed to maintaining the culture, history, and beliefs of all people on the Fort Peck Reservation. In addition to the Native peoples that live on the Fort Peck Reservation, non-native peoples also live on the reservation. Lead Researchers will be expected to demonstrate a commitment to our people and our cultural ways. The research must also align with the most recent "self study" of Fort Peck Community College (FPCC) (including the FPCC philosophy, vision, and mission), (Appendix A).
b. The principal aim of this Code of Ethics is to govern research at or involving the Fort Peck Tribes, and relating primarily to research involving humans. For clarity, this policy will govern such research projects involving any researcher, student or institution/organization, and the governing authority (FPCC Institutional Review Board - IRB) will be responsible for protecting intellectual property rights and traditional knowledge. Reports and documentation resulting from the research must be deposited with the Fort Peck Tribes with Fort Peck Community College.
c. Research is about seeking knowledge, about forming relationships with the ones who know, and the ethics that guide that search can only be understood in a spiritual context. The Lead Researcher must work in partnership with community members and take direction from the ones with the knowledge.
d. In traditional protocols there are relationships that precede the gifting of knowledge; an investment is made first in the relationship between the Lead Researcher and the research participants before asking for teachings of any kind (including a participant's thoughts, practices or beliefs). Presentations of traditional gifts to research participants may or may not be required; as may be an agreement that the knowledge will only be shared and used appropriately according to the way it is shared and used by the teacher. Knowledge is essential to survival, so the maintenance and transference of knowledge is a sacred trust. Trust and respect are essential elements of the relationship.

Sec. 102. Introduction

a. The history of research involving American Indian people serves as another compelling reason that human subjects must be protected. Language and cultural differences caused misunderstanding about the intent and content of the research in which Native people were engaged. In sometimes intimidating situations, subjects were not informed, nor were they given the opportunity to decline participation. Sacred knowledge, objects, and sites were all too often violated in the name of research and the generation of new knowledge about indigenous peoples and their cultures. While Fort Peck Tribes must and will demonstrate compliance with this research code of ethics, they are also committed to the protection of the citizens of Fort Peck Reservation so as not to repeat the history that took advantage of them. Further examples of concerns involving research include*:

    1. Individual Indian people have been persuaded to participate in research in which they did not fully understand the risk to their health and safety;
    2. Individuals may have felt that they were required to participate in research in order to maintain their right to health and social services;

3. Research was conducted which did not respect the basic human dignity of the individual participants or their religious and cultural beliefs;
4. Lead Researchers have not respected the confidentiality of Indian people to the same degree that they would have those of non-Indian individuals and communities;
5. Lead Researchers have treated Indian Lead Researchers as "less than" rather than as colleagues, allowing themselves to appropriate the work of Indian Lead Researchers as their own;
6. Lead Researchers have pursued issues of importance to the larger society but of marginal interest to Indian people and have been uninterested in problems of more urgent concern to the Indian community;
7. Lead Researchers have sought and published sensitive religious and cultural information, in some cases destroying its efficacy by publication;
8. Lead Researchers have taken cultural information out of context and, as a result, have published conclusions that were factually incorrect;
9. Lead Researchers have failed to respect the cultural beliefs and practices of the Indian community in their research methods;
10. Lead Researchers have accentuated and sensationalized Indian tribal, community, family and individual problems heedless of their impact on legitimate Indian social or political interests;
11. And despite promises at the outset that research would benefit the Indian community; Lead Researchers have failed or refused to follow through on promised benefits, to share preliminary results with the Indian community or to give the community an opportunity to participate in the formulation of recommendations or of a final report.

*(Fort Belknap Institutional Review Board Code of Ethics)

b. Given this legacy of miscommunication and exploitation, much misunderstanding and mistrust still exist. It is therefore paramount that principles, policies and procedures governing research activities are put in place that protect the rights and welfare of the Assiniboine and Sioux people and the students, staff and faculty of Fort Peck Community College.

c. Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects. An institution involved in biomedical or behavioral research should have in place a set of principles and guidelines that govern the institution, its faculty and staff, in the discharge of responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by the institution, regardless of the source of funding (the "Common Rule").

d. Fort Peck Community College adheres to the contemporary principle that any research involving human subjects, regardless of the funding source, must be conducted with the utmost integrity by the Lead Researcher and must demonstrate the highest ethical standards in dealing with research subjects. Research that may not directly involve individual human subjects but involves Fort Peck Community College resources or indirectly affects the community must also adhere to these policies, which provide a guarantee to protect the unique cultural survival of the Assiniboine and Sioux peoples' life ways.

e. Fort Peck Community College is fully aware of the value of research not only to Indian people but society in general. The college must and will demonstrate compliance with IRB policies and procedures, while, at the same time, working to protect the safety and well-being of individuals and the community. Research at, or sponsored by, Fort Peck Community College will be well designed and properly executed according to the following principles, policy, and guidelines.

Sec. 103. Statement of Principles

a. The ethical principles that govern acceptable conduct of research involving human subjects at or sponsored by Fort Peck Community College (FPCC) are found in The Belmont Report. The ethical principles are:

    1. **Respect for persons**. Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain informed consent.
    2. **Beneficence**. Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in a risk/benefit analysis and to minimize risks.
    3. **Justice**. Justice requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects be fairly selected.
    (Belmont Report)

Sec. 104. Research Policy

a. Research at or sponsored by Fort Peck Community College will be well designed and properly executed. All Lead Researchers will abide by ethical principles of respect for persons, beneficence, and justice. All Lead Researchers will respect the culture of the residents of the Fort Peck Reservation when designing and carrying out proposed research. All Lead Researchers will follow the guidelines and procedures for protection of human subjects outlined by Federal wide Assurance of compliance with 45 CFR part 46, and carried out by the Fort Peck Community College Institutional Review Board (FPCC IRB). Data collection cannot begin without FPCC IRB approval. All research results will be shared with Fort Peck Community College and the Fort Peck Tribal Council.

Sec. 105. LEAD RESEARCHER and PURPOSE OF RESEARCH

a. A member of the Fort Peck community that is appropriate for the research topic should be directly involved with the research, although non-native academics are invited to participate as supporting Lead Researchers or co-investigators. The results and the process of the research must demonstrate immediate and direct benefit to the participants and the community. As an educational institution, Fort Peck Community College places priority on opportunities for students, and each project approved by the FPCC IRB must involve at all stages, including planning, execution, and reporting, one or more students as assistant Lead Researchers.
b. University students conducting research for class assignments will submit proposals to the course instructor or program coordinator for review, and will not generally be required to submit proposals for review by the Institutional Review Board, unless required by their instructors.
c. Members from the Assiniboine and Sioux tribes, who are enrolled in other institutions and who wish to conduct research at or about Fort Peck, or involving Fort Peck staff or students as participants, will be required to submit their proposal to FPCC IRB as well as meet any requirements of their home institution.

Sec. 106. COLLECTION, OWNERSHIP, INTERPRETATION & DISSEMINATION OF DATA

a. In Tribal tradition, the learner is dependent on the one who holds and carries the knowledge for the people and future generations. The Lead Researcher is not independent and autonomous. The knowledge belongs to the people collectively, to be used on behalf of and for the benefit of the people. In accepting the knowledge Lead Researchers and learners accept a responsibility to share and practice the knowledge in a manner consistent with its original use and teachings.
b. This ethics policy is designed to protect research participants, individually and collectively, as well as the Fort Peck Tribes as an entity, and protection must be interpreted from the perspective,

interpretation, and methodology of the participant, the community, and the Fort Peck Tribes. The methods used to conduct research must align with the practices and philosophies of the community.

c. In the case of disputes, the Lead Researchers, participants or community representatives may request a review by the FPCC IRB Chair.
d. The data collected, including the notes, photos, videos, or other electronic recordings, interim reports, artifacts, sketches, results, and final reports of the research will be secured and owned by the people: research participants, communities, the Fort Peck Tribes and Fort Peck Community College. If only one copy exists, the FPCC IRB will determine which entity will secure it.
e. Data interpretation must also reflect the knowledge of the people and will be conducted in a collective process with participants. An evaluator appointed by FPCC IRB will review the final report and make recommendations to the Lead Researcher relating to culturally appropriate interpretation of data. It will then be the responsibility of the Lead Researcher to incorporate recommendations regarding cultural appropriateness to the final report.
f. Credit in writing will be given in the final product to all participants and Lead Researchers, with any original individual work being credited accordingly. Participants have the right to remain anonymous or be acknowledged by a pseudonym if they choose.
g. Dissemination of results will include the following steps:

