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Date Received:

AANIIIH NAKODA 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:
College 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., ANC, MSU):

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:

SUBJECTS

5a. Will the study involve any of the following participants? (Please check all that apply if your study specifically targets these populations.)

- ☐ Children (under 18)
- ☐ Prisoners or detainees
- ☐ Decisionally impaired
- ☐ Fetuses
- ☐ Non-English speakers
- ☐ Pregnant women
- ☐ Persons at high risk of becoming detained or imprisoned
- ☐ Patients (status of their health?)
- ☐ American Indian

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.

SUPPLEMENTAL MATERIALS

6. 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
- ☐ If the research has been approved by an IRB from another institution, submit of copy of IRB approved materials

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

7. 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

8. 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.

☐ (8.1) 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.

☐ (8.2) 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.

☐ (8.3) 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.

☐ (8.4) 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.

☐ (8.5) 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.

☐ (8.6) 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 Aaniiih Nakoda 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 Aaniiih Nakoda 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:

AANIIIH NAKODA 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:
College 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 2)
___ 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., ANC, MSU):

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?

NOTE: If not approved, IRB results must be shared prior to approval.

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)
__Prisoners or detainees
__Decisionally impaired
__Fetuses
__Non-English speakers
__Pregnant women
__Persons at high risk of becoming detained or imprisoned
__Patients (status of their health?)
__American Indian

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
__Newspaper/radio/television advertising
__Posters/brochures/letters
__Other (describe)

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 Aaniiih Nakoda 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 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 Aaniiih Nakoda 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:

Date Received:

AANIIIH NAKODA COLLEGE

APPLICATION FOR CONTINUING RESEARCH REVIEW

Protocol Title:	Date of Request:
Principal Investigator Name and Degree(s):	Department:
Phone:	Mailing Address:
Email:	Fax:
College 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):

STATUS OF THE STUDY

1. Mark the status of the study. (check all that apply)

___ No subjects recruited for the study, therefore termination requested.
___ Inactive with no subjects recruited for study to date, study will become active.
___ Active with ongoing recruitment of subjects.
___ Active with subject recruitment completed.
___ Completed (data collection & follow-up complete).

OVERVIEW OF PROGRESS TO DATE

2a. When did the study actually begin?

2b. What is the estimated completion date for the study?

2c. How many subjects have completed the study?

2d. Will new subjects be enrolled in the study?

2e. Did any subjects voluntarily withdraw from the study?

If yes, provide any known reasons for which subjects withdrew from the study:

2f. Were there any non-medical problems or complications in the study that affected the subject or others?

If yes, a description of any problems or complications must be provided:

2g. Did any subject suffer an unanticipated problem or adverse event which was reported to the IRB since the last IRB review?

If yes, specify the number of reported events and describe briefly their nature and significance:

2h. Are there any other expected changes in data collection, data analysis or reporting procedures?

If yes, please describe the changes:

2i. What is the funding source for the project? What is the anticipated length of funding?

SUMMARY OF RESULTS

1. Provide a brief summary of any results (preliminary or final) obtained in the study. If the project is still active and no results are appropriate to report to the IRB at this time, this should also be stated and explained.

CHANGE IN RISK/BENEFIT RELATIONSHIP

2. Has anything occurred during the conduct of the study that may have altered the risk/benefit relationship?

If the answer is yes, provide a current assessment of the risk/benefit relationship of the research based upon results, adverse events, and other factors.

PRINCIPAL INVESTIGATOR

In making this application for continuation, I certify that I have read and understand the Aaniiih Nakoda 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 continue 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 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 Aaniiih Nakoda 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: