Northern Oklahoma College

Institutional Review Board Application for

 Exempt, Expedited and Full Board Research Studies

Note: Before beginning the application, please review the Exempt and Expedited Categories to determine if a full review is required or if an Exempt Review or Expedited Review is appropriate. Applications with missing required information will not be processed.

**I. Investigator and Key Research Personnel**

1. Principal Investigator

(Graduate students must also complete the form for Student as Principal Investigator and a faculty co-investigator or sponsor must be listed below. Undergraduate student cannot serve as Principal Investigator, but may be listed as a Co-Investigator.)

Name: Please enter name of PI

Title: Please enter title of PI

Highest Degree Completed: Please enter the highest degree for the PI

Investigator Status: Select from dropdown

Institution: Please enter the name of the institution of the PI

College/Department: Please enter the college/department of the PI

Email Address: Please enter the PI email

Phone: Please enter the PI phone

1. Co-Investigator/Faculty Sponsor (if applicable)

Name: Please enter the name of the Co-Investigator

Title: Please enter the title of the Co-Investigator

Highest Degree Completed: Please enter the highest degree of the Co-Investigator

Investigator Status: Select from dropdown

Institution: Please enter the institution of the Co-Investigator

College/Department: Please enter the college/department of the Co-Investigator

Email Address: Please enter the Co-Investigator email

Phone: Please enter the Co-Investigator phone

II. Funding Information

List all funding sources for this research and provide one complete copy of any grant proposal submitted to the funding sponsor(s) with this application; this information will be use only to confirm the IRB proposal is in compliance with the funding requirements. For each funding source include the following information: Principal investigator for the grant, funding sponsor, grant number (if applicable), grant title, and whether funding has been approved or is pending.

III. Principal Investigator Assurance

* I certify that the information provided in this application is complete and correct.
* I understand that, as Principal Investigator, I have the responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and well-being of all participants, and I agree that I am knowledgeable about the protocol for research with human subjects.
* I agree to all of the following:
	+ I will obtain legal informed consent from all participants in the research.
	+ I will follow the approved protocol as stated in this research proposal, and I will adhere to all applicable federal, state, and local laws.
	+ I will inform the IRB in writing should protocol need to be changed for any reason and/or if my employment status or contact information changes.
	+ I certify that I have obtained all approvals from entities other than NOC IRB that are necessary to conduct this research.
	+ I further certify that no children under 18 will be used in this study.

Select date

Principal Investigator Date(mm/dd/yyyy)

 Select date

Co-Investigator or Faculty Sponsor Date(mm/dd/yyyy)

IV. Administrative Data

1. Title of Research Proposal:

Please enter the full title of the research proposal.

1. Proposed Start Date: Start date

Proposed End Date: End date

Note: Project work may **NOT BEGIN** prior to approval or exemption from the IRB.

1. Will this research result in a thesis or dissertation?

[ ] No [ ] Yes

If yes, please select.

[ ] Thesis [ ] Dissertation

1. Participant population
2. Please describe the study population:

Please describe your study population.

1. Inclusion Criteria:

Please describe the studies inclusion criteria.

Exclusion Criteria:

Please describe the studies exclusion criteria.

1. Maximum number of participants proposed: Number of participants
2. Age range: Minimum age to Maximum age
3. Gender: [ ] Male [ ] Female

[ ] Other Please specify if you selected other.

1. NOC Study Sites:

[ ] Tonkawa Campus [ ] Enid Location [ ] Stillwater-Gateway Location

[ ] Other Please specify if you selected other.

1. Potentially Vulnerable Populations

[ ] Cognitively Impaired [ ] Pregnant Women

[ ] Elderly (65 and older) [ ] Psychologically Impaired

1. Will you specifically recruit NOC employees? [ ] No [ ] Yes

Will you specifically recruit employees of other organizations? [ ] No [ ] Yes

If “Yes” to either question above, describe procedures for protecting employees’ confidentiality in their workplace. When studying employees in their workplace, a breach of privacy could Potentially put participants’ reputations and employability at risk.

Please explain how you will protect employees who are being studied at their workplace?

1. Will you recruit students from the courses you are teaching or your advisees?

[ ] No [ ] Yes

If “Yes”, explain how you will ensure you will not know which of your students have or have not consented to participate until AFTER semester grades are posted.

Please explain how you will avoid potential coercion with students.

1. Will medical clearance or medical screening be necessary for participants to participate because of tissue or blood sampling, administration of substances such as food or drugs, or physical exercise conditioning?

[ ] No [ ] Yes

If yes, attach an explanation on how clearance will be obtained. If a screening instrument will be used, please attach a copy to the application.

1. Conflict of Interest

Is there any potential or perceived conflict of interest (e.g. financial gain as a result of the study) between the researcher, sponsor and/or Northern Oklahoma College associated with the study?

[ ] No [ ] Yes

If yes, please explain:

Please explain the conflict of interest.

Additional information may be requested by the Board.