    1. The Lead Researcher will have a plan for how they will include/disseminate the information during the application process to the FPCC IRB.
    2. FPCC IRB will require the Lead Researcher work with a community group (project advisory board with at least 3 members), and that group provides oversight to the project to review the research results. The Lead Researcher and the community partner(s) have the responsibility to establish the board.
    3. Consensus among the Lead Researcher and the community group working with the Lead Researcher will be required in the writing and dissemination of the research results.
    4. Manuscripts written about the research results will be written in partnership with the community group working with the Lead Researcher and will be expected to be reviewed by the project's community group for technical content, validity, organization of content, and readability.

h. Any research that is published will be held in joint copyright between the Lead Researcher, the participants, the Fort Peck Tribes and FPCC on behalf of our ancestors and future generations. Royalty sharing agreements will be required if appropriate. Any concerns regarding royalties will be discussed with and decided upon with the IRB Chair as part of the initial IRB application process. Sponsorship must be disclosed at the beginning of the IRB process. The FPCC IRB will determine the appropriateness of the sponsorship as it relates to the proposed research project.
i. The Fort Peck Community College library must hold copies of all research projects involving the Fort Peck tribes and/or the Community College staff or students, unless determined otherwise by the Board. Where consent is obtained from participants, the raw data will be held in a secure, locked cabinet to support future research projects, and access may be granted only according to protocols outlined in this policy.

Sec. 107. <u>INTELLECTUAL PROPERTY and COLLECTIVE RIGHTS</u>

a. Assiniboine and Sioux people will hold knowledge in trust for future generations. The primary goal in research will be to align research projects with this policy, and the vision, mission, and philosophy statements of the College and any communities involved.

b. Consideration must be given to the protection of collective traditional knowledge, even in the event that an individual is willing to share this knowledge in a research project. The FPCC IRB will review each proposal to make every effort to avoid the appropriation or misrepresentation of collective cultural knowledge. Special care must be taken in situations that involve the research of ceremonial protocols. In these situations the FPCC IRB Chair may call in someone from the community who is regarded as knowledgeable about the proposed ceremonial protocol to be researched in order to assist the IRB and the Lead Researcher in the proposed research.
c. During the proposal stage, or at any of the regular reviews, or at the request of the Lead Researcher or a participant, a Lead Researcher may be required to present the project to appropriate individuals who have knowledge of the research topic in the community, including representatives identified by the Lead Researcher, to determine any requirements to protect the collective intellectual property rights of the People (for example: ceremonial or healing medicinal knowledge).

Sec. 108. PARTNERSHIPS WITH LEAD RESEARCHERS FROM OTHER INSTITUTIONS

a. Lead Researchers may wish to invite colleagues from other institutions (such as other colleges, universities or research organizations) to partner on Fort Peck research projects. Any Lead Researchers from other institutions who are involved in a Fort Peck project will be bound by this research policy, and the Board will hold final authority.
b. Fort Peck Lead Researchers participating in research projects from another institution will continue to be bound by this research policy. Any research at other institutions involving Fort Peck staff or students will require approval of the home institution, as well as of the Board.
c. In the event that there is a conflict between this policy and the policy of another institution involved in the research, a meeting involving Lead Researchers and both Boards will be arranged to address and resolve the conflict by the least restrictive means.

Sec. 109. PROTECTION OF RESEARCH PARTICIPANTS

a. The dignity of research participants is paramount. They must have the opportunity to consider their participation once they understand the full nature of the project, their role in it, and the benefits and implications of the research for them and for the community. They must offer this consent without coercion or the promise of undue personal financial or material gain. Participants retain the right to participate anonymously or under a pseudonym.
b. Research involving minors or dependent adults will require the consent, inclusion, and participation of a parent or legal guardian in the research project. The parent or legal guardian must be present at all times the minor or dependent adult is participating. In cases where the research may be compromised without the opportunity to interview minors or dependent adults in confidence, the Lead Researcher must demonstrate an overriding need to the Board during the proposal stage, and obtain the written consent of the parent or legal guardian. In cases where third party consent for the participation of minors or dependent adults has been achieved, but the participant is capable of clearly expressing their dissent and chooses to do so, this expression shall preclude any consent given by an authorized third party. Exceptions will be made on a case-by-case basis.
c. The Lead Researcher is responsible for describing and reporting the process of securing free and informed consent following accepted research protocols.
d. Lead Researchers must disclose to participants and to the FPCC IRB any personal benefit, including academic, financial, or commercial potential applications.
e. Any member of the research circle (Lead Researcher, co-Lead Researcher, community advisor or participant) has the option to remove her/himself from the process at any time without undue influence or interference from the Lead Researcher. If a Lead Researcher intends to remove her/himself from the project, a meeting with the Lead Researcher, research partners and the Board

