Sitting Bull College
Protection of Human Subjects in Research
Principles, Policy, and Procedures[1]
April 30, 2008[2]

Introduction

Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects.

An institution involved in biomedical or behavioral research should have in place a set of principles and guidelines that govern the institution, its faculty, and staff, in the discharge of its responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by the institution, regardless of the source of funding [Federal Policy §__.103(b)(1)].

The history of research involving American Indian people serves as another compelling reason that human subjects must be protected. Language and cultural differences caused misunderstanding about the intent and content of the research in which Native people were engaged. In sometimes intimidating situations, subjects were not informed, nor were they given the opportunity to decline participation. Sacred knowledge, objects, and sites were all too often violated in the name of research and the generation of new knowledge about indigenous peoples and their cultures. While Sitting Bull College must and will demonstrate research compliance, it is also committed to the protection of the citizens of Standing Rock so as not to repeat the history that took advantage of them. Therefore, research at, or sponsored by, Sitting Bull College will be well-designed and properly executed according to the following principles, policy, and guidelines.

Statement of Principles

The ethical principles that govern acceptable conduct of research involving human subjects at or sponsored by Sitting Bull College are found in *The Belmont Report*. The ethical principles are:

- Respect for persons

[1] Information in this document is from the Institutional Review Board Guidebook (http://www.hhs.gov/ohrp/irb/irbguidebook.htm) and from research review procedures used at the University of Montana and Arizona State University.

[2] Revised 5/8/08 by KGC; 5/9/08 by KGC, LV, KR; approved by IRB 5/20/08.

- Beneficence
- Justice

Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain informed consent.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in a risk/benefit analysis and to minimize risks.

Justice requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects be fairly selected.

Research Policy

Research at, or sponsored by Sitting Bull College will be well designed and properly executed. All researchers will abide by ethical principles of respect for persons, beneficence, and justice. All researchers will respect the culture of the residents of the Standing Rock Reservation when designing and carrying out proposed research. All researchers will follow the guidelines and procedures for protection of human subjects outlined by SBC and carried out by the Institutional Review Board (IRB). Data collection cannot begin without IRB approval. Research results will be shared with Sitting Bull College.

IRB Review and Approval Procedures

Sitting Bull College requires that all research projects and particularly those involving human subjects be approved by the Sitting Bull College IRB. The IRB meets quarterly during the academic year and as needed during the summer.

Any employee, adjunct faculty member, or student, who on behalf of SBC conducts research using human subjects must receive IRB approval prior to any data collection. The necessary forms for approval must be submitted to the IRB before a research proposal is submitted to a sponsor for funding. Faculty, adjunct faculty, or staff who wish to undertake research involving human subjects as part of their duties, and students who wish to conduct research as part of class requirements shall be subject to the same rules regarding IRB submission of their research proposal. Adjunct faculty and students must have a full-time faculty member as a co-principal investigator.

Applicant Responsibility:

1. Obtain application packet and Institutional Review Board Guidebook from the Office of the Academic Vice President or online at www.sittingbull.edu.
2. Complete PI training at http://ohsr.od.nih.gov/cbt/nonNIHpeople.html.
3. Determine type of IRB review application to be used (see section on Types of IRB Review).

4. Complete the appropriate IRB review application. Any required parts of the protocol such as an informed consent form or an interview instrument must be attached to the application.
5. Submit the complete application, with attachments, to the IRB Chair for review; indicate what will happen with the research results.
6. Secure IRB approval before data collection can begin.

Types of IRB Review Applications:

1. Exempt Review: An exempt review procedure consists of a review of research involving human subjects by the Chair or Member of the IRB.
    - Research conducted in established or commonly accepted education settings, involving normal education practices, such as (a) research on regular and special education strategies; or (b) research 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), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers liked to the subjects.
    - Research involving survey or interview procedures, except where the following conditions exist: (a) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception when the respondents are elected or appointed public officials or candidates for public office.
    - Research involving the observation (including observation by participants) of public behavior, except where the conditions named in number three above exist.
    - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

2. Expedited Review: An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. For full list of categories, see Appendix A.

