Salish Kootenai College Institutional Review Board

Standard Operating Procedures

Revised February 2019

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I. Introduction

The purpose of the Institutional Review Board (IRB) Standard Operating Procedures (SOP) is to provide direction to the IRB membership and staff in carrying out duties assigned to the IRB. The SOP follows existing SKC Policy as well as the regulatory requirements found in the Common Rule (45 CFR 46). At the time of the release of Version 2 of the SKC IRB SOP, SKC is not carrying out research on new investigational drugs or biomedical devices. Therefore, these SOP does not include requirements of the Food and Drug Administration (FDA) regulations found at 21 CFR 56.

Per SKC Policy 1000, the SKC IRB addresses the dual functions of protecting human research participants and the intellectual property rights of the Confederated Salish & Kootenai Tribes (CSKT). The SKC IRB SOP are designed to provide guidance in both functions.

The SKC IRB reviews all human participant research according to the standards set in the Belmont Report and the Common Rule, whether or not the research is funded by a federal entity. The SKC IRB follows the Common Rule regulations regarding categories of review, informed consent, and other areas as described in these SOP. Research deemed to pertain to the intellectual property rights of the CSKT is reviewed according to the SOP below.

These SOP are considered to be a living document that will be updated or reviewed annually or as needed as changes in statues, regulation, guidance, practice, or policy occur.

II. Background

The Salish Kootenai College IRB Procedures were developed with an understanding of the ethical principles that apply to the conduct of research on humans, federal regulations found in the Common Rule, and an understanding of the need for protection of research participants and the cultural intellectual property rights of the Confederated Salish & Kootenai Tribes. Therefore, the Salish Kootenai College Institutional Review Board is guided by the U.S. Federal Policy for the Protection of Human Subjects, historical perspectives of ethical treatment of research participants, the Belmont Report, as well as an understanding of the sovereignty of the Confederated Salish Kootenai Tribes and the definition of Cultural Intellectual Property Rights.

a. The Nuremberg Code

The modern history of human subject protections began with the ten principles developed by the Nuremberg Military Tribunal following documentation of the numerous atrocities committed by Nazi doctors during World War II. These principles were meant to be a means of judging research practices and were titled the Nuremberg Code. The code addresses the necessity of requiring the voluntary consent of human research participants and that any individual who “initiates, directs, or engages in the experiment” must bear personal responsibility for ensuring the quality of consent. The Nuremberg Code also is a statement of research participants’ legal rights.

b. The Belmont Report

In the 1970’s, questionable research including the United States Public Health Service Study of Untreated Syphilis in the Negro Male at Tuskegee resulted in legislation calling for regulations to protect human research participants. The National Commission for the Protection of Human Subjects of Biomedical and Biobehavioral Research produced a final report is known as the *Belmont Report:*

Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The Report provides three basic ethical principles:

1. Respect for persons (applied by obtaining informed consent, consideration of privacy and confidentiality, and additional protections for vulnerable populations);
2. Beneficence (applied by weighing risks and benefits); and
3. Justice (applied by the equitable selection of participants).

c. Cultural Intellectual Property Rights United Nations Declaration on the Rights of Indigenous Peoples, Article 31.1, *"Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions."*

III. Types of Human Research and Institutional Review Board Considerations

Per SKC Policy 1000, all research performed by SKC faculty members, staff members, or students, and all research being conducted at SKC by outside researchers, must be reviewed by the Institutional Review Board.

The following definitions pertain to research review.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Systematic Investigation means that a careful plan is followed to gather information. According to the Office of Human Subjects Protection (OHRP), a systematic investigation occurs when "…observations are obtained under clearly specified, and, where possible, controlled conditions that can be measured and evaluated."

Generalizable knowledge is information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Human subject or Human Research Participant means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Private Information or **Personal Identifying Information (PII)** means personal information that a research participant may normally consider to be private, or which through a combination of data might reasonably lea to knowing the identify of a person. Examples include the study subject's name, family names, social security number, computer IP address, photo identification, or other such information.

Cultural Intellectual Property refers to traditional cultural knowledge, cultural expressions, sacred cultural material, historical traditions and understandings, and other property such as natural resources that occur on the Flathead Indian Reservation.

Minors or Children refers to "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Under Montana law, a “Minor” refers to an individual who is less than 18 years of age. A minor is considered to be emancipated if the minor is between 16 and 18 years of age, is married, in the military, or is emancipated via a court order. Investigators with questions concerning whether an activity constitutes research with human participants should contact the Chair of the SKC Institutional Review Board at the contact number on the IRB website.

IV. IRB Authority and Institutional Assurance

The Chair of the Salish Kootenai College Institutional Review Board is SKC’s Institutional Official, signs the college’s Federal-Wide Assurance, and works with the IRB members to oversee the Institutional Review Board review of human research and research involving intellectual property rights of the CSKT.

The SKC IRB is authorized under SKC Policy 1000 to carry out review, approval, and monitoring of human research for SKC. The Roles and authority of the IRB are further described below. The college administration may determine that a study may not be conducted, however, no study may be conducted by researchers if the IRB has not approved the study. Thus, the IRB acts independently from college administration in approving or disapproving research, setting requirements for monitoring or reporting, or terminating a study. Undue influence by college administrators or staff that may curtail the independence of the IRB are to be reported to the IRB Chair, who will investigate the report and document resulting actions, if any.

The IRB has the sole authority to approve, disapprove, suspend, or terminate research based on these procedures. The IRB may suspend or terminate research involving human participants as it determines necessary to protect the participants or the cultural intellectual property of the Confederated Salish and Kootenai Tribes. The IRB has the authority to observe and/or monitor approved research to the extent it considers necessary to protect human participants.

<u>Multi-Site Investigations and Collaborative Research</u>

SKC researchers may participate in studies where investigators and/or study populations are involved at more than one study location. An investigator is engaged in a multi-site study when the activity involves multiple entities and/or research sites and meets the definition of human research or involves cultural intellectual property of the Confederated Salish & Kootenai Tribes.

The Salish Kootenai College Institutional Review Board does not accept reviews from outside institutional review boards.

V. IRB Roles and Membership

Federal Regulations require that Institutional Review Boards file a written "Assurance" of protections for human research participants with the Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS). The FWA is maintained on file in the Office of the Institutional Review Board. Regulations also require training for IRB members and researchers as part of the conditions of the FWA. SKC utilizes the online training program sponsored by the Collaborative Institutional Training Initiative (CITI) for training both researchers and IRB members.

Membership of the IRB

The Common Rule requires that the IRB be comprised of at least five members, with at least one non-scientist and at least one non-affiliated (or community) member. IRB members will represent a diversity relative to gender, cultural background, and a sensitivity to community attitudes so as to promote respect for the IRB's counsel in safeguarding the rights and welfare of human research participants. SKC seeks to maintain IRB membership that represents a balance of individuals with expertise in research areas commonly pursued at the College as well as members who are CSKT tribal members and able to represent tribal perspectives. One or more alternate IRB members may be named on the IRB's official membership roster; alternate IRB members should be able to represent similar interests as the member he/she may replace.

Individuals are appointed to the IRB by the SKC President. IRB membership may continue until the individual resigns the membership or is unable to fulfill membership responsibilities. Upon appointment, IRB members complete the IRB member component of CITI training, sign a form acknowledging responsibility for understanding the requirements of IRB membership and agreement to maintain confidentiality of IRB reviews and materials, and agrees to participate in IRB meetings and reviews. IRB members are not compensated for their service on the IRB. IRB members who participate in trainings that are off the Flathead Indian Reservation may be provided with travel funding.

The IRB Chair will maintain a record of IRB membership including name, gender, earned degree(s), specific scientific qualifications, area(s) of expertise, and cultural affiliation if a CSKT tribal member/descendant.

The IRB Chair is appointed by the SKC President. The Chair is responsible for conducting IRB meetings, ensuring IRB maintains operation within applicable regulatory requirements, and maintains IRB records as required.

Consultants

The IRB chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to expertise available by the IRB members. Consultants may not vote with the IRB or approve a protocol. Consultants complete an agreement that there is no conflict of interest related to the study and the subject of the study will remain confidential.

Conflict of Interest

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

including the Chair, who have conflict interests are required to disclose those interests and recuse themselves from deliberations, quorum counts, and votes on the relevant protocol.

Plan for Training IRB Members

IRB members will be required to update their CITI training every three years and provide documentation of training to the IRB Chair. Additional annual trainings will occur at the first meeting of each academic year to update the members on any changes in college or tribal regulations, federal regulations, or other updates.
Additionally, all SKC IRB members receive copies of these SOP and other reference materials.
Additional trainings may be provided through regional or tribal human subject protection trainings.

Attendance at IRB meetings

Convened IRB meetings will list names of members present, names of members absent, alternates attending in lieu of specified absent members, names of consultants present, names of guests present (if any).

Quorum Requirements and Voting at Convened IRB Meetings

A convened IRB meeting will have a simple majority of members present in order to conduct official IRB reviews. Members may be present in person or via audio (telephone) or audiovisual teleconference. Members present via audio or audiovisual means will be noted as such in meeting minutes.

VI. Responsibilities of Principal Investigators

As the individual responsible for the implementation of approved research, the principal investigator bears direct responsibility for ensuring the protection of every research participant. This responsibility starts with research design, which must minimize risks to participants while maximizing research benefits. In addition, the Principal Investigator must ensure that all members of the research team comply with the findings, determinations, and requirements of the IRB.

In the event that the research is being conducted outside the United States or on tribal lands, the Principal Investigator will have primary responsibility for seeking and receiving approvals from local IRBs or other review bodies as may be required by the cognizant foreign or tribal government.

Principal Investigators are responsible for ensuring that:

1. Training in protection of human research participants is completed by all researchers who will have access to participant disaggregated data or be involved in data collection or analysis. SKC utilizes the online training program sponsored by the Collaborative Institutional Training Initiative (CITI) for training both researchers and IRB members.
2. Any research involving human participants or cultural intellectual property has been approved by the SKC IRB.
3. The IRB is notified of all changes in the research protocol. No changes in approved research may be initiated without prior IRB approval, except where necessary to eliminate immediate hazards to participants.
4. Continuing review and approval has been accomplished within the time frame stipulated by the IRB.

5. Any stipulated reporting or monitoring requirements are met.
6. Final documentation and closure of the research protocol is accomplished within the stipulated time frame. No research may be continued beyond the IRB-designated approval period.
7. The IRB is notified in writing if there are adverse impacts to research participants, including:
    - Data breach or breach of confidentiality
    - New information that indicates a change to the risks or potential benefits of the research
    - Any harm experienced by a participant which is both unexpected and
    - Change or violation of an approved protocol
    - Termination, suspension, or restriction of a study by a sponsor or principal investigator
    - The results of the research are returned to the community which was the subject of the study, as included in the approved protocol.

The SKC IRB may consider certain participant categories to be more vulnerable to coercion or undue influence, including children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or tribal elders. Additional safeguards should be in place to ensure that the rights and welfare of these participants are protected. This includes obtaining informed assent from all minors and informed consent from parents or legally responsible adults.

VII. Application for IRB Review

Submission of IRB Materials for Review

The Salish Kootenai College Institutional Review Board accepts only electronic materials. All documents should be sent to the IRB email, irb@skc.edu. Electronic materials are stored in a secured IRB file share on the SKC server.

The Primary Investigator is responsible for making timely application to the IRB for review of protocols.

IRB applications must Include all pertinent materials: completed and signed IRB protocol, informed consent and assent (for minors) documents, recruitment materials, copies of surveys or interview materials, and other materials as listed. The IRB protocol must be signed and dated. If the researcher is a student, the student's research chair or responsible faculty member must also sign the protocol. The application must be complete prior to IRB review. Researchers submit incomplete applications, e.g. missing informed consent forms or other materials, will receive an email from the SKC IRB requesting the additional materials.

The SKC IRB requires a letter of permission from the site in which the research is to occur. The letter of site permission may be obtained from the pertinent educational or tribal entity. A letter from one or both of the Culture Committees may be required if the research involves cultural intellectual property of the Confederated Salish & Kootenai Tribes. Guidance concerning the appropriate entity from which to obtain a letter of site permission may be provided by the SKC IRB.

Access to current IRB forms and additional information about applying for review by the SKC IRB shall be maintained on a website accessible to both internal and external stakeholders.

Investigator's Assurance

It is the responsibility of each PI to formally "assure" the IRB that the researcher(s) will comply with regulations governing the protection of human participants. This assurance is supplied through the PI's signature on the research protocol.

Additionally, aligned with principles of indigenous research, researchers are asked to assure that results and/or findings of the research will be shared with participants, sponsors, and/or the community of interest.

Seeking Informed Consent

The Principal Investigator is responsible for ensuring that informed consent procedures are followed for all research participants. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the participants' legal rights, or releases or appears to release the investigator, sponsor, or its agents from liability for negligence.

Informed consent forms must include all basic elements as required by CFR 46.116.6(b), unless consent is waived by the IRB. Researchers should use the SKC Informed Consent form. The SKC IRB will accept Informed Consent forms from other institutions if the form contains the required elements as specified in CFR 46.116.6(b).

The IRB may waive the requirement for informed consent under the following circumstances:

(1) If the participants have provided broad consent for the storage, maintenance, and secondary research use of identifiable private information.
(2) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and meets the requirements of CRF46.116.(3)i.
(3) The research involves no more than minimal risk to the participants AND could not practicably be carried out without the requested waiver or alteration, AND the waiver or alteration will not adversely affect the rights and welfare of the participants AND wherever appropriate, the participants or legally authorized representative will be provided with additional pertinent information after participation.
(4) The IRB may also waive written consent if the research involves no more than minimal risk, informed consent will be sought via telephone (e.g. prior to a telephone interview), and the waiver will not adversely affect the rights and welfare of the participants.
(5) If the only record linking the subject and the research would be the informed consent form AND the principal risk would be potential harm resulting from a breach of confidentiality; in that case the subject or legally authorized representative will be asked whether the subject wants documentation linking the participant with the research and the participant's wishes will govern.

If informed consent is waived, the IRB may require the investigator to provide participants with a written statement about the research.

VIII. IRB Procedures

Regulations at 45 CFR 46.111 ("The Common Rule") delineate specific criteria for approval of research. The IRB will use the Standard Operating Procedures contained in this document to ensure that all requirements are satisfied prior to approving proposed research.

IRB Protocol Tracking System

The IRB Director shall ensure the maintenance of a reliable, computerized protocol tracking system.

Retention of IRB Records

Electronic records of all IRB materials will be retained in a password protected file for three years after completion of the research project. Access to the IRB's electronic records is limited to the IRB Chair, IRB members, and officials of federal and state regulatory agencies including the Office for Human Research Protections (OHRP). Other access to IRB records may be afforded to others with legitimate need as determined by the IRB Chair and the SKC President.

Materials to be retained include:

- IRB Protocol and all other required materials as described in xx below.
- All electronic and/or written communication between the PI and the IRB
- Documentation of type of review, rational for exempted and expedited reviews
- Documentation of convened meetings including meeting minutes and attendees
- Documentation of data monitoring activities conducted
- Documentation of project closeout
- Documentation of reports of unanticipated problems
- Reports of research misconduct and resulting actions following the procedure for research misconduct below.
- Training records of IRB members

IX. Determination of Type of IRB Review

Research activities that involve human participants or cultural intellectual property will be reviewed by the IRB Chair or Administrator, who will determine the category of review based on CFR 46.104 and IRB policies.

The SKC IRB may consider certain participant categories to be more vulnerable to coercion or undue influence, including children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or tribal elders. The IRB may request specific additional safeguards to protect the rights and welfare of these participants.

X. Procedures for Exemption from Review

The following categories of human participants research are exempt from review:

(1) Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content, or the assessment of educators who provide instruction.
(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if at least one of the following criteria is met:
(1) The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained either directly or through identifiers linked to the participants;
(2) Any disclosure of the human participants' outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation, or
(3) The information obtained is recorded by the investigator in such a manner that the identity of the human participant can be ascertained and linked to the participant, AND an IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Limited Review

If an IRB protocol meets the criteria for exemption from review, the IRB may conduct a limited IRB review to determine that identifiable private information or identifiable biospecimens are maintained with adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Even if a protocol meets the criteria for exemption from review, the IRB may require considerations or modifications to a protocol to maintain client confidentiality.

XI. Procedures for Expedited Review

The IRB may utilize an expedited procedure for the initial or continuing review of research that meets eligibility criteria as set forth below and that falls within the Common Rule list of research eligible for expedited IRB review.

Evaluating if Proposed Activities are No More than Minimal Risk

Most research falling within one or more of the categories below will, ordinarily, present no more than minimal risk to participants and will be eligible for review through the expedited review procedure. However, the IRB reviewer is required to evaluate all proposed research and consider whether the proposed research is more than minimal risk.

In evaluating if the proposed research presents no more than minimal risk, an IRB reviewer should consider the nature of the study procedures, the implications of study findings for the subject (e.g., the results of genetic testing of blood samples), other study characteristics, and steps taken to minimize risk. The IRB reviewer should also consider the characteristics of the subject population, including but not limited to age, health conditions, social or economic circumstances and experience in relation to the anticipated harms and discomforts.
The expedited review procedure may not be used, for example, when identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, educational

advancement, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. In evaluating the risks, the IRB reviewer should consider only those risks that may result from the research (as distinguished from the risks of therapies participants would receive even if not participating in the research).

If a protocol qualifies for expedited review, two assigned reviewers will complete their reviews in accordance with IRB SOPs and discuss the review to reach consensus. Either reviewer may request that the protocol be presented to the convened IRB for review. The names of the reviewers and the category of expedited procedure will be documented in the IRB records.

Eligibility requirements for expedited review:

(1) The research presents no more than minimal risk to participants.
(2) The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
(3) Research either a) does not involve the cultural intellectual property rights of the CSKT OR a letter of consent from tribal council or a cognizant tribal entity is included with the protocol.

Categories of Expedited Review

(1) Categories one (1) through fourteen (14) apply to initial IRB review of research that has been determined to be no more than minimal risk.
(2) Category fifteen (15) applies to continuing review of research previously approved by the convened IRB that does not otherwise qualify for expedited review.

Note: Category 8(b) is never eligible for expedited review.

1. Research involving the use of drugs and medical devices only when condition (a) or (b) is met.
a. Research involving use of "over-the-counter" drugs, when used within their approved indications and dosages, and exempt from the IND requirements of 21 CFR 312.
2. The collection of blood specimens for research purposes using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits: (a) from adults whose health will not be adversely affected by the blood draws who weigh at least 50 kg, the amounts collected should not exceed 550 ml in an 8-week period; or (b) from children2 and other adults whose health will not be adversely affected by the blood draws, the amounts collected should not exceed the lesser of 150 ml or 3 ml per kg in an 8-week period. Examples: Finger stick, heel stick, ear stick, venipuncture, collection of blood from an indwelling peripheral venous catheter (not including a PICC line) placed for research purposes, or collection of blood from an indwelling catheter already in place for clinical purposes.
3. Prospective collection of biological specimens, excluding blood, for research purposes by noninvasive means and not requiring sedation for research purposes.
4. Prospective collection of biological specimens, excluding blood, for research purposes by minimally invasive means and not requiring sedation for research purposes. Examples: (a) tissues from non-facial, non-genital skin punch biopsy with allowable local anesthesia and limited to 2mm in diameter and not requiring sutures; (b) Specimens collected by swab (nasal, oral, urethral, vaginal, rectal); (c) teeth if routine patient care indicates a need for extraction.

