INSTITUTIONAL REVIEW BOARD  
RESEARCH APPLICATION

Please contact the IRB Chair, Dr. Sophia Sweeney, if you have questions about completing or submitting your Research Application.

Prior to completing this application, please review the NSU IRB Policies & Procedures on the Institutional Review Board website.

For IRB use only: ___ Exempt ___ Expedited ___ Full Board Review

Project Title:

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

PART I - INVESTIGATOR and KEY RESEARCH PERSONNEL

1) PRINCIPAL INVESTIGATOR (PI)/CONTACT

<table>
<thead>
<tr>
<th>Name:</th>
<th>Dr.</th>
<th>Mr.</th>
<th>Ms.</th>
<th>Mrs.</th>
</tr>
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<tbody>
<tr>
<td>Investigator Status:</td>
<td>Faculty</td>
<td>Graduate Student</td>
<td>Undergraduate</td>
<td>Optometry Student</td>
</tr>
<tr>
<td>E-mail Address:</td>
<td>@nsuok.edu</td>
<td>Other email:</td>
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<td>Daytime Phone:</td>
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2) FACULTY SPONSOR OR CO-INVESTIGATOR (if applicable)

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If more space is needed to list additional co-investigators please copy and paste this section.
**ADDITIONAL CO-INVESTIGATOR (if applicable)**

<table>
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<th>Co-investigator:</th>
<th>Sponsor</th>
<th>Faculty</th>
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**Principal Investigators (and Faculty Sponsors, if the Principal Investigator is a student) will receive an email for digitally signing this application. Primary investigators are responsible for communicating the terms of the approved application to all investigators.**

**PART II – FUNDING INFORMATION**

1) Check all of the appropriate boxes of funding sources for this research. Include pending funding source(s).

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<th>University</th>
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<th>State</th>
<th>Federal</th>
<th>Other</th>
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<tr>
<th>P.I. of Grant or Contract:</th>
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<tr>
<th>Contract/Grant No. (if available):</th>
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<th>Contract/Grant Title:</th>
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*Please attach one complete copy of the proposal submitted to the sponsor. Submission of your grant application is a regulatory requirement and will be maintained for the record with your 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.*

**PART III – ADMINISTRATIVE DATA**

**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.
1) **Proposed start date:** ____________ or ____________ upon IRB approval

2) Please check the **most appropriate** box.

- Course Project (student)
- Honors Project (student)
- Thesis (student)
- Research Project (faculty)
- Capstone (student)
- Optometry Project

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

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
   - Yes

   If yes, explain how clearance will be obtained. If a screening instrument will be used, please attach a copy to the application, or copy the text of the instrument in the box below.

4) **Study Sites:**

- NSU-Tahlequah
- NSU-Broken Arrow
- NSU-Muskogee
- Other: ____________

5) **Potentially Vulnerable Populations:**

   Please check any groups included in the study. Inclusion of any group below requires full board review:  

- 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 (if applicable):**

   Check the items listed below that apply to this research project:

- NSUOCO (Optometry) Student Projects Committee
- Cherokee Nation IRB
- IHS Oklahoma Area Office IRB
- Other institutional oversight committee ____________

   Note: This information may be forwarded to the appropriate University personnel and/or committee(s).

7) **Conflict of Interest**

   Is there any potential or perceived conflict of interest between the researcher, sponsor and/or Northeastern State University associated with this study?  

   - No
   - Yes

   If yes, please explain: ____________

   Please refer to NSU IRB Policies on Conflict of Interest. Additional information may be requested by the IRB Board.
PART IV – SUMMARY OF STUDY ACTIVITIES

Submission of a copy of a grant application does not replace completion of this form. Please respond to each item. Incomplete forms will be returned.

1) Provide background information for the study in the box below, including the objective of the proposed research, purpose, research question, hypothesis and any other relevant information.

2) Describe the research design of the study in the box below.

3) Describe the tasks that participants will be asked to perform in the box below. Include a step-by-step description of the procedures you plan to use with your subjects. Provide the approximate duration of subject participation for each procedure. If data collection instruments will be used, indicate the time necessary to complete them, and the frequency and method of administration, such as telephone, mail, or face-to-face interview.

Attach a copy of each study document, or copy the text of the document in the box below. This includes all questionnaires, surveys, protocols for interviews, etc.

4) Describe the recruitment procedures. Attach a copy of any material used to recruit subjects, or copy the text of those materials in the box below. Materials can include advertisements, hand-outs, telephone scripts, verbal recruitment scripts, cover letters, etc. Explain who will approach potential participants and what will be done to protect the individual’s privacy in this process.

PART V – PRIVACY PROCEDURES

1. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc?    No         Yes
   If yes, explain why it is necessary to record findings using these identifiers. Describe the coding system you will use to protect against disclosure of these identifiers. Describe how subject identifiers will be maintained or destroyed after the study is completed.

2. 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.

3. Will you provide a link or identifier to anyone outside the research team? No         Yes
   If yes, explain why and to whom.

4. Will audio, video, film, or digitally captured data be recorded? No         Yes
Please explain how the disposition of the recorded data (tapes/photographs/negatives or digital/electronic media) will be handled. Indicate if recorded data will be erased or destroyed at the conclusion of the study. If you wish to retain the recorded data beyond the conclusion of the study, you must provide justification. Subjects must be informed of the disposition of any recorded data via the informed consent process. __________

Please clarify how subjects will be identified in audio/video/film/digitally-captured responses. __________

5. Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? Describe what security provisions will be taken to protect this data (password protection, encryption, etc). Finally, specify when and how the data will be destroyed. __________

6. Will you place a copy of the consent form or other research study information in the participant’s medical, personal or educational record? (This information should be clearly explained in the consent document and/or process) No [ ] Yes [ ]
If yes, explain why this is necessary. __________

7. Will you require a Federal Certificate of Confidentiality? No [ ] Yes [ ]
If yes, submit documentation of application (and a copy of the Certificate of Confidentiality award if granted) with this application form.
If the data collected contains information about illegal behavior, visit the NIH Certificates of Confidentiality Kiosk http://grants1.nih.gov/grants/policy/coc for information about obtaining a Federal Certificate of Confidentiality.

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 [ ]
If yes, please explain. __________

PART VI – INFORMED CONSENT INFORMATION

1) Informed Consent: Please attach a copy of all informed consent forms, or copy the text of these documents in the box below.
   a. If subject participation is anonymous, 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 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
      ii. For adult participants, include the text for the consent form.
View sample Informed Consent Documents at http://arapaho.nsuok.edu/~irb/

PART VII – RISKS AND BENEFITS

1) Does the research involve any of the following possible risks or harms to subjects? No [ ] Yes [ ] (if YES, a FULL BOARD REVIEW is required)
   If you answered YES, please check all that apply:
   □ Use of deception*
*If deception is used, describe this in detail in the box below. This includes 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.*

- Use of confidential records (e.g. education or medical records)
- Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stressors
- Any 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
- Other risks, specify: __________

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

3) Explain what steps will be taken to minimize risks or harms and to protect subjects' welfare. If the research will include protected populations (See Part III, Item 6), identify each group and answer this question for each group. __________

4) Describe the anticipated benefits of this research for individual participants in each subject group. If none, state “none”. __________

5) 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, i.e. course credit, be offered to the subjects for their participation?  

- No □
- Yes □

If yes, describe those inducements and include a statement in the informed consent document explaining how compensation will be handled in the event the participant withdraws from the study. __________
Submit your Application

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/Surveys)
- 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.

Upon receipt of the emailed application, the Principal Investigator (and the Faculty Sponsor if the Principal Investigator is a student) will receive a confirmation email that can be digitally signed by using Reply, typing the name and date in the appropriate space, and sending the reply email back to irb@nsuok.edu

**ELECTRONIC SIGNATURE POLICY FOR NSU IRB**

This policy outlines the procedures for use of electronic signatures for research proposals submitted by students and faculty to the Institutional Review Board.

- An “electronic signature” is an electronic sound, symbol, or process, attached to or logically associated with an electronic record or adopted by a person with the intent to sign a record.
- An electronic record or transaction is a record or transaction created, generated, sent, communicated, received, or stored by electronic means.
- Research applications submitted to the IRB by computer will be considered electronic records and transactions for purposes of this policy.
- For purposes of submitting research applications to the Institutional Review board the following shall all be recognized as an electronic signature:
  - Typed Name
  - E-Mail Address
  - Scanned image of a signature
  - Automatic e-mail signature
- The authentication for these electronic signatures is based on the University policy that furnishes a unique username; and the student or faculty member setting his or her own password. The user/applicant logs into the University network using his or her own username and password. Investigators should use their NSU email for authentication.
- The applicant and the IRB agree that electronic signatures can be utilized when submitting research applications and when the IRB responds to the applicant(s) research application after review by board members.
- The applicant agrees to the terms of this policy whenever he or she submits electronically a research application.
- The burden of refuting the authenticity of the electronic signature will be on the applicant.
Only submit ONE file. 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. Alternatively, print them out, send them by mail, and indicate below which documents will be mailed.

Below, check off which documents will be mailed to the IRB Chair
☐ Approval from Study Sites (ie, public schools)
☐ Other: (if applicable)_________________________