NORTHEASTERN STATE UNIVERSITY
Institutional Review Board

INSTITUTIONAL REVIEW BOARD (IRB) RESEARCH APPLICATION

For IRB use only: ___ Exempt __ Expedited ___ Full Board Review **IRB #**

Notice: All investigators listed on this application must complete the IRB Research Training *before* submitting this application for each academic year. The link in the next section will take investigators to the training module and log your training. Each investigator must indicate that she/he has completed the training by checking the corresponding box after selecting the title.

Review the NSU IRB Policies & Procedures prior to completing this application**.** Please contact the IRB Chair, Dr. Jim Ferrell, at irb@nsuok.edu if you have questions about completing or submitting your research application.

RESEARCH **MUST NOT BE INITIATED** UNTIL YOU RECEIVE AN APPROVAL EMAIL FROM THE IRB
If you are notified that your application has been evaluated as acceptable contingent on certain changes, you must not start data collection until you have submitted the requested changes and received notification that the revised application has been fully approved. Starting data collection before receiving documentation of study approval constitutes research misconduct as defined in the university policies.

Project Title:

**Note: The project title should be consistent with the title used in the consent document(s).*

PART I - INVESTIGATORS and KEY RESEARCH PERSONNEL (Cut and paste sections for additional investigators)

The Principal Investigator is responsible for communicating the terms of the approved application to all investigators. Student projects must be supervised by a faculty sponsor.

PRINCIPAL INVESTIGATOR (PI)

Title (*select one*) ☐ Dr. ☐ Mr. ☐ Ms. ☐ Mx.
☐ Check this box to indicate the investigator has completed training.

Full Name

Institutional email address

College/Department

Daytime Phone

Institution and mailing address, if not affiliated with NSU

Investigator Status (*select one*):
☐ Faculty ☐ Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other (specify)

CO-INVESTIGATOR

Copy and paste the Co-Investigator information if needed for additional investigators.

Title (*select one*) ☐ Dr. ☐ Mr. ☐ Ms. ☐ Mx.

☐ Check this box to indicate the investigator has completed training.

Full Name

Institutional email address

College/Department

Daytime Phone

Institution and mailing address, if not affiliated with NSU

Investigator Status (*select one*):

☐ Faculty ☐ Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other (specify)

CO-INVESTIGATOR

Title (*select one*) ☐ Dr. ☐ Mr. ☐ Ms. ☐ Mx.

☐ Check this box to indicate the investigator has completed training.

Full Name

Institutional email address

College/Department

Daytime Phone

Institution and mailing address, if not affiliated with NSU

Investigator Status (*select one*):

☐ Faculty ☐ Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other (specify)

PART II – FUNDING INFORMATION

Provide complete information about all funding sources for this research, including pending sources.
Attach a complete copy of the proposal submitted to the sponsor. Submission of your grant application is a regulatory requirement that will be retained as part of your IRB Research Application.

You must submit all necessary documentation for this application, such as consent forms and survey questionnaires, in addition to the copy of the grant, even if those forms are included in the grant application.

1) Check all of the appropriate boxes of funding sources for this research. Include pending funding source(s).
   - ☐ Not applicable *(skip to Part III)*
   - ☐ University
   - ☐ College
   - ☐ Federal
   - ☐ State
   - ☐ Tribal
   - ☐ Other *(please specify)*

2) Contract/Grant Title

3) Funding Source

4) P.I. of Grant or Contract

5) Sponsor

6) Contract/Grant Number *(if applicable)*

PART III – ADMINISTRATIVE DATA

1) Proposed start date _____ or ___ upon IRB approval

*Approval will be granted for up to one year. After this time, request an extension by email to **irb@nsuok.edu**. Records will be retained for five years after last approval end date.*

2) Project type
- ☐ Course project (student)
- ☐ Honors project (student)
- ☐ Thesis (student)
- ☐ Capstone (student)
- ☐ Optometry project (student)
- ☐ Faculty research project

3) Will **medical clearance or screening** be necessary for subject recruitment because of inclusion or exclusion criteria, administration of substances such as food or drugs, or physical exercise conditioning?
- ☐ No. *Skip to Question 4.*
- ☐ Yes. *If yes, complete Questions a and b.*

a. Explain how clearance will be obtained in the gray text box below.

b. If a screening instrument be used, please attach a copy to the end of the application, or copy the text of the instrument in the gray text box below. The text box will expand to accommodate your information.

4) **Study Sites** (select all that apply)
- ☐ NSU Tahlequah
- ☐ NSU Broken Arrow
- ☐ NSU Muskogee
- ☐ Other. *Please specify in the gray text box below. Hardcopies of letters must be submitted to the IRB chair or emails sent from an official account granting access to the institution. Mail site permissions to irb@nsuok.edu.*

5) **Potentially Vulnerable Populations**
Indicate any groups included in the study. Inclusion of any group below requires full board review. Check all that apply.

- ☐ Children (under 18 years of age)
- ☐ Pregnant Women
- ☐ Elderly (65 & older)
- ☐ Psychologically Impaired
- ☐ Cognitively impaired
- ☐ Prisoners
- ☐ Native American Tribes and/or Tribal Organizations
- ☐ Students enrolled in a class in which the instructor is an investigator in the study

6) **Other Institutional or External Oversight**
Check the items listed below that apply to this research project. This information may be forwarded to the appropriate institutional personnel and/or committee(s).

- ☐ Not applicable
- ☐ NSUOCO (Optometry) Student Projects Committee
- ☐ Cherokee Nation IRB
- ☐ Indian Health Services Oklahoma Area Office IRB
- ☐ Other institutional oversight committee *(please specify in the gray text box below):*

7) **Conflict of Interest**
Please refer to NSU IRB Policies on Conflict of Interest.
Is there any potential or perceived conflict of interest associated with this study between the researcher, sponsor and/or Northeastern State University?

- ☐ No
- ☐ Yes. *Please explain in the gray text box below. The IRB may require additional information.*

PART IV – SUMMARY OF STUDY ACTIVITIES

Submission of a copy of a grant application does not replace completion of this section. Please respond to each item. Incomplete forms will be returned. The text fields will expand as you type.

1) Provide background information for the study including the purpose of the proposed study, research question, hypotheses and any other relevant information.

2) Describe the research design of the study.

3) Describe the potential research subjects (participants). Explain your relationship to them, if applicable.

4) Present a step-by-step description of the procedures that you will ask participants to complete, including the method of administration (e.g. *telephone* interview, *online* test, *paper* survey).
Review the IRB policies regarding internet research, if applicable.

5) Indicate the approximate amount of time it will take participants to complete each step of the procedure, including the time to complete any data collection instruments. Note any tasks that participants might be asked to complete multiple times.

6) Attach a copy of each study document or copy the text of the document below. This includes all surveys, tests, interview or observation protocols, etc.

7) Describe the recruitment procedures. Explain who will approach potential participants and what will be done to protect the individual's privacy in this process.

8) Attach a copy of any material used to recruit subjects or copy the text of those materials below. Materials can include advertisements, hand-outs, telephone scripts, verbal recruitment scripts, cover letters, etc.

PART V – PRIVACY PROCEDURES

1) Will you collect or record any direct identifiers (names, social security numbers, addresses, telephone numbers, e-mail addresses, etc.)?

   ☐ No. S*kip to Question 2.*

   ☐ Yes. *Complete Questions a-e.*

   a. Explain why it is necessary to record findings using these identifiers.

   b. Describe the coding system you will use to protect against disclosure of these identifiers.

   c. Describe how subject identifiers will be maintained or destroyed after the study is completed.

   d. Will you retain a link between the study code numbers and direct identifiers after the data collection is complete?

   ☐ No
   ☐ Yes. *If yes, explain why this is necessary and state how long you will keep this link.*

   e. Will you provide a link or identifier to anyone outside the research team?

   ☐ No
   ☐ Yes. *If yes, explain why and to whom.*

2) In what format(s) will data be collected and stored (handwritten field notes, electronic spreadsheets, online survey software/program, video recordings, etc.)?

3) Do your data formats include photographs, audio recordings, or video recordings?

   ☐ No.

   ☐ Yes. *Explain if and how subjects will be identified in photographs, audio, and/or video files.*

4) Where will the data be stored? What security provisions will be taken to protect these data (password protected computer or files, encryption, locked file cabinet, etc.)? Address each data source.

5) When will the data be destroyed? You must provide justification if you wish to retain the data beyond the conclusion of the study.

6) How will the data be destroyed? Address each data source.

7) Will you place a copy of the consent form or other research study information in the subject's medical, personal or educational record? This information should be clearly explained in the consent document and/or process.

☐ No

☐ Yes. *Explain why this is necessary.*

8) Will any record of the subject's participation in this study be made available to his or her supervisor, teacher, or employer?

☐ No

☐ Yes. *Explain why this is necessary.*

9) Will you require a Federal Certificate of Confidentiality? Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure.

☐ No

☐ Yes. *Explain why this is necessary.*

PART VI – INFORMED CONSENT INFORMATION

View sample informed consent documents on the Resources for Researchers page.

1) **Informed Consent**: Please attach a copy of all consent documents or copy the text of these documents in the box below.
    a. If subject participation is anonymous, the IRB recommends including the text of an information sheet or cover letter containing all required elements of informed consent.
    b. If subject participation is not anonymous, you must include the text to the consent form.
        i. For adult participants, include the text for the consent form.
        ii. For children and youth participants, provide both the text for the assent form for the child/youth and the text of a permission form for the parents

PART VII – RISKS AND BENEFITS

1) Indicate if the research involves any of the following possible risks or harms to subjects. Check all that apply. If you check any, complete questions 1a) and 1b).

- ☐ Use of confidential records (education or medical records, etc.)
- ☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stressors
- ☐ Probing for personal or sensitive information in surveys or interviews
- ☐ Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
- ☐ Possible invasion of privacy of subject or family
- ☐ Risk of physical injury or harm
- ☐ Social or economic risk
- ☐ Legal risk
- ☐ Employment/occupational risk
- ☐ Use of deception (if yes, complete 1c)
- ☐ Other risks, specify:

a) Describe the nature and degree of the risk of harm checked above. The described risks/harms must be disclosed in the consent form.

b) Explain what steps will be taken to minimize risks or harms and to protect participants' welfare. If the research includes potentially vulnerable populations (Part III-V), identify each group and answer this question for each group.

c) If **deception** is used, describe the use of deception in detail. Include the debriefing process and the debriefing script. The principal investigator must offer the participant the opportunity to withdraw his/her data after finding out that deception was used in the study.

2) Describe the anticipated **benefits** of this research to the individual subject or to others that may reasonably be expected from the research.

3) Describe the anticipated **benefits** of this research for society and explain how the benefits outweigh the risks.

PART VIII – COMPENSATION INFORMATION

Will any compensation or inducements (monetary inducements, extra credit, etc.) be offered to the subjects for their participation?

☐ No

☐ Yes. *If yes, describe the inducements. Include a statement in the informed consent document explaining how compensation will be handled in the event the participant withdraws from the study.*

Submitting your Application

Submit only ONE file as a Word document. Emails with more than one file will not be accepted. If you have separate PDF files, Word files, etc, copy and paste them to this Word document.

Save this file (in Microsoft Word format) and send it **as an email attachment** to: irb@nsuok.edu
As part of the application form, include ***as appropriate***

- Solicitation Announcements
- Recruitment materials
- Data Collection Instruments (i.e. Interview questions/Questionnaires/Survey(s))
- Informed Consent Documents (*Parental/Legal Guardian Permission Form, Child Assent Form)*
- Medical Screening Instrument
- Proposal and/or Contract or Grant
- Debriefing Script (for studies involving deception)

You can also copy and paste them to the back of the document.

Below, check off which documents will be mailed to the IRB Chair

Dr. Jim Ferrell, IRB Chair
Northeastern State University
College of Education
600 N. Grand Ave.
Tahlequah, OK 74464

___ Original hardcopy or faxed letter of approval from off-campus study sites (i.e., public schools) or email from appropriate representative originating from his/her official email account in the capacity to grant permission.

___ Other: (if applicable) _____

Upon receipt of the emailed application, the person submitting the application will receive an automated confirmation of receipt.