5. Collection of additional information or biological specimens, excluding blood, for research purposes during procedures already being performed for clinical purposes, provided the additional collection does not introduce more than a minimal increase in risk, pain or discomfort over that imposed by the underlying procedure. When extension of general anesthesia is required, it must meet the criteria for minimal risk. Examples: (a) collection of additional bodily fluids and tissues (e.g., peritoneal fluid, bone marrow or cerebrospinal fluid); (b) tissue collected from pap smears; (c) collection of additional clinical information (e.g., vital signs, electroencephalography or echocardiography).

6. Collection of information for research purposes through noninvasive procedures and interventions routinely employed in clinical practice and not requiring general anesthesia or sedation.

Examples: (a) physical sensors that are applied either to the surface of the body or used at a distance; (b) testing sensory acuity; (c) magnetic resonance imaging without use of contrast agent and using magnet and sequence parameters within accepted clinical use guidelines; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and transthoracic echocardiography; (e) measures of cognitive functioning;

7. Collection of information for research purposes through activities performed by persons in daily life in individuals and groups whose health will not be adversely affected by the activities.

Examples: (a) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing; (b) measures of symptoms, mobility, range of motion, quality of life and activities of daily living in patient and non-patient populations by clinical or other trained personnel (e.g., nurses, physicians, social workers, physical and occupational therapists); (c) manipulations of diet and lifestyle; (d) measuring height, weight, circumference; (e) assessment of reading levels.

8. Activities at statistical and data coordinating centers or biospecimen repositories that are not responsible for the primary oversight of the primary data collection activities and are not involved in the primary collection of information or specimens, which may be ongoing at other sites.

9. Collection of information from voice, video, digital, or image recordings made for research purposes that are not exempt under §__.104(d).

10. Research that only includes interaction involving (1) educational tests (cognitive, diagnostic, aptitude, achievement); (2) survey procedures, interview procedures, or observation of public behavior (including visual and auditory recording) not eligible for exemption under §__.104(d)(2) either because there are risks to participants other than informational risks, or because the informational risks are not addressed as specified under §__104(d)(2)(i) through (iii); (3) other data collection procedures (e.g., written or computer-assisted interactions or assessments) where the subject provides self-reports for the purposes of the research and/or may choose what data to provide; (4) non-invasive physical or behavioral tasks or manipulation of the subject's environment; and (5) observations of individual group behavior where the subject is a voluntary participant in the behavior and is aware that data are being collected.

11. Benign behavioral interventions that are not eligible for exemption under §__.104(d)(3) because they (a) involve children as participants; (b) involve individuals with impaired decision-making capacity; (c) are conducted without the prospective agreement of the subject, including interventions involving deception; (d) are not brief in duration, or; (e) are not limited to verbal or written responses by the subject, data entry by the subject, or observation of the subject.

12. Creation and maintenance of subject databases to which participants have provided prospective informed consent or informed consent has been waived by an IRB and does not qualify for exemption under §__.104(d)(7). Examples: (a) collection of identifiable information for the purpose of establishing subject pools; (b) disease-specific patient registries; (c) screening protocols

including interviews, questionnaires and minimally invasive physical assessments, when performed for research purposes, that could not be expedited under one of the categories listed above.

13. Secondary research uses of identifiable private information or identifiable biospecimens that are not exempt under §__.104(d)(4) because (a) the identifiable private information or identifiable biospecimens are not publicly available; (b) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human participants can be readily ascertained directly or through identifiers linked to the participants, or the investigator intends to contact the participants or will re-identify participants; (c) research use of identifiable health information not regulated under 45 CFR parts 160 and 164, subparts A and E.

14. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use that is not exempt under §__.104(d)(8) because the investigator includes returning individual research results to participants as part of the study plan.

Continuing Review of Previously Approved Research

15. Research previously approved by the convened IRB and not otherwise eligible for expedited review under categories (1) through (13) above, where one of the following conditions apply:
the research remains active only for long-term follow-up of participants;5 or
no participants have been enrolled at sites under the purview of the reviewing IRB and no additional risks have been identified;

<u>Procedure for Expedited Review</u>

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In general, two reviewers conduct expedited reviews. The names of the reviewers are included in IRB documentation.

Unless an IRB determines otherwise, continuing review of research is not required for research eligible for and approved by expedited review in accordance with §__.109(f)(1)(i).

<u>Expedited Review of Minor Changes in Previously Approved Research</u>

Investigators must request in writing any proposed changes in IRB-approved research, including proposed changes in informed consent process, documents, or data collection methods. No changes may be initiated without prior approval of the IRB, except where necessary to eliminate apparent immediate hazards to participants.

The IRB may use expedited procedures to review a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

A minor modification is one which, in the judgment of the IRB reviewer, makes no substantial alteration in the level of risks to participants, the research design or methodology, the number of participants enrolled in the research, the qualifications of the research team, or other factors which would warrant review of the proposed changes by the convened IRB. Any added procedures must involve no more than minimal risk and fall into categories 1-7 of research that would allow review using the expedited procedure.

If proposed changes are judged to be more than minor, the proposal will be reviewed by the convened IRB at the next regularly scheduled meeting.

XII. Full Board Review

The Common Rule delineates specific criteria for the approval of research. In addition, the Salish Kootenai College IRB will review research for appropriate conduct and procedures related to any implications for the cultural intellectual property rights of the Confederated Salish & Kootenai Tribes.

If a given research protocol does not qualify for expedited or exempt review, as indicated by the criteria above, the protocol will be reviewed by the full IRB with a quorum of members present. The IRB will determine that all of the following requirements are met before approving the proposed research.

(1) Level of Risk. The IRB will consider the overall level of risk to participants. The regulations require that the IRB distinguish research that is greater than minimal risk from research that is no greater than minimal risk. Minimal risk is defined as "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.

(2) Risks are Minimized. The IRB must determine that risks are minimized by using procedures that are consistent with sound research design and do not expose participants to unnecessary risks.

The IRB verifies that the research plan, including research design and methodology, will not place participants at unnecessary risk. Additionally, the IRB will determine whether the researcher and research team has appropriate qualifications to be undertaking the research.

(3) Risks Reasonable Relative to Anticipated Benefits. The IRB must determine that the risks of the research are reasonable in relation to the anticipated benefits (if any) to participants, and the importance of the knowledge that may reasonably be expected to result. The IRB will consider only those risks and benefits that result from the research, and should not consider long-range effects (e.g. public policy implications) that arise from the knowledge gained through the research.

(4) Equitable Selection of Participants. The IRB should determine that the selection of participants is equitable, in adherence to the concept of "Justice" as set forth in the Belmont Report. To determine equitable selection, the IRB should evaluate the purposes of the research, the research setting, and the inclusion/exclusion criteria.

The IRB should be particularly aware of the problems of research involving vulnerable populations, and should be mindful of the importance of including members of minority groups in research, particularly when the research holds out the prospect of benefit to individual participants.

(5) Recruitment. The IRB will review any recruitment materials such as flyers, pamphlets, web announcements, or emails. The IRB will review the announcements to ensure that they do not offer benefits beyond those explained in the risk/benefit section. Recruitment materials may not differ materially from the informed consent document. The IRB will determine that payments, incentives, or other benefits offered as a result of participation are reasonable and are not coercive.

(6) Review of the Informed Consent Requirements. The IRB must determine that effective and voluntary informed consent is sought from each prospective participant or the participant's legally authorized representative unless a waiver of consent is approved by the IRB. Reasons for waiving informed consent are delineated below.

Informed consent may only be sought under circumstances that provide the participant or legally authorized representative with sufficient opportunity to consider whether or not to

participate in the study and that minimize the possibility of coercion or undue influence. The informed consent form must be written in a language understandable by the participant and at a reading level appropriate for the anticipated participants. Informed consent forms should not contain technical jargon that may not be understood by participants.

Informed consent information must include the following:

(a) A short statement that the study involves research and an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures or activities for the participant, an anticipated risks and benefits to participation.

(b) Reasonably Foreseeable Risks or Discomforts. Informed consent information must describe any reasonably foreseeable risks or discomforts associated with the research. Risks should be listed in descending order of probability.

(c) Reasonably Expected Benefits to Participants or Others. Informed consent information must describe any benefits to participants or to others that may reasonably be expected from the research. However, care must be taken not to overstate the benefits and create an undue influence on participants. Payment for participation in the research is not considered a benefit of the research.

(d) Appropriate alternatives if present. Informed consent should disclose any appropriate alternative procedures or courses of treatment. For example, if the research is a particular medical treatment, alternative treatments should be presented.

(e) Procedures For Confidentiality. Informed consent information must describe the extent to which confidentiality will be maintained or not maintained. Consent information should describe any procedures that the research team will use to protect participants' private records. In some research, loss of privacy may be the greatest risk of participation. If records are subject to inspection or audit by a funding agency or sponsor, a statement should be included indicating that the sponsor may choose to inspect and copy research records that identify individual research participants.

(f) Compensation or Treatment for Injury. Informed consent information for research involving more than minimal risk must include explanations regarding whether any compensation is available if injury occurs, how participants can receive medical care and treatment for injuries suffered as a result of participation in a research program, a description of any such compensation or treatments or where more information about them is available.

(g) Contact Information. Informed consent information must include details, including telephone numbers, about who to contact for three specific questions:

    (i.) For answers to questions about the research. The principal investigator and other members of the research team are appropriate contacts for this information.

    (ii.) For answers to questions about participants' rights. The IRB Office telephone number should be provided for this information.

    (iii.) For projects with more than minimal risk, who to contact in the event of a research-related injury. The principal investigator may serve as appropriate contact for this information.

(h) Voluntary Participation Statement. Informed consent information must contain clear statements of the following:
    (i.) Participation in research is voluntary.
    (ii.) Refusal to participate not involve a penalty or loss of benefits to which the participant is otherwise entitled.
    (iii.) The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

(i) Additional Elements Where Appropriate. If appropriate the following elements should be included in the informed consent:
    (i.) Additional Costs. If the participant must bear any additional costs, e.g. transportation, health costs, time away from work, the informed consent should specify this information.
    (ii.) Investigator-initiated Termination of Participation. If there are instances or circumstances that would require investigators to terminate the participation of particular participants (e.g. noncompliance with research), the informed consent information should specify those circumstances.
    (iii.) Significant New Findings. If there is a possibility that during the course of research, significant new knowledge or findings might impact the participants' willingness to continue participation, the informed consent should detail the procedures for contacting participants about this new information and affirming their continued participation.

(j) In considering the adequacy of informed consent procedures, the IRB may require special monitoring of the consent process by an impartial observer, or include a required "waiting period" within the consent process.

(k) The IRB may consent to waive informed consent requirements in specific instances as defined in CFR 45.46.102(e.1.). If there is more than minimal risk to the participants and the only linkage between the participant and research data is the informed consent form, the IRB may provide waiver of consent.

(l) Broad Consent Information. Salish Kootenai College does not provide for broad consent for use of research specimens or data due to the burden of tracking compliance with broad consent regulations.

Data Safety Monitoring Plans and Review of Reports

The SKC IRB may require monitoring in addition to requirements for annual reporting. This may include a requirement for a Data Safety Monitoring Plan to be developed by the researcher and approved by the IRB. If required, the IRB will specify components to be included in the plan, which may include elements to ensure data integrity, additional protections for participant confidentiality or safety, or additional information about roles and responsibilities related to study coordination and data management. Additionally, the SKC IRB may request periodic reports that include information about informed consent procedures, data safety, unanticipated risks, and other such information.

Disposal of Data and Biospecimens

The SKC IRB may require researchers to provide a detailed plan for storage or disposal of data and/or biospecimens collected during the research process. The plan may include disposal of biospecimens

or detailed procedures for storage of data or returning the data to an appropriate tribal entity. If required, the IRB will specify components to be included in the plan and may provide assistance in determining appropriate resolution of data storage and return issues.

Outcomes of IRB Review

IRB actions for research reviewed may include the following:

(1) Approved with no changes. The research may then proceed.
(2) Approvable with non-substantive changes to be reviewed by the IRB Administrator or Chair. Such changes must be clearly delineated by the IRB or designated reviewer. The research may procee3d after the required changes are verified and the protocol is approved.
(3) Approvable with substantive changes to be reviewed by the designated reviewer or by the convened IRB. The research may proceed only after the convened IRB has reviewed and approved the required changes to the research, unless the IRB determines that the protocol meets established criteria for expedited review.
(4) Deferred pending receipt of additional substantive information. If the designated reviewer or IRB determines that it lacks sufficient information about the research to proceed with the review, the IRB may defer or table the review until additional specific information is received. The research may not proceed until the IRB has approved the protocol.
(5) Disapproved. The IRB has determined that the research cannot be conducted at SKC or by faculty, staff, or students of SKC.

Written Notification of IRB Determination

The IRB provides written notification of its determination to investigators. Notification includes:

(1) The IRB's decision to approve, disapprove, or require modifications of the research.
(2) Any modifications or clarifications required by the IRB as a condition for approval.
(3) If the research is disapproved or approved with modifications, adequate information for the investigator to understand the reasons for the IRB's decision.

Review of Approved Research

The Common Rule requires that the IRB conduct a review of approved research not less than once per year. Therefore the IRB approval period for research is 365 days after the date of approval. No research work can continue on the project after the end of the approval period without a continuing review having been completed and new approval granted by the IRB.

If the continuing review is not approved by the date specified, the study approval automatically expires and the study is closed. All research must stop, including recruitment, screening, enrollment, consent, interventions, collection of private identifiable information.

Suspension or Termination of IRB Approval of Research

The IRB is authorized to suspend or terminate research in order to protect the rights and welfare of research participants and others. The IRB Chair or a designated IRB member may temporarily suspend research when there is evidence of the presence of additional risk to participants or others. Suspensions may be lifted if an investigation determines that the harm was not associated with the

research, or if compliance with the approved protocol is re-established, and is determined to be sufficient to protect the rights and welfare of human participants. In some cases, protection of the rights and welfare of the research participants may require the transfer of the study to a different researcher, or the continuation of the protocol under a stricter monitoring protocol.

SKC Student Class Projects Requiring IRB Review

SKC students who are conducting research as a component of their academic work must follow the IRB procedures for conducting student research. These procedures are contained as a separate document that may be downloaded from the SKC IRB website.

IRB review is required for class projects that do not meet the criteria and include the following types of projects: class projects that may be published or presented outside of the college and independent studies such as honors theses, Master's theses, and similar independent research projects. All of these must be reviewed and approved by the IRB before students may begin their research.

Responsibilities of Instructors

- Instructors are responsible for ensuring appropriate design and ethical conduct of class projects involving human participants data or cultural intellectual property of the CSKT.
- Instructors are responsible for review of each student's project to determine whether the project does or does not meet the above definition of research and therefore needs review by the IRB.
- Instructors provide for training in ethical conduct of research projects. If the project will require IRB review and involves human participants, each student must complete the Collaborative Institutional Training Initiative (CITI) training and provide a certificate of training along with the submitted IRB materials.
- Instructors ensure that appropriate site permissions are obtained for all projects that are completed either as class projects or as formal research.
- Instructors advise students that data from human participants must not contain any personal and identifying information.
- Instructors closely monitor class projects to ensure that students are following correct procedures and conducting the project as was proposed.
- Instructors, to the best of their ability, monitor that the student projects are not shared, presented and/or published outside the SKC community, or submitted into SKC's repository without prior approval from the IRB. Should this occur, the instructor is to contact the IRB immediately.

Responsibilities of Students

- Students are responsible for following the guidelines for class projects as outlined in the course syllabus. Students are responsible for completing training in Human Participants Protection if required as part of an IRB review.
- Students inform participants that their data will be destroyed after the class project is completed (end of the semester).

- Students must notify their instructor should the class project change in any way from what was originally proposed.
- Students do not share, present and/or publish any part of the class project outside the SKC community without prior approval from the IRB.

XIX. IRB Procedures for Research Noncompliance and Research Participant Complaints

1. Research Participant Complaints

The Salish Kootenai College IRB is committed to the protection of research participants. Research participants are encouraged to express any concerns or complaints regarding the involvement in a research study. Consent documents must include the investigator's contact information for any questions, complaints and/or concerns the participant or legal representative may have about the research or related matters. Consent documents must also include contact information for the IRB office. Contact information for the IRB is made available for the reporting of questions, complaints and/or concerns. Information about how to report complaints or concerns is also provided on the IRB website.

The IRB will investigate all complaints or concerns received regarding human subject research conducted under its jurisdiction. All complaints or concerns will be handled in a confidential manner. This includes any reporting of an alleged violation of investigator compliance.

Complaints received by an investigator or members of the research team must be reported to the IRB Chair. All complaints, including those directly reported to the IRB, will be documented in IRB minutes. Records of complaints and communication related to complaints will be maintained in the IRB electronic files. The IRB Chair or designee will response to the complaint or concern in a timely manner. As necessary, complaints may be brought to the full IRB for discussion and recommendation. If the concern or complaint involves possible non-compliance or research misconduct, the complaint will be handled according to IRB procedures related to research noncompliance or misconduct.

2. Procedures for Research Noncompliance or Misconduct

The Salish Kootenai College Institutional Review Board complies with federal regulations and applicable ordinances of the Confederated Salish & Kootenai Tribes to review of research studies and communicate certain actions to entities that may have an interest in the status of the research being conducted.

Examples of violations include but are not limited to:

- Doing research with human participants or with considerations for the intellectual property rights of the Confederated Salish & Kootenai Tribes without prior approval of the Board;
- Doing research in a way different from that described in the approved proposal;
- Failure to follow approved informed consent procedures;
- Failure to report adverse reactions, injuries, breaches of confidentiality or detrimental effects;
- Doing research after approval has expired.

The IRB will notify institutional officials, funding sources, and regulatory agencies, as appropriate, once the IRB takes any of the following actions:

- Determines that an event represents an unanticipated problem involving risks to participants or others;
- Determines that non-compliance was serious or continuing; or
- Suspends or terminates approval of research.

Allegations of research misconduct will be reported by the IRB Chair to the College President. Inquiry, investigation and hearings will be conducted by the full Institutional Review Board as needed to determine the extent of noncompliance or misconduct and the appropriate response. The IRB Chair will attempt to ensure that the inquiry and final determination as well as appropriate notifications are completed within 30 days of the initiating action. The IRB Chair will expedite responses for serious actions.

If the IRB determines that serious research misconduct or noncompliance has occurred, the IRB Chair will prepare a letter that contains the following information:

- The nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research);
- Name of the institution conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem including the findings of the organization and the reasons for the IRB decision;
- Corrective actions and/or sanctions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.);
- Plans, if any, to send a follow-up or final report by a specific date or when an investigation has been completed or a corrective action plan has been implemented.