must be arranged prior to the withdrawal being effective. The IRB reserves the right to appoint an alternate Lead Researcher, or to discontinue the project.

f. Participants also have the right to clarify or delete any contribution they have made at any time to the project, and to request confidentiality or anonymity. Failure to respect the rights of participants may result in the Lead Researcher being sanctioned or removed from the project.
g. The research project must make available support services for participants, including ceremony and counseling, that may be needed.
h. Any research involving naturalistic observation will be subject to greater scrutiny requiring that the Lead Researcher demonstrate the necessity of unobtrusive observation, that every effort is made to ensure minimal risk and protect the rights of participants and may require that the Lead Researcher involve the participants after the observation and obtain their consent in the event that the person is identifiable in any photographic or written research record. Consideration will be given to research involving public events when there is no reasonable expectation of privacy, or where it can be expected that participants are seeking public visibility.
i. Special care must be taken in situations involving ceremonial protocols. These will be considered by the FPCC IRB.

Sec. 110. <u>Membership and Quorum</u>

a. Members of the first FPCC Institutional Review Board will be appointed by the Ceremony of Research Project Advisory Board, and thereafter, when needed, the Vice President of Academic Affairs will appoint new members following consensus agreement by the remaining Board members. To achieve gender balance as well as be reflective of the population on the Fort Peck Reservation, the Board will include a minimum of eight members*:
    1. Fort Peck Community College Vice President of Academic Affairs –ex-officio
       Wayne Two Bulls
    2. Fort Peck Community College – Staff/Faculty
       Adriann Ricker
    3. Faculty member, Fort Peck Community College American Indian Studies
       Bob McAnally
    4. Faculty Member, Fort Peck Community College Science Department
       Zara Berg
    5. Designated Tribal Employee
       Rodney Miller
    6. Three Community Representatives preferably Tribal members/elders who are not otherwise affiliated with Fort Peck Community College and who are not part of the immediate family of a person who is affiliated with Fort Peck Community College;

    *A POOL OF ELDERS/COMMUNITY PEOPLE WILL BE TRAINED TO COMPLETE INSTITUTIONAL REVIEW BOARD QUAROM

    John H. Morsette
    Jonnie Lee Stiff Arm
    Pearl Hopkins
    Sharon Red Thunder
    Helen Ricker
    Loretta Bear Cub

b. The Fort Peck Community College Vice President of Academics will appoint as IRB Chair one of the FPCC faculty members appointed to the Board.
c. In addition, the FPCC IRB may, at its discretion, invite individuals with competence and knowledge in special areas, cultural or academic, to assist in the review of issues or specific research projects which require expertise beyond or in addition to that available on the IRB, and

provide recommendations to the Board. However, these individuals may not vote with the FPCC IRB.

d. In selecting FPCC IRB members, the appointing authorities will ensure that the Board does not consist entirely of men or entirely of women. Neither shall the Board consist entirely of members of one profession.
e. The Board membership and any external reviewers will be selected to ensure appropriate research expertise, such as in qualitative and quantitative methods involving humans and Community Based Participatory Research. Elders and academics will be selected for their knowledge of local ethics and ethics in research, to ensure that Indigenous knowledge and philosophy are reflected in a scholarly review, and will take into account any prior IRB (from another institution), peer and funding agency reviews of the planned project and its involvement of human subjects.
f. A quorum of five, including one Elder and both college faculty members will be required for all decisions of the Board.
g. Preliminary reviews, audits, and investigations will not require a quorum and may be handled by a committee of Board members appointed by the Board.
h. Due diligence and proportionate review will be applied to research proposals to ensure that greater scrutiny is given to those proposals which are potentially more invasive or harmful to participants.

