

3470A IRB HUMAN SUBJECTS RESEARCH REVIEW PROTOCOL

PART I. Cover Sheet.

Original Submission	Proposal Modification:	Renewal:
IRB USE ONLY		
Date Received: _____	Approval Date: _____	Protocol Number: _____
Signed: _____		Reapproval Date: _____

This application is to be submitted to and approved in writing by the IRB prior to the initiation of any investigation involving human subjects, data or material.

A. Principal Investigator

Name: _____ Title: _____
Department/Program: _____ Telephone: _____

Sponsor (if PI is a student):

Name: _____ Title: _____
Department/Program: _____ Telephone: _____

Project Title: _____

Beginning Date: _____ Ending Date: _____

Parts II and III of the protocol must be completed in detail for board review. Please submit an electronic version that has all signatures on it. Attach all relevant materials. If you are co-conducting this study at other institutions also include approval from those IRBs as well.

D. Statement of assurance: I/We have read the Northland Community and Technical College Policies and Procedures for Research Involving Human Subjects, and will comply with the informed consent requirement. Further, I/we will inform the IRB if significant changes are made in the proposed study.

Signature of PI *Date* *Signature of Sponsor* *Date*

Part II DESCRIPTION OF STUDY

A. Research question. Beginning on a second page, provide a brief statement of the question(s) being asked and the supporting rationale. For example: "The study is designed to determine if conformity is related to perceptions of group strength. This project is based on the social impact theory of group influence which suggests that social influence will increase as a function of perceived 'strength' among the group members. Perceived strength in this study is being defined by the expertise of the members." Notice that the statement is brief and expresses not only the research question but the theoretical rationale behind the question. Some projects will undoubtedly require a bit more explanation, but a complete literature review is not necessary for IRB review purposes.

B. Hypothesis(es). Provide a clear statement of the research hypothesis(es) as related to the rationale and theory behind the study. For example: "Higher levels of conformity will be observed for groups that have undergone a preliminary cohesion enhancement." Stating hypotheses in the null form is of little help to reviewers.

C. Subject Selection.

1. Number of subjects:
2. Human subject pool:
 - a. Describe relevant features of the subjects you will be using (e.g. sex, race, or ethnic group; age range; general state of mental and physical health; etc.).
 - b. Note the relevant affiliations of your subjects (e.g. institutions, hospitals, general public, etc.).
3. If human subjects are children, mentally incompetent, or other legally restricted groups:
 - a. Explain the necessity of using these particular groups.
 - b. Describe any special arrangements to protect their safety.

D. Procedures.

1. Describe your recruitment procedures and any material inducements given for participation.
2. Note the location of the study. Be as specific as possible.
3. Describe all personnel, including names and affiliation with Northland (and any other relevant affiliations).
4. Describe the information to be gathered and the means for collecting and recording data. *If previously collected data is to be used, describe both the previous and proposed uses of these data.*
5. Provide a step by step description of everything subjects will be asked to do in your study.
6. Note the title and source of instruments (i.e. personality scales, questionnaires, evaluation blanks, etc.). Include copies of original instruments.

Part III HUMAN SUBJECTS PROTECTION

A. Potential Risks you can anticipate for subjects.

1. Describe immediate risks, long term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.
2. Describe any potential legal, financial, social or personal effects on subjects of accidental data disclosure. Though the potential for disclosure may be extremely remote, if a fire or bombing exposed your data, how would it affect subjects?

B. Expected benefits for subjects (if any) and/or society:

The IRB is required to insure that the potential risks to subjects (however minimal) are clearly justified by the potential benefits of the research both to the subjects and to the current state of theoretical knowledge on the topic. You can assist this process by providing a statement clarifying the potential for new knowledge resulting from the study as well as any benefits directly to the subjects. Stating that "more research is needed on this topic" will be of little help. Please explain why more research will be a benefit.

C. Deception used in gathering data.

Justify and support the use of deception in the project, particularly if subjects are being provided with any untruthful or misleading information. Realize that not providing complete information is minimally deceptive. Provide a detailed written description of the debriefing process.

D. Safeguarding Subjects' Identity.

1. What uses will be made of the information obtained from the subjects? What elements of your project might be openly accessible to other agencies or appear in publications?
2. What precautions will be taken to safeguard identifiable records or individuals? How will confidentiality of data be protected?

E. Informed consent.

Please refer to additional guidelines with respect to [informed consent](#) and [sample consent forms](#) if you have additional questions. Submit a copy of the consent form, survey questions, script for approaching candidates, and *all materials* used in the recruitment, selection and participation of subjects.

If the study involves children, the informed consent form must be signed by the child's parent or guardian. However, the IRB usually requires that a second form be signed by the child as well, so that s/he understands as completely as possible the research which is being performed. This second form may be written in simpler language to match the age and understanding of the subjects.

When a signed consent form is required, a copy must be made available to the subjects. At the very least (e.g. when completion of the instrument serves as giving consent) subjects must be given a form identifying the researcher by name, address, and phone number, and including these statements:

Some researchers might meet this requirement by detaching the signature portion of the consent form and giving the rest to the subject. Others might print a separate card or sheet with the required information for distributing to subjects.

For simple surveys, written consent is not required.

CONSENT FORM
[Insert Title of Study]
[Insert Northland IRB number]

You are invited to be in a research study of [Insert general statement about study]. You were selected as a possible participant because [Explain how subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: [Name of PI, department (indicate College affiliation)]

Background Information

The purpose of this study is: [Explain research question and purpose in lay language]

Procedures:

If you agree to be in this study, we would ask you to do the following things:
[Explain tasks and procedures: subjects should be told about video or audio taping, assignment to study groups, length of time for participation, frequency of procedures, etc.]

Risks and Benefits of being in the Study

The study has several risks: First, [Risk]; Second, [Risk] *(Risk must be explained, including the likelihood of the risk)*

(If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study)

The benefits to participation are: [Benefit(s)] *(If no benefits, state that fact here.)*

Compensation:

You will receive payment: [Include payment or reimbursement information here.] *(If subjects receive class points or some other token, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw.)*

Confidentiality:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. *(If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be erased.)*

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota [or with other cooperating institutions, insert names here]. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:

The researchers conducting this study are: [Name of researcher] and [Name of researcher]. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact them at [Location], [Phone number], [E-mail address]. *(If the researcher is a student, include advisor's name, telephone number and e-mail address here.)*

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact Brian Huschle, Provost or David Christian or Justin Berry, the Co-

Chairs of the Institutional Review Board. These people may be reached at Northland Community and Technical College, 2022 Central Ave NE, East Grand Forks, MN, 56721, (218) 793-2800.

You will be given a copy of this information to keep for your records.

Statement of Consent:

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature: _____ Date: _____

Signature of parent or guardian: _____ Date: _____
(If minors are involved)

Signature of Investigator: _____ Date: _____

mlf 04/16/20