# APPLICATION FOR HUMAN SUBJECTS RESEARCH APPROVAL

*Date received:*

*IRB #:*

Chief Dull Knife College requires all projects that involve human subjects undergo review by the College’s Institutional Review Board (IRB). Approvals are valid for 12 months and may be eligible for a 6-month renewal. For more information regarding human subjects research, see <https://ori.hhs.gov/content/basic-research-concepts-brc>.

1. Project Title Click or tap here to enter text.
2. Principal Investigator

Name Click or tap here to enter text.

Email Click or tap here to enter text.

Phone Click or tap here to enter text.

Relationship to CDKC:  Faculty  Staff  Student  None-explain: Click or tap here to enter text.

1. Faculty Sponsor - required for student projects

Name Click or tap here to enter text.

Email Click or tap here to enter text.

1. Co-Principal Investigators

* Name Click or tap here to enter text.

Email Click or tap here to enter text.

* Name Click or tap here to enter text.

Email Click or tap here to enter text.

* Name Click or tap here to enter text.

Email Click or tap here to enter text.

1. All Investigators need to complete a self-study course in human subject protection. A copy of your certification from either CITI Program or Protecting Human Research Participants (NIH) must be included with this application.
2. If this project will be funded under agrant to another investigator, provide the title of the grant, name of funding agency or institution, and the investigator’s name: Click or tap here to enter text.

# TYPES OF REVIEW

### EXEMPT

Research activities in which the only involvement of human research participants will be in one or more of the following categories, are usually exempt from further IRB review. Check all that apply:

1. Research conducted in established or commonly accepted educational settings, involving normal education instruction practices, such as:
   1. research on regular and special education instruction strategies, or
   2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research\* involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior**:**
   1. information obtained will be recorded in such a manner that research participants can be identified, directly or through identifiers linked to the participants;
   2. any disclosure of the research participants’ responses outside the research could reasonably place the them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

*\*Research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators* ***DO NOT*** *participate in the activity being observed. Research involving children that uses survey or interview procedures and research involving the observation of public behavior if the investigators participate in the activity being observed would need to be reviewed by expedited or full board procedures.*

If you checked 2a and 2b, your research is not exempt from IRB review. You must apply for Expedited or Full IRB review.

1. Research involving the use of educational tests (as above), survey procedures, interview procedures, or observation of public behavior that is not exempt under 2b of this section, if:
   1. the research participants are elected or appointed officials or candidates for public office; or
   2. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:
   1. the sources are publicly available, or
   2. the information will be recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
3. 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.

\**Data must exist at the time of IRB submission.*

### EXPEDITED

In order to qualify for expedited review, the study must be no more than minimal risk\* and must fall into one of the categories below. Check all that apply:

1. Clinical studies of drugs and medical devices only when an investigational new drug application (IND) or investigational device exemption application (IDE) is not required.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   2. from other adults and children, 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.

\**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*.

1. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings, saliva or cheek swabs, sweat, etc.
2. 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/approved for marketing. Examples:
   * 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
   * Magnetic resonance imaging
   * Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   * Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
3. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
4. Collection of data from voice, video, digital, or image recordings made for research purposes.
5. 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.

### FULL BOARD

The IRB will make the final determination on the Type of Review

# PROJECT INFORMATION

Fill out completely. Use NA when necessary.

1. Project Type

Faculty Research  Thesis/Capstone  Contract  Training Grant

Research Grant  Class Project  Other-explain: Click or tap here to enter text.

1. Anticipated dates of project

From Click or tap here to enter text. To Click or tap here to enter text.

1. Name of funding agency to which proposal is being submitted (if applicable): Click or tap here to enter text.
2. Are any other institutions involved the in the proposed project?  No  Yes-name and nature of collaborator/s: Click or tap here to enter text.
3. Has another IRB approved the research study?  No  Yes-attach a copy of the approval.
4. Rationale and purpose of research - what question is being asked: Click or tap here to enter text.
5. Provide a short description of sequence and methods that will be performed with human subjects. Include details of painful or uncomfortable procedures, frequency of procedures, time involved, names of psychological tests, questionnaires, restrictions on usual life patterns, and follow up procedures: Click or tap here to enter text.
6. Location(s) where procedures will be carried out: Click or tap here to enter text.
7. If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary and attach debriefing statement: Click or tap here to enter text.
8. Subjects

* Approximate number and ages
  + How many subjects: Click or tap here to enter text.
  + Age range of subjects: Click or tap here to enter text.
  + How many normal/control: Click or tap here to enter text.
* Criteria for selection: Click or tap here to enter text.
* Criteria for exclusion: Click or tap here to enter text.
* Source of subjects (including patients): Click or tap here to enter text.
* Who will approach subjects and how: Click or tap here to enter text.
* Explain steps taken to avoid coercion: Click or tap here to enter text.
* Will subjects receive payments, service without charge, or extra course credit: Click or tap here to enter text.

1. Risks and benefits

* Describe nature and amount of risk and /or adverse effects (including side effects), substantial stress, discomfort, or invasion of privacy involved: Click or tap here to enter text.
* Will this study preclude standard procedures (e.g., medical or psychological care, school attendance, etc.)?  No  Yes-explain: Click or tap here to enter text.
* Describe the expected benefits for individual subjects and/or society: Click or tap here to enter text.

1. Adverse effects

* How will possible adverse effects be handled: Click or tap here to enter text.
* Are facilities/equipment adequate to handle possible adverse effects?  No  Yes-explain: Click or tap here to enter text.
* Arrangements for financial responsibility for any possible adverse effects

Chief Dull Knife compensation-explain: Click or tap here to enter text.

Sponsoring agency insurance

Subject is responsible

Other-explain: Click or tap here to enter text.

1. Confidentiality of research data

* Will data be coded?  No  Yes
* Will master code be kept separate from data?  No  Yes
* Will any other agency have access to identifiable data?  No  Yes-explain: Click or tap here to enter text.
* How will documents, data be stored and protected?

Locked file

Computer with restricted password

Other-explain: Click or tap here to enter text.

1. Will human blood be utilized in your proposal?  No  Yes

* Will blood be drawn?  No  Yes-who will draw the blood and how is the individual qualified to draw blood: Click or tap here to enter text..
* What procedure will be utilized: Click or tap here to enter text.
* What disposition will be made of unused blood: Click or tap here to enter text.

1. Will academic records be used?  No  Yes
2. Will audio-visual or tape recordings or photographs be made?  No  Yes
3. Will written consent form(s) be used?  No  Yes-attach a copy of the consent form.
4. Attachments

Provide all necessary documentation

questionnaire, survey, list of potential interview questions, etc. to be used with research participants

consent agreement, cover letter, introductory script

permission to use existing data and/or permission from external institution

other-explain: Click or tap here to enter text.

# ASSURANCES

By submitting this protocol, I:

* Attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
* Agree to conduct the describe research in an ethical manner.
* Agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
* Agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
* Agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
* Agree to comply with any relevant HIPAA and FERPA regulations if applicable.

|  |  |
| --- | --- |
| Principal Investigator | Date |
| Co-Principal Investigator | Date |
| Co-Principal Investigator | Date |
| Co-Principal Investigator | Date |
| Faculty Sponsor | Date |

**Make sure you answered each question completely and have included all corresponding documents.** Failure to do so will delay the IRB’s ability to grant approval; expect decision notification within 10 working days.

~\*~