V. Summary of Study Activities

Please respond to each item. Incomplete forms will be returned.

1. Provide background information for the study including the purpose of the study, research questions to be answered, and other relevant information.

Please describe purpose of the study.

1. Describe the research design of the study.

Please describe the research design.

1. Describe the activities that participants will be asked to participate in. Explain the duration of the activities, how data will be collected, the setting used for collecting data (e.g. telephone, mail, email, face-to-face interviews, etc.) provide a copy of each study instrument, including all questionnaires, surveys, protocols for interviews, etc.)

Please describe the activities of the participants of the study.

1. Describe the procedures you will use to recruit research participants and attach any materials used to advertise.

Please describe the procedures and material to recruit participants.

VI. Privacy Procedures

1. Will data be recorded by audio? [ ] No [ ] Yes

Will data be recorded by video? [ ] No [ ] Yes

Will photographs be taken? [ ] No [ ] Yes

Will recordings and photographs be destroyed after the study is complete?

[ ] No [ ] Yes

If no, explain why not and how the location of the data will be secure.

Explain why the data will not be destroyed and how it will be secure.

1. Who will have access to data during the reteach and, if applicable, after the study? (Please give title and need for information).

Please list persons who have access to data including their title.

1. Please clarify how participants will be identified in audio or videotaped responses.

How will the participants be identified?

1. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc.? [ ] No [ ] Yes

If yes, explain why these identifiers are necessary to the study.

Please explain why necessary.

1. 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.

Please explain why necessary.

1. Will you provide a link or identifier to anyone outside the research team (e.g. the participant’s employer)? [ ] No [ ] Yes

If yes, explain why and to whom.

Please explain why and to who.

1. Will you place a copy of the consent form or other research study information in the participant’s record such as medical, personal, or educational? (This information should be clearly explained in the consent document and/or process)

[ ] No [ ] Yes

 If yes, explain why this is necessary.

 Please explain why necessary.

1. Will you obtain a Federal Certificate of confidentiality for the research?

[ ] 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.

VII. Informed Consent Information

1. Informed Consent: Please attach the informed consent document you will be using in the research to this application.

If subject participation is anonymous, an information sheet or cover letter that contains all required elements of informed consent is recommended. If subject participation is not anonymous, you must attach a consent form to this application.

1. Request for Waiver of Informed Consent: Provide a written justification for a waiver of informed consent according to Section 46.116 of 45 CFR 46

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Are you requesting a waiver of informed consent? [ ] No [ ] Yes

If yes, please explain.

Please explain the need for a waiver of informed consent.

1. Requests for Waiver of Documentation of Consent (applies to studies that do not wish to have signatures of the participants, i.e. informed consent via a consent form cover letter: three options are included in Appendix B). Provide a written justification for a waiver of documentation of consent according to Section 46.116 of 45 CFR 46

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>

Are you requesting a wavier of documentation of consent?

If yes, please explain.

Please explain the need for a waiver of documentation of consent.

VIII. Risks and Benefits

1. Does the research involve any possible risks or harms to the participants? (See list below)

[ ] No, go to section IX

[ ] Yes. Independent scientific review may be required to determine if scientific merit justifies this risk. Check all that apply:

 [ ] Use of deception

 [ ] Use of confidential records (e.g. education or medical records)

[ ] Manipulation of psychological or social variable such as sensory deprivation, social

 isolation, psychological stressors

[ ] Presentation of materials which participants might consider sensitive, offensive,

 threatening or degrading

[ ] Physical harm

[ ] Possible invasion of privacy of participant or family

[ ] Social or economic risk

[ ] Legal risk

[ ] Employment/occupational risk

[ ] Other risks Specify: Please specify other risks.

1. Describe the nature and degree of the risk. Also, include the script the principal investigator will use to describe these risks to the participants as well as describing their rights to withdraw from participation.

Please describe the risk.

IX. Compensation Information

1. Will any compensation or incentives, e.g. monetary award, be offered to the subjects for their participation? [ ] No [ ] Yes

If yes, describe those incentives and include the statement as provided to the participant in the consent form of how this compensation will be handled, as well as penalties for withdrawing from the study.

Please describe the incentives.

X. Submission Instructions

PLEASE DO NOT save or share this form on Google Drive. Save this file as a MS Word document.

Faculty or Staff Principal Investigators:

Submit this form with all the supporting documents as an email attachment to shelly.mencacci@noc.edu.

Student Principal Investigators:

1. Submit this form with all the supporting documents as an email attachment to shelly.mencacci@noc.edu.
2. Your advisor must read and sign this form along with completing the form, IRB Student as Principal Investigator, and email the form, IRB Student as Principal Investigator, to shelly.mencacci@noc.edu.

If you have any questions or need assistance completing this application, contact Dr. Shelly Mencacci.

Dr. Shelly Mencacci

Vice President for Academic Affairs

shelly.mencacci@noc.edu

(580) 628-6431

Northern Oklahoma College

1220 East Grand, P.O. Box 310

Tonkawa, OK 74653