CHIEF DULL KNIFE COMMUNITY COLLEGE

INSTITUTIONAL REVIEW BOARD

IRB

07/23/2013

CDKC Institutional Review Board

- **Mission Statement for IRB:**

Chief Dull Knife College is a community based, land grant, tribally controlled college established to provide quality educational opportunities to residents of the Northern Cheyenne Reservation and surrounding communities. Inspired by Chief Dull Knife's determination, our mission is to provide Northern Cheyenne culturally influenced education through quality life-long learning opportunities.

The mission of Chief Dull Knife College (CDKC) is to achieve excellence in the interrelated areas of education, research and public service. CDKC contributes to the advancement of society through research, creative activity, scholarly inquiry and the development of new knowledge.

CDKC is responsible for ensuring that the Human Research Protections Program (HRPP) has the resources and support necessary to comply with federal regulations and guidelines that govern human subjects' research.

In general, it is the responsibility of all faculty and research staff, IRB members, CDKC staff negotiating with research sponsors, and anyone else involved in human subjects research to uphold the ethical standards delineated in the Belmont Report and assure that the highest level of human subjects protections are in place and implemented.

Therefore, research will demonstrate research compliance regarding the protection of safety, health and wellbeing of individuals and the community it is working for by following the Mission Statement, ethical principles, policy, and procedures set forth.

- **Research Policy** http://www.hhs.gov/ohrp/index.html

The CDKC IRB has authority to approve, require modifications of, or disapprove all research activities involving human subjects and cultural materials, 45 CFR 46.109 (a). Approval obtained by other research institutions or universities are not to be replaced or used for CDKC IRB approval. All researchers will follow the guidelines and procedures for protection of human subject outlined by CDKC and carried out by the IRB. All researchers will abide by ethical principles which are set forth by The Belmont Report.

- *Respect for Persons* – In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information therefore by obtaining informed consent. This provides individuals to be treated as autonomous agents, understanding that moral statues apply with those with diminished autonomy.

- *Beneficence* – The obligation of beneficence affect both the individuals, investigators and the society at large. There are two general rules that have been formulated as complementary expression of beneficent actions in this sense: Do No Harm and Maximize possible Benefits and Minimize possible Harms. This requires all that is involved to analyze the risk-benefit ratio meanwhile minimizing the risk.

- *Justice* – This principle requires the selection of research subjects to be fairly selected.

Data collection cannot begin without CDKC IRB approval. Research results will be copied and kept by and in the Dr. John Woodenlegs Memorial Library where the IRB office is located.

Research that will involve CDKC students, faculty, staff or facilities must be approved by the CDKC IRB and the Chairperson of the board will inform the President's Council at a regular scheduled meeting. CDKC staff, faculty and adjunct faculty are subject to the same rules regarding IRB submission of their research proposal(s). Any student wanting to conduct research on human subjects or cultural materials for their class requirements must have a full time faculty member as the principal investigator. Adjunct faculty will also list their departmental heads as their principal investigator on each of their research proposals.

Definition of research used in this policy is taken from Title 45 CFR Part 46; 46.102(d): *"research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes."*

- **IRB Review Procedures:**

All research must obtain prior approval from the CDKC IRB prior to data collection. Approval from institutions or agencies outside of CDKC cannot be used in place of CDKC IRB approval. CDKC requires that all research projects and particularly those involving human subjects and Northern Cheyenne culture, language, and all other aspects of the Indian Community be approved by the CDKC IRB.

All researchers who are involved with human subject or cultural resources are required to take online web based training. The following trainings listed must be completed by each researcher (anyone in contact with individuals and data) and the principal investigator.

- Protecting Human Research Participants through the National Institutes of Health (NIH) http://phrp.nihtraining.com/users/login.php
- University of Montana, Online Research Ethics Course http://www.umt.edu/research/Ethics/research_ethics.html

In the event that a research project needs to be terminated or termination is requested by the Principal Investigator, documentation of cause must be in a written document for the request. In cases of adverse events happening during the research project, termination by the board may be decided. The principal investigator will be contacted immediately either by phone or email and confirmed in a written letter. All research activities must be stopped immediately with this action. After corrected actions have been made, the principal investigator can then complete another application to be submitted to the IRB with proper documentation.

Principal Investigator's Responsibility: http://answers.hhs.gov/ohrp/categories/1567

1. Prior to data collection, an application must be submitted to the IRB office. The principal investigator must determine which type of application to apply for regarding the Levels of Review. Data collection does not commence after submitting an application. Data collection can take place after an approval from the CDKC IRB and a letter has been awarded to the PI from the Chairperson of the IRB.
2. The PI and the researchers must be familiar with the Office for Human Research Protections (OHRP) Policy and Guidance. These can be found and printed at **http://www.hhs.gov/ohrp/policy/index.html**
3. It is the PI's responsibility to contact the Chairperson of the IRB immediately:
   - With material changes
   - Unanticipated changes or problems involving risks to the subjects or others
   - Possible changes in or alternatives to the programs procedures
   - Possible changes in methods
4. The PI must ensure that research investigators are also responsible for obtaining informed consent and ensuring that no human subject will be involved in the research prior to obtaining the consent.
5. It is also the PI's responsibility to submit a copy of any reports given to the agency or departmental head regarding the research conducted. Mechanisms for monitoring the progress of the research must be in place.

6. It is the PI's responsibility to submit an annual continuation review application. The continuation application will need to be submitted prior to the date of original review approval, no longer than 364 days.
7. The PI must maintain records relating to research that are conducted for at least three (3) years. The records must be kept in a safe and secure manner to protect the privacy of the individual and community subjects.
    - After the three (3) year holding period, each document containing private information must be shredded and destroyed, and cannot be used in further research activities, unless listed in the application otherwise.
    - Data collected cannot be used for any other purposes other than the original application submitted. However, a new application could be submitted for review on other uses.

Levels of Review

45 CFR 46.102 Defines **Minimal Risk**: *"means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*

✓ Exempt Review: research activities in which the only involvement of human subjects will be in one or more of the following categories as defined in the 45 CFR 46.101(b). This does not mean that the IRB cannot place an application for a full review, but gives some criteria as to whether an application can be within exempt review.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) on regular and special education instructional strategies or (ii) on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior IF & WHEN:
    - The information is recorded by the investigator in such a manner that subjects <u>cannot</u> be identified, directly or through identifiers linked to the subjects.
    - Any disclosure of the human subjects' responses outside the research should reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
- 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 subjects.

- In the event research is undertaken without the intention of involving human subjects.

✓ Expedited Review: Under this type of review, 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. This does not mean that the IRB cannot place an application for a full review, but gives some criteria as to whether an application can be expedited review.

- Involves no more than minimal risk; regardless of the age of subjects.
- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- Collection of blood samples by finger stick, heel stick , ear stick or venipuncture from the following categories;
    - Healthy, non-pregnant adults who weigh at least 110 pounds and no more than twice (2) a week or not exceeding 550 ml in an 8 week period
    - From other adults, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means: examples may include:
    - Hair and nail clippings in a non-disfiguring manner
    - Excreta and external secretions (including sweat)
    - Saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue. Procedure done without sticking a small tube for insertion into a body cavity, duct, or vessel.
    - Mucosal and skin cells collected by mouth cavity scraping or swab, skin swab, or mouth washings.
    - Sputum collected after saline mist nebulization
- Collection of data through noninvasive procedure routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Not involving anesthesia or sedation. Examples include:

    - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
    - Weighing or testing sensory acuity
    - Ultrasound, diagnostic infrared imaging, and Doppler blood flow,
    - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- A continuing review of research that has been approved not longer than a period of one year. The application must provide:
    - Progress reports
    - Information about participant complaints
    - Accrual update and any compliance monitor site visits
    - Summary of changes to research since last review
    - Any new changes to the study
    - Protocol deviations

✓ Full Review: Applies to all research involving human subjects' conducted, supported or otherwise subject to regulation, any research involving more than minimal risk and/or at the discretion of the board. Applications for review will be conducted at convened meetings at which a majority of members of the IRB are present. In order for the research to be approved, it will require the approval of the majority of the IRB members present at the meeting. The Principal Investigator can be present at the meetings but must refrain from voting and may only respond to the IRB members if they ask a question or comment on issues that need clarification. The PI must leave the room prior to voting on the research application.

The full review will also include, but not limited to, the following:

- Greater than minimal risk
- Cultural aspects of the community
- Maximal exercise testing
- Questions about the participants illegal activities or sexual practices
- Research involving pregnant women and neonates
    - Duties will follow the 45 CFR 46.203-207
- Research involving Children.
    - Duties will follow the 45 CFR 46.401-409

- Definition 45 CFR 46.402. *Children are 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.*

- **IRB Application (form)**
  - ✓ Copies of Informed Consent forms must be submitted with application. Please see requirements of informed consent forms.
  - ✓ Certifications of training and ethical training for human subjects must be submitted with the application for the PI and all researchers associated with the application.
  - ✓ Copies of previous IRB approvals from other institutions or agencies must be submitted with the application. This does not suggest nor affirm approval from the CDKC IRB.
  - ✓ Applications of review for research that have not been approved by other IRBs will not be approved by CDKC IRB.
- **Requirements for Informed Consent forms.**

The general requirements for informed consents are established in 45 CFR 46.116. **http://www.hhs.gov/ohrp/policy/consent/index.html**

Research involving human subjects must first include the legal consent of the subject or the subject's legally authorized representative to be a part of the research data collection. The investigator for the research must obtain the consent of each subject or the subject's legal authorized representative prior to data collection. Informed consent will be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legal authorized representative. The following information must be on the informed consent form:

- The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
- No informed consent may include any exculpatory language through which the subject or the representative is to waive or appear to waive any of the subject's legal rights, or release or appears to release the investigator or its agents from liability for negligence.
- Basic elements of informed consent:
  - A statement that the study involves research
  - An explanation of the purposes of the research
  - The expected duration of the subject's participation
  - A description of the procedures to be followed

    - Identifying any procedures which are experimental
    - A description of any reasonably foreseeable risks or discomforts to the subject. Includes unforeseeable risks
    - A description of any benefits to the subject or to others which may reasonably be expected from the research
    - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
    - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
  - For research involving more than minimal risk: an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
  - Principal Investigator's contact information. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
  - A statement that the participation is voluntary and the refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled.
  - The statement should also include that the subject may discontinue participating at any given time without penalty or loss of benefits to which the subject is otherwise entitled.
  - Any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
  - Any costs associated in participating in the research.

The IRB may waive the requirements to obtain informed consent provided the IRB finds and documents the following:

  - The research involves no more than minimal risk to the subjects
  - The waiver will not adversely affect the rights and welfare of the subjects
  - The research could not practicably be carried out without the waiver
    - See details with Oral Consent
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation

The IRB may accept oral consents when the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and when the following elements have been met:

- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- A short form written consent document stating that the elements of informed consent required above have been presented orally to the subject or the subject's legal authorized representative.
  - With this method, there shall be a witness to the oral presentation.
  - A copy of the summary shall be given to the subject or the representative.

➢ **IRB Membership & Duties**

Members of the IRB will be appointed by the CDKC President in accordance to the guidelines set for membership outlined in Title 45 CFR Part 46.107 Protections of Human Subjects. The board may not constitute entirely of one gender or one profession. Each member is selected with the following criteria in notion:

1. Director of Library Services
2. Science faculty
3. Human Service faculty
4. Layperson – not part of an immediate family member of anyone affiliated with the institution.
5. Cultural awareness – maybe a part of the community or affiliated with the institution
6. Communication faculty
7. An individual having prior IRB experience
8. Alternate member(s) – as needed for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting. An alternate member who replaces a primary member at any given meeting should have background and knowledge equivalent to that of the primary member. The replacement will be paired and listed on the meeting minutes.

The board will have the authority to elect a Secretary within them to designate the duty of documenting the meeting minutes and carry out the delegated authority given by the Chairperson. The secretary position can be selected by nomination and seconded by one other person of the board. This position maybe selected annually.

