

**Request for Approval of Research with Human Participants**

**In Social and Behavioral Research**

Institutional Review Board for Research with Humans

University of Northwestern – St. Paul

3003 Snelling Avenue North

St. Paul, MN 55113

College and Federal policies require that each project involving studies on humans be reviewed to consider:

1. The rights and welfare of the individuals involved,
2. The appropriateness of the methods used to secure informed consent, and
3. The risk and potential benefits of the investigation.

**RESEARCH MAY NOT BE INITIATED PRIOR TO FORMAL, WRITTEN APPROVAL**

**BY THE APPROPRIATE COMMITTEE OR PERSON**

Please answer each item thoroughly, and put N/A for those that do not apply. Label each piece of information by section letter (A – G), item number (1, 2, etc.), and use the boldface headers for each item.

**PROPOSALS LACKING INFORMATION WILL BE RETURNED WITHOUT REVIEW**

Submit the completed form by e-mail to Dr. Don F. Johnson (dfjohnson@unwsp.edu), or if this is Northwestern student research, to your research advisor. You *will not* receive this proposal back, so be sure you keep a copy of the materials you submit. You will be notified by e-mail of the committee’s decision.

FOR OFFICE USE ONLY

ACTION:

DATE REVIEWED:

1. **IDENTIFYING INFORMATION**
2. **Date:**

(Insert date)

1. **Principal Investigator:**

(Name, university department, campus address, phone number, and e-mail address OR off campus mailing address phone number, and e-mail address)

1. **Co-Investigators:**

(Name, university department, campus address, phone number, and e-mail address OR off campus mailing address phone number, and e-mail address)

1. **Project Title:**

(Insert title)

1. **Inclusive Dates of Project:**

(Give the beginning and ending dates for data collection and reporting of the results)

1. **Research Advisor:**

(If the principal investigator and co-investigators are all students, give the name, university department, campus address, and phone number of the research advisor)

1. **Funding Agency**:

(Organization name, contact person’s name, address, phone number, agency-assigned grant number or other identifier)

1. **Investigational Agents:**

(If the research involves the use of any drugs or experimental substances, give the IND or IDE number assigned by the FDA and the expiration date)

1. **PARTICIPANTS**
2. **Type of Participants:**

(Adults are considered those 18 and older who are of normal cognitive functioning. Any other groups [mentally disabled, emotionally disturbed, senile, special minorities] must be identified. Be sure to indicate the nature of the participants [e.g., adult college/university students, high school students, working adults, etc.])

1. **Institutional Affiliation:**

(If participants are affiliated with some organization or institution through which they will be recruited, i.e., schools, prisons, hospitals, human services organizations, etc., this must be identified)

1. **Approximate Number of Participants:**

(Insert number)

1. **How Participants are Chosen:**

(Records, classes, referrals, canvassing, etc. Be specific in describing this. If records are used, indicate who gave approval for use of records)

1. **How Participants are Contacted:**

(Ads, announcements in class, telephone, letters, etc. Be specific about how people will be asked to participate)

1. **Inducements:**

(Describe what, if any, inducements before or rewards after the study will be offered)

1. **Monetary Charges:**

(If participants will be charged for any research-related procedure, please describe)

1. **INFORMED CONSENT**

Complete the informed consent form that includes all the elements in the sample consent form at the end of this document. Attach a copy of your informed consent form to the proposal. For research with minors or with vulnerable populations consent from parents or guardians is required in most cases.

1. **ABSTRACT AND PROTOCOL**
2. **Hypothesis and Research Design:**

(Clearly state the hypothesis or the research question of the study, and describe the design that will be used to address it)

1. **Protocol:**

(Describe exactly what will be done to and for the participants. Include when and where the data will be collected [attach copies of permission letters if participants are being recruited and/or tested in a field location], what instructions will be given to the participants [attach a copy if the instructions are written out for the researcher and/or the participants to read], precisely how and when the informed consent will be requested, what tasks the participants will perform [attach a copy of all verbal and/or visual materials to be used], and how the participants will be debriefed regarding the purpose of the study. **Be sure to include a copy of any surveys or instruments**)

1. **RISKS**

Evaluate the following items carefully to see which apply to your study. For those that do apply, state which one(s) and **what precautions will be taken to minimize risk to the participants.** If an item is not a risk for your study, please state “No known risk identified.” If, in the course of review, the committee finds evidence of possible risk that is not addressed, **the proposal will be returned for modification as needed**.