Meetings and Attendance

i. The Board will meet in person at Fort Peck Community College quarterly or as required to review research proposals and to audit projects in progress.
j. Members of the committee will be expected to attend all regularly scheduled meetings or provide sufficient notice of absence to allow the meeting to proceed.

Honoraria and Expenses

k. Members will receive a small honorarium based on their active participation on the IRB and an expense allowance for actual mileage, meals, and accommodations expenses where applicable.

Conflict of Interest

l. To avoid conflict of interest or the appearance of conflict of interest, members of the Board must declare and fully disclose any sponsorship.
m. Affiliation or personal interest in any project presented for review. The Board will collectively decide whether any member will be excused from the review of a particular project.

Sec. 111. <u>REVIEW PROCESS and DECISION MAKING</u>

a. Proposals must be received no later than four weeks prior to the posted quarterly meeting of the IRB. Unless the IRB requires additional information or revisions, a decision will be rendered within four weeks following the regularly scheduled meeting, and written notice of the Board's decision will be provided to the Lead Researcher within 10 working days of the decision.
b. Each review will begin with a culturally appropriate opening such as a prayer, involving the Lead Researcher, research partners, and the IRB members. The Lead Researcher will then have the opportunity to present the research proposal and discuss how the research activities and results align with the spiritual laws and teachings of the Assiniboine/Sioux people, and will honor and benefit generations past, present and future.
c. The Lead Researcher will be required to submit a quarterly report to the Board, which may request a review or audit based on the reports or whenever requested by the research circle, including participants, or when concerns are raised by the community.
d. The Board will discuss the project with the Lead Researcher with the intent of clarifying any elements, and making recommendations, which will ensure the project meets the criteria of the ethics policy.

e. Decisions will be reached by consensus, and inclusion of the Lead Researcher in these discussions is at the discretion of the IRB.
f. Minutes will be kept at every meeting and made available to College management and the Fort Peck Tribal Council, Lead Researchers, and funding agents.
g. The Lead Researcher will be provided with written notice of the IRB decision within 10 working days of the decision. In the event approval is not granted, written reasons shall be given with the intent of assisting the Lead Researcher to improve resubmission or future submissions following the same procedures as the original application.

Sec. 112. MISCONDUCT

a. Consistent with the philosophy and intent of this policy, allegations of misconduct will be addressed.
b. Misconduct may include, but is not limited to: violations of traditional protocols, plagiarism, altering research data, violation of confidence or protection of participants, mismanagement of finds or materials, equipment, and issues relating to personnel management and relationships.
c. Reports or evidence (written or verbal of impropriety or misconduct in research or project / financial management) will be addressed to the Vice President of Academic Affairs and FPCC IRB Chair. Any individual at the College receiving information relating to alleged misconduct in research has a responsibility to forward or redirect the complaint to the attention of the FPCC IRB Chair.
d. Upon receipt of a complaint by a member of the research team (staff, student, or participant), the administration, granting agency, peer review agency or a community member, the FPCC IRB Chair will review the alleged misconduct. The FPCC IRB Chair has 30 days to review the alleged misconduct and make a decision.
e. The IRB Chair has the authority to appoint another Lead Researcher to lead or co-lead the project, to apply strict audit procedures, to remove the Lead Researcher from the project, or move to reverse approval of the project or exclude the Lead Researcher from qualifying for future project applications to the IRB for a period of up to 5 years. In cases where a Lead Researcher has been removed from the project, they will be deemed and reported to be in breach of this policy, if within five years they publicly disclose any information obtained through the project. After five years if the research is to continue in any way, a full research protocol must be submitted to the FPCC IRB for approval.
f. A Lead Researcher found to have committed misconduct will be responsible for refunding any misappropriated funds, and may be required to participate in ongoing training and reconciliation.

Sec. 112. APPEALS

a. Appeals will be heard by the FPCC IRB Chair.
b. A notice of the intent to appeal must also be filed with the FPCC IRB Chair within 30 days of a negative decision.