- Clinical studies of drugs and medical devices only when certain conditions are met.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- Continuing review of research previously approved by the convened IRB.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Regular Review: A regular or full review procedure consists of a review of research involving human subjects by the full IRB.
    - Any research involving the use of vulnerable subjects. A vulnerable subject is defined as follows: "Vulnerability refers to the risks that researchers request their subjects to undertake in relation to the ability of the subjects to make fully informed consent. Populations routinely considered to be vulnerable include: children; prisoners; pregnant women; non-English speaking people; the mentally handicapped; those subjects engaged in illegal activities; people who are under medical treatment for

an illness that is relevant to the risk they are being asked to assume by the researcher; and subjects who may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study.

- Any research involving more than minimal risk, either mental or physical to the subject. Examples of protocols of this type may include surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subject's behavior, including sexual practices, studies that solicit information regarding instances of child or sexual abuse suffered by the subject, criminal activities and for studies regarding eating disorders. Examples of studies that involve more than minimal physical risk to the subject include stress testing, drug and alcohol use by the subjects and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject. This should not be considered an exhaustive list of studies that may involve more than minimal risk to the subject. The investigator should include a comprehensive statement of the potential risk/benefit ratio to the subject for consideration by the committee.

IRB Chair Responsibility:

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

Researcher or Principal Investigator (PI) Responsibility:

1. **Material changes**. The PI is expected to immediately notify the IRB, through the Chair, if any material changes occur. These changes include: a) substantial changes in procedure; b) significant unanticipated problems; or c) adverse reactions of, or effects on, the subjects and/or any changes as a result of same.
2. **Extended or continuing projects.** If data collection is extended beyond 12 months from the date of the original IRB approval, the PI must submit a continuation report for approval. The report must be submitted to the IRB before the 12^{th} month from the original approval date. The continuation report for can be obtained from the IRB Chair. If there are significant changes, the project will be treated as a new one and the entire review process must be repeated. If there are no significant changes, the project may be re-reviewed by an expedited review.
3. **Maintain required records.** The PI is expected to maintain required records for required time period. The secure place where records will be kept must also be indicated.

Possible IRB Actions:

1. Designate the research as exempt from IRB review as outlined above.
2. Approve the research. The research may involve some risk to subjects, but the IRB does not consider the risk to be unreasonable and/or the researcher has taken all practical steps to minimize the risk. The project is well designed and the research will be properly executed.
3. Conditionally approve the research. The researcher may proceed with the project as long as certain conditions set by the IRB are fulfilled by the researcher. Conditions might include revising the consent form to more clearly explain the procedure; receiving appropriate clearance from a particular agency or department; or discontinuing the research if deleterious effects occur. **Data collection may not commence until all conditions are met and approved by the IRB Chair or Board**.
4. Ask that the researcher resubmit the summary/study overview. If the IRB believes that it has insufficient information to take action, when it believes the research design contains clear dangers and should be revised to reduce risk or harm to human subjects, or there is language or cultural conflict, it will ask the researcher to resubmit applicable information.
5. Disapprove the research. The IRB will suggest revisions in the research design and ask that the researcher redesign his/her procedure and resubmit the summary/study overview. Final disapproval should come only after attempts to redesign the research have failed to remove the clear potential harm to human subjects.

Record Keeping Responsibilities:

IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained for at least three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.

The following records shall be kept in the Office of the Academic Vice President:

1. Copy of written IRB procedures and IRB membership lists.
2. The IRB application with any required attachments and correspondence received by the IRB Chair for each project reviewed.
3. Action by the full IRB or the IRB Chair for each proposed project.
4. Minutes of IRB meetings with records of attendance, actions taken and votes on the actions, basis for requiring changes or resubmission, and summary of discussions of controversial issues and their resolutions.
5. Records of continuing review activities, copies of all correspondence between the IRB and researchers, and statements of significant new findings provided to the subjects.

Institutional Review Board Guidelines and Federal Policy 45 CFR 46

Authorized institutional representatives, IRB members, and researchers or investigators must be familiar with the Institutional Review Board Guidebook developed by the Office for Human Research Protections (OHRP), and the Federal Policy 45 CFR 46. These resources can be found at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm or through a link at www.sittingbull.edu. Printed copies of the Guidebook are available in the Office of the President, Office of the Academic Vice President, from the Coordinator of Institutional Data, and from the IRB Chair.