1. **Privacy:**

(Any possible invasion of privacy of the participants or their families, including the use of personal information or records)

1. **Physical Stimuli:**

(Administration of any stimulus other than sensory stimuli associated with normal classroom situations and/or daily life)

1. **Deprivation:**

(Withholding of physiological requirements such as nutrition or sleep, manipulation of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc.)

1. **Deception:**

(Any situation in which full-informed consent cannot be obtained before the study begins. In these cases, the protocol must include a statement of why the deception is necessary and how participants will be debriefed upon completion of the study. Informed consent is *not* waived when deception is used; it must be obtained after the data are gathered but before analysis is performed)

1. **Sensitive Information:**

(Anything participants are being asked that they may consider to be personal or sensitive)

1. **Offensive Materials:**

(Presentation of any materials that participants might find to be offensive, threatening, or degrading)

1. **Physical Exertion**:

(Any exertion beyond normal classroom and daily life situations)

1. **CONFIDENTIALITY**

Specify steps that will be taken to insure the confidentiality of the information collected. Please include information on who will have access to the data, where the data will be securely kept, and other steps you will take to protect the information. Also, please note that confidentiality also extends to the reporting of the data in written papers or presentations. Data should not be reported in a way that violates participants’ confidentiality. If data will become part of a participant’s permanent record or if some third party will be informed of anyone’s participation in the study, explain exactly why this is necessary. If video- or audio-taping is used, specify when and how the tapes will be destroyed.

1. **SIGNATURES**

Type the following paragraph at the end of the proposal and have all investigators and the research advisor (if applicable) sign and date below it.

**“I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any substantive modification in the proposal and will report promptly any unexpected or otherwise significant adverse effects in the course of this study.”**

**Consent to Participate in a Research Study**

University of Northwestern – St. Paul

3003 Snelling Avenue North

St. Paul, MN 55113

**SAMPLE INFORMED CONSENT**

**TITLE OF THE RESEARCH PROJECT:** Title

**PRINCIPAL INVESTIGATOR**: Name, credentials, department or institutional affiliation

**CO-INVESTIGATOR**: Name, credentials, department or institutional affiliation

**FACULTY ADVISOR**: Name, credentials, department or institutional affiliation

**INVITATION TO PARTICIPATE IN A RESEARCH STUDY**

 [PI name(s)] invites you to participate in a research study about [topic/purpose].

The study is funded by [sponsor, if any].

**DESCRIPTION OF SUBJECT INVOLVEMENT**

If you agree to be part of the research study, you will be asked to [details].

**BENEFITS**

You will directly benefit from being in this study because [details].

OR

Although you may not directly benefit from being in this study, others may benefit because [details].

**RISKS AND DISCOMFORTS**

There are no risks associated with this study because the data collection is completely anonymous and the topic is not sensitive.

OR

The researchers have taken steps to minimize the risks of this study. Even so, you may still experience some risks related to your participation, even when the researchers are careful to avoid them. These risks may include the following [details].

**COMPENSATION**

[List details if applicable].

**CONFIDENTIALITY**

We plan to publish the results of this study (or describe other use), but will not include any information that would identify you. There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly [name].

To keep your information safe, the researchers will [details].

Also, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

**STORAGE AND FUTURE USE OF DATA**

The data you provide will be stored [details].

The researchers will retain the data/specimens for [duration].

The researchers will dispose of your data/specimens by [details].

The data/specimens will/will not [select] be made available to other researchers for other studies following the completion of this research study and will/will not [select] contain information that could identify you [details].

**VOLUNTARY NATURE OF THE STUDY**

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time. If you decide to withdraw early, [details about disposition of data].

**CONTACT INFORMATION**

If you have questions about this research, you may contact [name, contact info for PI (and faculty advisor if PI is a student).

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the University of Northwestern Institutional Review Board, 3003 Snelling Avenue North, St. Paul, MN 55113 or Dr. Don F. Johnson (651-631-5693, dfjohnson@unwsp.edu).

**CONSENT**

By signing this document, you are agreeing to be in the study. You will be given a copy of this document for your records and one copy will be kept with the study records. Be sure that questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

I agree to participate in the study.

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Printed Name

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Signature Date