Institutional Review Board (IRB) Form 104
Human Subjects IRB Application for External Investigator

Study Title

External Investigator (EI)

The EI who is directly responsible for the project's design, implementation, consent process, data collection, and/or data analysis, must complete the CITI Basic Human Subjects Protection Training. The EI cannot be listed as the PI and must have an NSU Representative too serve as the Project Supervisor/PI and be held accountable for all aspects of the project.

First Name:	**Last Name:**	
Work Phone:	**Mobil Phone:**	**E-mail:**
University/Business /Organization:		
Title and Affiliation:	**Department:**	
Full Address:		
CITI Completion Date:		

NSU Principal Investigator (Internal Representative)

Principal Investigator(s): The PI must be an NSU Faculty or Staff member who will serve as the Project Supervisor and be held responsible for all aspects of the project, to include the IRB Proposal submission in IRBNet. Students cannot be listed as PI. All PIs must complete the CITI Basic Human Subjects Protection Training.

First Name:	**Last Name:**	
Telephone:		**Email:**
Office Address:		
City:	**State:**	**Zip:**
Department:	**College:**	
Affiliation: ☐ Faculty ☐ Graduate Student ☐ Undergraduate Student ☐ Staff ☐ Other:		
CITI Completion Date:		

Additional Investigator

First Name:	**Last Name:**	
Telephone:		**Email:**
Office Address:		
City:	**State:**	**Zip:**
Department:	**College:**	
Affiliation: ☐ Faculty ☐ Graduate Student ☐ Undergraduate Student ☐ Staff ☐ Other:		
CITI Completion Date:		

Upload a copy of the Additional Investigators form if more rows are needed.

1. Type of Research

1.a. This study is being conducted as part of (check all that apply):

☐ Faculty Research
☐ Doctoral Dissertation
☐ Masters Thesis
☐ Non-Thesis Graduate Student Research
☐ Honors or Individual Problems Project
☐ Other:

2. Funding

2.a. Funding Status:

☐ Research is **not funded** **(go to 3)**
☐ Research is **funded** **(go to 2a)**
☐ **Funding decision is pending** (funding decision has not been made) **(go to 2a)**

2.b. Type of funding source: (Check all that apply)

☐ Federal Grant or Contract
☐ State or Municipal Grant or Contract
☐ Private Foundation
☐ Corporate contract
☐ Other (specify):

2. c. Funding Agency Information:

Funding Agency Name:	
Agency Proposal Number	
Grant Start & End Date (MM/DD/YY):	

2.d. List the point of contact at the funding source:

Name:	
Mailing Address:	
Telephone:	
Email:	

3. Research Dates

3.a. Date you wish to start research (MM/DD/YY):

3.b. Date you plan to end research (MM/DD/YY):
(End date for data collection and analysis)

4. Research Location

4.a. Where will the experiment be conducted? (Check all that apply)

☐ On Campus	(Building and Room Number):

☐ Off-Campus	(Site Name and Street Address):

5. Human Subjects Review

5.a. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

☐ Yes
☐ No **(If no, go to 6)**

5.b. List the other committee(s) that have reviewed this project and indicate which IRB is serving as the primary IRB

6. Study Purpose

6.a. Describe the rationale for the research project:

7. Subjects

7.a. What will be the maximum number of subjects in the study?		
7.b. Indicate the approximate number of:	**Males:**	**Females:**

7.c. What is the age of subjects? (Check all that apply)

☐ Children (Birth-17 years old)	☐ Adults (18-89 years old)	☐ Elderly (90+ years and older)

7.d. Will students be enrolled in the study? (Check all that apply)
*If students are under 18 years old, parental consent must be obtained

☐ Undergraduate students	Department:	☐ Advanced students	Department:

7.e. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age of the subject population. (e.g., symptomatology, history, socio-economic status).

8. Vulnerable Subjects

8.a. Are research subjects being used whose ability to give informed voluntary consent may be in question?(e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)

☐ Yes
☐ No

8.b. What type of vulnerable subjects are being enrolled? (Check all that apply)

☐ Critically Ill Patients	☐ Mentally Disabled or Cognitively Impaired Individuals
☐ Prisoners	☐ Physically Handicapped
☐ Pregnant Women	☐ Children
☐ Other (describe):	

If yes, explain the procedures to be employed to enroll them and to ensure their protection:

9. Recruitment

Copies of all recruitment materials must be attached to this application.

9 a. Check all types of recruitment that will be utilized in the study.

☐ **Internet**	☐ **Letters**
☐ **Newspaper/radio/television advertising**	☐ **Posters/brochures**
☐ **Other: Flyer**	

9.b. What methods will be used to identify and recruit prospective subjects? Specify the source of potential subjects. If an outside agency or organization will recruit subjects on the investigator's behalf, a support letter must be included.

10. Inclusion and Exclusion Criteria

10.a. Are subjects equitably chosen for participation in the study? (no one group is excluded without justification)
☐ Yes
☐ No **(If no, specify criteria and justify in detail below.)**
Comments:

10.b. Does the study require special evaluation and screening of potential subjects to determine their appropriateness for inclusion in the study?
☐ Yes **(If yes, elaborate on the screening process below and attach the screening questionnaire.)**
☐ No

Screening Criteria:

Outline the inclusion and exclusion criteria for the study:

Inclusion:

Exclusion:

11. Experimental Procedures

11.a. Describe the experimental procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)

11.b. Will any aversive or painful procedures be employed (e.g., shock, the threat of shock or punishment, experimentally induced stress?)

☐ Yes **(If yes, specify and justify in detail below.)**
☐ No

Comments:

11.c. Will the deliberate deception of research participants be involved as part of the experimental procedure?

☐ Yes **(If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.)**
☐ No

Comments:

12. Compensation

12.a. How much time will be required of each subject?

12.b. Will research subjects receive course credit for participating in the study?

☐ Yes **(If yes, please explain in comments section.)**
☐ No

Comments:

12.c. Are there any other forms of compensation that may be used? (e.g. Money, Gift Cards)

☐ Yes
☐ No

Comments: **If yes, please explain in comments section. You MUST be specific in how you will track the incentives. If merchandise, gift cards, or money, etc are distributed you must provide the date given, a pseudo name, the type of incentive given (merchandise, gift card, or money) the amount, and how it was given. For example, will the incentives be given on site, via electronic gift cards, or after all research data has been collected. See Form 107**

13. Informed Consent

13.a. Do you intend to obtain informed consent from subjects?

☐ Yes **(If yes,please answer question 13.b.)**
☐ **No (If no, complete Appendix F: Request for Waiver of Consent Form)**

13.b. Describe the procedures that will be used to obtain Informed Consent and attach the Informed *Consent Document (follow the guidelines for preparation of the University Informed Consent Form).*

Note: Subjects MUST be given a description of the procedures and rationale for the study to the extent possible. The benefits and ANY risks associated with participating in the study MUST be enumerated. The subjects MUST be informed of their right to terminate the experiment at any time. If there is no risk associated with the study and participants' signature on the informed consent sheet is the only identifying information about the name of the subject, then the subjects' signature may not be necessary.

14. Risks

14.a. What are potential risks of the research? (Check all that apply)

☐ **Physical harm**	☐ **Psychological harm**
☐ **Release of confidential information**	☐ **Other:**

According to 45 CFR 46.102 (i), Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- **What is the investigator's overall assessment of the risk classification of the study? (none, minimal, or more than minimal risk)?**

  Risk is:

14.b. Describe any potential risks to subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, emotions, employability, and criminal and legal status. A detailed, comparative statement of the risk (harm or likelihood) must also be described in the consent form.

15. Benefits

15.a. Assess the potential benefits that may accrue to the individual subject as well as to others as a result of the proposed study. Do the potential benefits justify the possible risks involved? Although you may mention general benefits to society, such speculative benefits should not be presented to a subject as a direct benefit for informed consent.

16. Protection of Anonymity

16.a. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.

17. Drugs or Devices

17.a. Will any drugs, devices, or chemical biological agents be used with the subjects?

☐ Yes **(If yes, please attach Appendix G: Drugs, Agents, and Devices Form)**

☐ No

18. Biological Materials

18.a. Will this research involve the collection, analysis, or banking of human biological materials (cells, tissues, fluids, DNA?)

☐ Yes **(If yes, please attach Appendix H: Biological Materials Form)**

☐ No

19. Training

19.a. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the PI and investigators possess the necessary skills or qualifications to conduct the study.

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PLEASE NOTE:

- You may begin research when the University Institutional Review Board gives you final WRITTEN notice of its approval.
- You MUST inform the committee of ANY adverse event, changes in the method, personnel, funding, or procedure.
- At any time the committee reserves the right to re-review a research project, to request additional information, to monitor the research for compliance, to inspect the data and consent forms, to interview subjects that have participated in the research, and if necessary to terminate a research investigation.

External Investigator Signature _____ Date _____

NSU Principal Investigator (Internal Representative) Signature _____ Date _____

NSU Department Head/Dean Print Name _____ NSU Department Head/Dean Signature _____ Date _____

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