APPENDICES

APPENDIX A

Expedited Review

Procedure[1]

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

I The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, 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.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) 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

(b) from other adults and children[2], 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) 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 subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, oppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation,

human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

I where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "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." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

APPENDIX B

EXEMPT CATEGORIES
45 CFR 46.101(b)

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) 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.
(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

APPENDIX C – APPLICATIONS

Application for Exempt Human Subjects Research Review
Application for Expedited/Regular Human Subjects Research Review

Date Received:

SITTING BULL COLLEGE

APPLICATION FOR EXEMPT HUMAN SUBJECTS RESEARCH REVIEW

Protocol Title:	Date of Request:
Principal Investigator Name and Degree(s):	Department:
Phone:	Mailing Address:
Email:	Fax:
University Affiliation: __ Faculty __ Staff __ Adjunct Faculty __ Other: Please specify.	Co-Investigators: Name: Study Role: Affiliation: Department: Email/Tel/Fax: Student (yes/no):
Please note: PIs must attach Curriculum Vita to this application. List all Co-PIs (attach an extra sheet if necessary). A Co-PI is anyone who has responsibility for the project's design, implementation, data collection, data analysis, or who has contact with study participants.	Co-Investigators: Name: Study Role: Affiliation: Department: Email/Tel/Fax: Student (yes/no):

STUDY OVERVIEW

1. Provide a brief description of the **background, purpose,** and **design** of your research. Be sure to list **all of the means you will use to collect data** (e.g., tests, surveys, interviews, observations, existing data). Provide a short description of the tests, instruments, or measures and attach copies of all instruments and cover letters for review. If you need more than a few paragraphs, please attach additional sheets. **For all of the questions, write your answers on the application rather than just saying "see attached."**

RECRUITMENT

2. Describe how you will recruit participants (attach a copy of recruitment materials).

PROJECT FUNDING

3. How is the research project funded? (A copy of the grant application(s) must be provided prior to IRB approval)

___ Research is **not funded** (Go to Question 4)
___ Funding decision is pending
___ Research is **funded**

What is the source of funding or potential funding? (Check all that apply)
__Federal __Private Foundation __Department Funds
__Subcontract __Fellowship __Other

Please list the name of the sponsor(s):

If grant funded, identify the institution(s) administering the grant (e.g., SBC, UND):

STUDY POPULATION – If you are doing data analysis only, please write DA.

4. Indicate the **total number of participants** that you plan to enroll in your study:

Indicate the **age range** of the participants that you plan to enroll in your study:

SUPPLEMENTAL MATERIALS

5. Attach a copy of the following items as applicable to your study (Please check ones that are attached):

__Research Methods (research design, data source, sampling strategy, etc.

__Any letters (cover letters or information letters), recruitment materials, questionnaires, etc., which will be distributed to participants

__If the research is conducted off-site, provide a permission letter where applicable

__If the research is part of a proposal submitted for external funding, submit a copy of the full proposal

Note: The information should be in sufficient detail so IRB can determine if the study can be classified as EXEMPT under Federal Regulations 45CFR46.101(b).

DATA USE & STORAGE

6. How will the data be used? (Check all that apply)

__Dissertation
__Thesis
__Results released to participants/parents
__Results released to agency or organization
__Publication/journal article
__Undergraduate honors project
__Results released to employer or school
__Conferences/presentations

Where will the data be stored?

EXEMPT STATUS

7. Identify which of the 6 federal exemption categories below applies to your research proposal and explain why the proposed research meets the category. Federal law 45CFR46.101(b) identifies the following EXEMPT categories. Check all that apply to your research and provide comments as to how your research falls into the category.

SPECIAL NOTE: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

___(7.1) Research conducted in established or commonly accepted education settings, involving normal educational practices, such as (a) research on regular and special education strategies; or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Please provide an explanation as to how your research falls into this category.

___(7.2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers liked to the subjects.

Please provide an explanation as to how your research falls into this category.

___(7.3) Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency heads and which are designed to study, evaluate or otherwise examine:(a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures or (d) possible changes in methods or levels of payment for benefits or services under those programs.

Please provide an explanation as to how your research falls into this category.

___(7.4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
NOTE: Please review the OHRP Guidance on Research Involving Coded Private Information or Biological Specimens at http://hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.
Please provide an explanation as to how your research falls into this category.

___(7.5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. (Generally does not apply to the college/university setting.)
Please provide an explanation as to how your research falls into this category.

