**NEBRASKA WESLEYAN UNIVERSITY**

**Institutional Review Board (NWU-IRB)**

5000 Saint Paul Avenue; Lincoln, Nebraska 68504

FWA 00024370

**Application: Protocol Review for Use of Human Subjects in Research**

The primary goal of the NWU-IRB is to protect the dignity, rights, safety, and welfare of all human participants used in research carried out by students, faculty, and/or staff. NWU-IRB policies are based on the U.S. Department of Health and Human Services (HHS) Code of Federal Regulations regarding the protection of human subjects in research (CFR Title 45 Part 46). Students must submit application through their faculty sponsor.

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| **ANTICIPATED TYPE OF REVIEW:** (check appropriate category; see guidelines for criteria for levels of review) | | |
|  | Exempt | Exempt Category #: |
|  | Expedited Review | Expedited Category #: |
|  | Full Board Review  *By Permission Only* | Researchers must meet with IRB **PRIOR** to submitting in this category. Date of meeting with IRB: |

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| **PROJECT TITLE:** |  |
| Estimated date the data collection starts: |  |
| Estimated date project is completed: |  |

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| **INVESTIGATOR(S) INFORMATION:** |  |
| Principal Investigator (PI): |  |
| Email:  Phone:  Campus Address: |  |
| **Co-Investigator(s)** |  |
| Email:  Phone:  Campus Address: |  |
| **Faculty Sponsor(s) (if PI is student):** |  |
| Email:  Phone:  Campus Address: |  |

**CHANGES IN PROCEDURES INVOLVING HUMAN SUBJECTS AS WELL AS ANY PROBLEMS CONNECTED WITH THE USE OF HUMAN SUBJECTS ONCE THE PROJECT HAS BEGUN MUST BE IMMEDIATELY BROUGHT TO THE ATTENTION OF THE NWU-IRB COORDINATOR OR CHAIR.**

*I agree to provide whatever supervision is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any contact with human subjects before I have received approval from the NWU-IRB and/or complied with all contingencies made in connection with that approval.*

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Signature of Principal Investigator Date

**Approval by Faculty Sponsor (If this is a student project, the faculty sponsor must also sign):**

*I affirm the accuracy of this application and I accept the responsibility for the conduct of this research, and the protection of human subjects, as required by law.*

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Signature of Faculty Sponsor Date

The Faculty Sponsor is responsible for submitting the completed application for student projects. The completed application and all attachments should in PDF format, in one file, and submitted electronically. Submit to the NWU-IRB at [irb@nebrwesleyan.edu](mailto:irb@nebrwesleyan.edu)

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| **Note: The following information must be included in the header of your documents distributed to research participants. Your specific protocol number will be assigned if/when the project is approved** |
| PI: (enter first initial and last name)  Title: (enter title of protocol)  Protocol #: (Assigned by NWU-IRB) |

**NWU-IRB Application for Use of Human Subjects in Research**

**Code of Federal Regulations:**

Title 45-Public Welfare; Department of Health and Human Services; **Part 46 –P**rotection of Human Subjects)

[http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/)

**BACKGROUND:**

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| **1. Provide a brief summary of your research project including review of relevant academic studies, rationale, objectives/purposes and/or major hypothesis(es):** (*Include academic reference list as an appendix)* |
| Description: |

**POPULATION STUDIED; SAMPLE SELECTION PROCESS:**

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| **2. Describe the population to be studied and information on selecting of your sample. Explain how participants will be recruited into your study. Include copies of any recruitment emails, letters, etc. as an appendix:** *(Provide information about population from which the sample is drawn, anticipated number of participants in the study, and relevant demographics (age, sex, etc.). Reminder: if you are selecting anyone under the age of 19, including NWU students, you must seek permission from their parent/guardian first before asking them to be in your study. Also, for any research on vulnerable populations, the researcher must meet with the IRB* ***PRIOR TO*** *submitting a proposal. See IRB Guidelines for details.)* |
| Description: |

**PROCEDURES FOR DATA COLLECTION (including any data collection instruments):**

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| **3. Describe the procedures for data collection:**  *(Provide information on the nature of the participants’ involvement; their time commitment; etc. include a copy of your data collection instrument(s) in the appendix. If you are collecting data at a place of business, you must also include a site permission letter showing that you are allowed to conduct research at/with members of that business/organization. This does not include informal meetings with research participants in public places such as coffee shops, etc.)* |
| Description: |

**RISKS AND BENEFITS FOR RESEARCH PARTICIPANTS:**

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| **4. Explain and justify any potential risks/discomforts to participants in the study. Include whether there will be any cost to the participants for participating in the study (such as transportation, childcare, etc.):**  *(Provide information on any physical, social, or psychological risks that could be experienced by the research participants in this study. Describe any special arrangements to protect their safety, including protecting their privacy and confidentiality. Specify where and how both physical/paper and electronic data will be stored/protected. NWU policy requires that all data be kept in a secure location for a minimum of three years after study completion.* |
| Explanation/justification: |

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| **5. Describe any benefits to participants:**  *(Provide information on any direct benefits, such as payments, gift cards, reimbursement for travel, etc., and any indirect benefits that may result from participating in the study. This does not include benefits to the larger research community, outside agencies, etc. This question is in regard to benefits to the participant.)* |
| Description: |

**INFORMED CONSENT PROCEDURES:**

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| **6. Clearly explain Informed Consent procedures and attach applicable forms (if needed):** |
| Description: |

**ATTACHMENTS TO APPLICATION:**

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| **7. Checklist of materials submitted with this application:**  \_\_ Reference list for academic sources  \_\_ Recruitment materials (emails, letters, social media communications, phone communications, etc.)  \_\_ Site Permission letter(s)  \_\_ Informed Consent form(s) (including parental consent form and youth assent form, if appropriate)  \_\_ Data gathering instrument(s) [surveys, interview/focus questions, and/or other forms of data gathering]  \_\_ Copy of certificate showing completion of “protection of human subjects training” for all project personnel  (NIH or CITI)  \_\_ Any other attachments relevant to your study. Please specify: |