Current members for the IRB will be posted on the IRB Members Page. There will be no term limitations set forth for members of the board. There is also no term limitation set on the Chairperson for the IRB.

1. Name, degrees, representative capacity, indications of experience such as board certifications, licenses, etc. This is describing each member's chief anticipated contributions to IRB deliberations and any employment or other relationship between each member and the institution. 46.103(3)

2. Changes in the IRB board shall be reported to the Office for Human Research Protections, HHS.

Following 45 CFR 46.108 (b), a quorum to review proposed research will consist of the majority of the members of the IRB, which also includes at least one member whose primary concerns are in the nonscientific areas. In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting.

In complying with the OHRP guidelines, the board members will complete the following training modules online and submit a copy of the completion certificates to the IRB office, Development Office.

- The Human Subject Assurance Training online. This training can be accessed through the web. http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp
- Protecting Human Research Participants through the National Institutes of Health (NIH) http://phrp.nihtraining.com/users/login.php

The CDKC IRB has authority to suspend or terminate an approval of research. Following the 45 CFR 46.113, research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects gives authority to CDKC IRB to suspend or terminate an approved research application. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to the investigator and the agency or other institutions in which the research is being conducted, in order to stop all research activities.

The IRB will conduct annual reviews for research that have been given approval. Continuing reviews will be conducted as appropriate to the degree of risk.

IRB Chairperson Duties:

1. Primary Reviewer: to review the application and determine what type of review is necessary. This can also be decided upon with other board members inputs if requested by the chair.
2. The Chairperson will provide copies of the application to all board members for their review, at least one week prior to the scheduled meeting.

3. Under an expedited review procedure, the chairperson must notify the principal investigator within five working days of approval.
    a. If chair decides there needs to be a full review, the chairperson will notify the principal investigator within five working days after the application has been submitted, also including the date of the full review.
    b. The chairperson will also provide the IRB with a listing and a copy at the next scheduled meeting regarding applications used for expedited review & exempt review applications.
4. Full review applications will be done on an as needed basis and a letter to the principal investigator will be sent out within five working days of the decision of the board on the application.
    a. If the IRB decides to disapprove an application, the letter will include a statement of the reasons for its decision and will set a date deadline for the principal investigator to respond in writing and further actions will either be placed on the next meeting or a decision by the chairperson will made if enough action has taken place for an approval.
    b. The IRB may impose additional conditions prior to or at the time of approval when additional conditions are necessary for the protection of human subjects. The conditions will be sent forth in the letter of approval to the Principal Investigator. 46.124
5. The Chairperson has the responsibility of setting up and conducting a convened meeting by the IRB members. She/he will notify the members of an IRB meeting no less than 1 week in advance, by email, phone, or letter sent to all members of the IRB. The chairperson can also direct this responsibility to the Secretary of the Board or the administrative assistant.
6. It is the Chairperson's duty to provide and submit an update to the OHRP-IORG of new/changed membership to the IRB, within 90 days after the changes occur.
7. The Chairperson will also submit a renewed application of FWA to the OHRP at a minimum of every 3 years.
8. The Chairperson will share and update the President's Council of CDKC on IRB applications at least annually.

- **Record keeping**

45 CFR 46.115: All records will be kept for a period of no less than three (3) years by the IRB Office, after the completion of the research. Documentation will be placed in a safe and secure

location associated with the Dr. John Woodenlegs Memorial Library Office. Records will include the following:

- ✓ Copies of applications: including research proposals, scientific evaluations, consent documents, progress reports submitted by principal investigators, & Reports of Injuries to subject*.
- ✓ Continuing Review activities
- ✓ Copies of all activities between IRB and principal investigators
- ✓ Following 46.116 (b) (5) – A copy of the statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subjects.
- ✓ Minutes of Meeting of IRB
    - Attendance
    - Actions: including members voting actions (approve vs disapprove, abstaining)
    - The basis for requiring changes in or disapproving research
    - Written summary of the discussion of disputed issues & resolutions
- ✓ A list of IRB members in detail
- ✓ A copy of all policy and procedures for the IRB
- ✓ A printed copy of the OHRP IRB Guidebook