Sec. 113. FPCC IRB Review and Approval Procedures and Responsibilities

a. Regardless of previous FPCC IRB approvals by other research institutions or universities, Fort Peck Community College requires that the FPCC IRB approve all research projects and particularly those involving human subjects. The FPCC IRB meets quarterly or more frequently as needed. Any employee, researcher, organization or student who conducts research at or involving the Fort Peck Tribes using human subjects must receive FPCC IRB approval prior to any data collection. The necessary forms for approval must be submitted to the FPCC IRB before a research proposal is submitted to a sponsor for funding. Faculty, adjunct faculty, or staff who wish to undertake research involving human subjects as part of their duties, and students who wish to conduct research as part of class requirements, shall be subject to the same rules regarding FPCC IRB submission of their research proposal. Adjunct faculty and students must

have a full-time faculty member as a co-principal investigator.

b. **Applicant Responsibility:**
   1. Obtain application packet and background Regulations, Policies and Guidance published by the HHS Office for Human Research Protections from the Fort Peck Community College Office of Vice President of Academic Affairs.
   2. Complete PI training at http://phrp.nihtraining.com/users/login.php.
   3. Determine type of FPCC IRB review application to be used (see section on Types of FPCC IRB Review). (Note that though applicant may submit an application for exempt review, the IRB may choose to require an application for regular review.)
   4. Complete the appropriate FPCC IRB review application, including any required parts of the protocol such as an informed consent form, interview instrument. Or, if applicable, IRB approval from another institution must be attached to the application.
   5. Submit the research prospectus and complete application, with attachments to the FPCC IRB Chair for review; indicate what will happen with the research results.
   6. Secure FPCC IRB approval before data collection can begin.

c. **Types of FPCC IRB Review Applications**:
   1. Exempt Review: An exempt review procedure consists of a review of research involving human subjects by the Chair and one member of the FPCC IRB. Types of research which may be considered Exempt include:

      (a) Research conducted in established or commonly accepted education settings, involving normal education practices, such as (i) research on regular and special education strategies; or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
      (b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers liked to the subjects.
      (c) Research involving survey or interview procedures. except where the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the subject's responses. if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct., drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
      (d) Research involving the observation (including observation by participants) of public behavior, except where the conditions named in Section 109(h) above exists.
      (e) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

   2. Expedited Review: An expedited review procedure consists of a review of research involving human subjects by the FPCC IRB chairperson or by one or more experienced

reviewers designated by the chairperson from among members of the FPCC IRB in accordance with the requirements set forth in 45 CFR 46.110.

(a) Clinical studies of drugs and medical devices only when certain conditions are met.

3. Full Board Review: A regular or full review procedure consists of a review of research involving human subjects by the full FPCC IRB.

(a) Any research involving the use of vulnerable subjects. A vulnerable subject is defined as follows: "Vulnerability refers to the risks that Lead Researchers request their subjects to undertake in relation to the ability of the subjects to make fully informed consent. Populations routinely considered to be vulnerable include: children; prisoners; pregnant women; non-English speaking people; the mentally handicapped; those subjects engaged in illegal activities; people who are in need of medical treatment for an illness that is relevant to the risk they are being asked to assume by the Lead Researcher; and subjects who may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study. Furthermore, Fort Peck Community College includes American Indians as a vulnerable population.
(b) Any research involving more than minimal risk, either mental or physical to the subject. Examples of protocols of this type may include surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subject's behavior, including sexual practices, studies that solicit information regarding instances of child or sexual abuse suffered by the subject, or criminal activities, or studies regarding eating disorders. Examples of studies that involve more than minimal physical risk to the subject include stress testing, drug and alcohol use by the subjects and studies where subjects are asked to engage in more than moderate physical exercise that could result in injury to the subject. This should not be considered an exhaustive list of studies that may involve more than minimal risk to the subject. The investigator should include a comprehensive statement of the potential risk/benefit ratio to the subject for consideration by the committee.
(c) Collection of blood samples by finger stick, head stick, ear stick, or venipuncture.
(d) Prospective collection of biological specimens for research purposes by noninvasive means.
(e) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared and approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
(f) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b). This listing refers only to research that is not exempt.)
(g) Collection of data from voice, video, digital, or image recordings made for research purposes.
(h) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity. language,

communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b). This listing refers only to research that is not exempt.)

(i) Continuing review of research previously approved by the convened FPCC IRB.

(j) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (b) through (i) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

d. FPCC IRB Chair Responsibility:

1. Review application and determine type of review necessary.
2. For exempt projects and projects qualifying for expedited review (no foreseeable risk), the Lead Researcher(s) and, if applicable, the FPCC faculty sponsor, will be notified within five working days after necessary information is received by the FPCC IRB Chair.
3. For projects requiring full 1kB review, notice of the Board's decision will be mailed within ten working days after the FPCC IRB meeting.

e. **Lead Researcher (also known as Principal Investigator or Pl) Responsibility (Following IRB Approval)**:

1. Material changes. The Lead Researcher is expected to immediately notify the FPCC IRB through the Chair if any material changes occur. These changes include: a) substantial changes in procedure; b) significant unanticipated problems; or c) adverse reactions of, or effects on the subjects and/or any changes as a result of same.
2. Extended or continuing projects. If data collection is extended beyond 12 months from the date of the original FPCC IRB approval, the Lead Researcher must submit an Application for Continuing Review (Sec Appendix D) for approval. The continuing review form must be submitted to the FPCC IRB before the 12th month from the original approval date. The continuing review form can be obtained from the Fort Peck Community College Office of Vice President of Academic Affairs. If there are significant changes, the project will be treated as a new one, and the entire review process must be repeated. If there are no significant changes, the project's continuation may be granted an expedited review.
3. Maintain required records. The Lead Researcher is expected to maintain required records for the required time period. All FPCC IRB records must be retained for at least three years, and all records pertaining to the research conducted must be retained for at least three years after the completion of the research. The Lead Researcher must provide for a safe and secure location for housing project records and indicate where all records will be kept.

f. Possible FPCC IRB Actions will depend on the FPCC IRB Chair decisions.

1. Designate the research as exempt from FPCC IRB review as outlined above.
2. Approve the research. The research may involve some risk to subjects, but the FPCC IRB does not consider the risk to be unreasonable and/or the Lead Researcher has taken all practical steps to minimize the risk. The project is well designed and the research will be properly executed.
3. Conditionally approve the research. The Lead Researcher may proceed with the project as long as the Lead Researcher fulfills certain conditions set by the FPCC IRB. Conditions

might include revising the consent form to more clearly explain the procedure; receiving appropriate clearance from a particular agency or department; or discontinuing the research if deleterious effects occur. l) Any collection may not commence until all conditions are met and approved by FPCC IRB Chair or Board.

4. Ask that the Lead Researcher resubmit the summary/study overview. If the FPCC IRB believes that it has insufficient information to take action, when it believes the research design contains clear dangers and should be revised to reduce risk or harm to human subjects, or there is language or cultural conflict, it will ask the Lead Researcher to resubmit applicable information.
5. Disapprove the research. The FPCC IRB will suggest revisions in the research design and ask that the Lead Researcher redesign his/her procedure and resubmit the summary/study overview. Final disapproval should come only after attempts to redesign the research have failed to remove the clear potential harm to human subjects.

g. Record Keeping Responsibilities:

1. FPCC IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained by the FPCC IRB at least three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.
2. The following records shall be kept in the Office of the Vice President of Academic Affairs:
    (a) Copy of written FPCC IRB procedures and FPCC IRB membership lists.
    (b) The FPCC IRB application with any required attachments and correspondence received by the FPCC IRB Chair for each project reviewed.
    (c) Action by the full FPCC IRB or the FPCC IRB Chair for each proposed project.
    (d) Minutes of FPCC IRB meetings with records of attendance, actions taken and votes on the actions, basis for requiring changes or resubmission, and summary of discussions of controversial issues and their resolutions.
    (e) Records of continuing review activities, copies of all correspondence between the FPCC IRB and Lead Researchers, and statements of significant new findings provided to the subjects.

h. Institutional Review Board Guidelines and Federal Policy 45 CFR 46

Authorized institutional representatives, FPCC IRB members, and Lead Researchers or investigators must be familiar with the Regulations, Policies and Guidance published by the HHS Office for Human Research Protections. These resources can be found at http://www.hhs.gov/ohrp/humansubjects/index.html and http://www.hhs.gov/ohrp/policy/index.html. Printed copies of select materials are available at Fort Peck Community College's Office of the Vice President of Academic Affairs.