___(7.6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Please provide an explanation as to how your research falls into this category.

PRINCIPAL INVESTIGATOR

In making this application, I certify that I have read and understand the Sitting Bull College Protection of Human Subjects in Research Principles, Policy, and Guidelines and that I intend to comply with the letter and spirit of the policy. I may begin research when the Institutional Review Board gives notice of its approval. I must inform the IRB of <u>any</u> changes in method or procedure that may conceivably alter the EXEMPT status of the project. **I also agree that records of the participants will be kept for at least 3 years after the completion of the research**.

Name:
Signature: Date:

FOR OFFICE USE:

This application has been reviewed by the Sitting Bull College IRB:

___Exempt Category:

___Approved___Deferred to other review___Recommended that PI submit for EXPEDITED or FULL REVIEW by IRB.

Signature of IRB Chair: Date:

Date Received:

SITTING BULL COLLEGE

APPLICATION FOR EXPEDITED/REGULAR HUMAN SUBJECTS RESEARCH REVIEW

Protocol Title:	Date of Request:
Principal Investigator Name and Degree(s):	Department:
Phone:	Mailing Address:
Email:	Fax:
University Affiliation: __ Faculty __ Staff __ Adjunct Faculty __ Other: Please specify.	Co-Investigators: Name: Study Role: Affiliation: Department: Email/Tel/Fax: Student (yes/no):
Please note: PIs must attach Curriculum Vita to this application. List all Co-PIs (attach an extra sheet if necessary). A Co-PI is anyone who has responsibility for the project's design, implementation, data collection, data analysis, or who has contact with study participants.	Co-Investigators: Name: Study Role: Affiliation: Department: Email/Tel/Fax: Student (yes/no):

PROJECT FUNDING

1. How is the research project funded? (A copy of the grant application(s) must be provided prior to IRB approval)

___ Research is **not funded** (Go to Question 4)
___ Funding decision is pending
___ Research is **funded**

What is the source of funding or potential funding? (Check all that apply)
__Federal __Private Foundation __Department Funds
__Subcontract __Fellowship __Other

Please list the name of the sponsor(s):

If grant funded, identify the institution(s) administering the grant (e.g., SBC, UND):

PROJECT SUMMARY

2. Provide a brief description of the **background, purpose,** and **design** of your research. Describe all interactions with potential study participants (e.g., how identified, how recruited) including **all of the means you will use to collect data** (e.g., instruments, measures, tests, questionnaires, surveys, interviews, interview schedules, focus group questions, observations). Provide a short description of the tests, instruments, or measures and attach copies of all instruments and cover letters for review. If you need more than a few paragraphs, please attach additional sheets. **For all of the questions, write your answers on the application rather than just saying "see attached."**

STUDY DURATION

3. What is expected duration of the study through data analysis? (Include timeline, if applicable)

a. When is the expected date that you wish to begin research? (MM/DD/YY) / / (Must be after submission date.) NOTE: Protocols are approved for a maximum of 1 year. If a project is intended to last beyond the approval period, continuing review and re-approval are necessary. Research cannot begin until you have received an approval letter.

IRB APPROVAL

4. Has this project been reviewed by another IRB? ___Yes ___No (If yes, please complete the information below and attach a copy of the IRB approved materials.)
- **a.** What is the name of the institution?
- **b.** What is the approval date/status of current IRB application?

STUDY SITES

5. Where will the study be conducted? (Check all that apply)

___On campus (Please indicate building(s) and room number(s) when known.)

___Off campus (Please provide location and letter of permission, where applicable.)

SAMPLE SIZE/DURATION

6.a. What is the expected number of individuals to be screened for enrollment?

b. What is the MAXIMUM number of subjects that you plan to enroll in the study?

c. What is the approximate number of: Males Females

d. Indicate the age range of the participants that you plan to enroll in your study: to

e. What is the expected duration of participation for each subject (at each contact session and total)?

SUBJECTS

7a. Will the study involve any of the following participants? (Please check all that apply if your study specifically targets these populations.)

__Children (under 18)
__Pregnant women
__Prisoners or detainees
__Persons at high risk of becoming detained or imprisoned
__Decisionally impaired
__Patients (status of their health?)
__Fetuses
__Native Americans
__Non-English speakers

b. If any of the above categories have been checked, please state how you will protect the rights and privacy of these individuals.

c. Please provide the rationale for the choice of the subjects including any inclusion criteria.

d. Will any ethnic/racial or gender groups be excluded from this study? If so, provide the rationale for the exclusion criteria.

RECRUITMENT

8. Describe the process(es) you will use to recruit participants and inform them about their role in the study. (Attach copies of any recruitment materials.)

Will any of the following be used?

__Internet/Email
__Posters/brochures/letters
__Newspaper/radio/television advertising
__Other

DECEPTION

9. Does the proposed research require that you deceive participants in any way? __Yes __No
If your response is yes, describe the type of deception you will use, indicate why it is necessary for this study, and provide a copy of the debriefing script.

COMPENSATION

10a. Will any type of compensation be used? (e.g., money, gift, raffle, extra credit)
__Yes (Please describe what the compensation is) __No (go to question 11)

b. Explain why the compensation is reasonable in relation to the experiences of and burden on participants

c. Is the compensation for participation in a study or completion of the study? (NOTE: Participants must be free to quit at any time without penalty including loss of benefits.)

d. If any of the participants are economically disadvantaged, describe the manner of compensation and explain why it is fair and not coercive.

INFORMED CONSENT

11. Describe the procedures you will use to obtain and document informed consent and assent. **Attach copies of the forms that you will use.** In case of secondary data, please attach original informed consent or describe below why it has not been included. Fully justify a request for a waiver of written consent or parental consent for minors.

RISKS

12a. What are the potential risks of the research? (Check all that apply)
__Physical harm
__Psychological harm
__Release of confidential information
__Other

b. Describe any potential risks to human subjects and the steps that will be taken to reduce the risks. Include any risks to the subject's well being, privacy, emotions, employability, criminal, and legal status.

BENEFITS

13a. What are the potential benefits to the individual subject, if any, as a result of being in this study?

b. What are the potential benefits to others, if any, from the study?

DATA USE & STORAGE

14. How will the data be used?

__Dissertation
__Thesis
__Results released to participants/parents
__Results released to agency or organization
__Other
__Publication/journal article
__Undergraduate honors project
__Results released to employer or school
__Conferences/presentations

Where will the data be stored?

PROTECTION OF CONFIDENTIALITY

15a. Describe the steps you will take to ensure the confidentiality of the participants and data.

b. Indicate how you will safeguard data that include identifying or potentially identifying information (e.g., coding).

c. Indicate when identifiers will be separated or removed from the data.

d. Will the study have a master list linking participants' identifying information with study ID codes, and thereby, their data? If so, provide a justification for having a master list. (NOTE: In many cases, the existence of a master list is the only part of a study that raises it above minimal risk, that is, places participants at risk.)

e. If you have a master list, when will it be destroyed?

f. How long do you plan to retain the data?

g. How will you dispose of the data?

h. Where on campus will you store the signed consent, assent, and parental permission forms?

INVESTIGATOR INTERESTS

16a. Does the PI have a current conflict of interest disclosure form on file? __Yes __No

b. Do any of the PIs or their family members have a financial interest in a business which owns a technology to be studied and/or is sponsoring the research? (If yes, please describe) __Yes __No

c. Are there any plans for commercial development related to the findings of this study? (If yes, please describe) __Yes __No

d. Will the PI or a member of the PI's family financially benefit if the findings are commercialized? (If yes, please describe) __Yes __No

e. Will participants financially benefit if the findings are commercialized? (If yes, please describe) __Yes __No

TRAINING

17. The research team must document completion of human subjects training.

Please provide the date that the PI/Co-PIs completed the training.

PRINCIPAL INVESTIGATOR

In making this application, I certify that I have read and understand the Sitting Bull College Protection of Human Subjects in Research Principles, Policy, and Guidelines and that I intend to comply with the letter and spirit of the policy. I may begin research when the Institutional Review Board gives notice of its approval. I must inform the IRB of any changes in method or procedure that may conceivably alter the EXEMPT status of the project. **I also agree that records of the participants will be kept for at least 3 years after the completion of the research**.

Name:
Signature: Date:

FOR OFFICE USE:

This application has been reviewed by the Sitting Bull College IRB:
___Full Board Review
___Expedite Category:
___Exempt Category:

___Approved ___Deferred ___Disapproved

___Project requires review more often than annual. Every ___ months.

Signature of IRB Chair/Member: Date: