UNIVERSITY OF NORTHERN IOWA
INSTITUTIONAL REVIEW BOARD (IRB)
Standard Application for Human Participants Review

Instructions for Submission:

1. Review guidance at http://www.uni.edu/rsp/irb-policies-and-procedures.
2. Review training requirements at http://www.uni.edu/rsp/irb-training.
3. Download and complete most current form version at http://www.uni.edu/rsp/irb-forms.
4. **In order for this form to save your changes,** you must open it directly using Adobe Acrobat Reader (or Acrobat Professional/ Acrobat DC), not through an internet browser. If it was automatically opened in your browser, close it, go back, and download/save the blank form to your computer, and then open it using Adobe Reader or Professional.
5. Attach requested supplementary documents ("attach" button found in Comments view), or combine into separate Word or PDF file.
6. Email document(s) to anita.gordon@uni.edu. If you are a student, you must "cc" your advisor on the email.
7. Submission of this application indicates that the Principal Investigator (PI) and Faculty Advisor (if student PI) acknowledge they are responsible for ensuring that all personnel comply with university requirements and federal regulations for human subjects research.

A. General Information

Project Title

PI Name

PI Email | PI Department

PI Status ☐ Faculty/Staff ☐ Undergraduate Student ☐ Graduate Student

Faculty Advisor (if applicable)

Advisor Email

Est. Start Date | Est. End Date

Other Key Personnel

List names, emails, and departments for all other key personnel. Consult guidance for definition of key personnel. If none, list none. For higher risk studies, list training or experience relevant to the proposed activities. Also enter organization for any non-UNI collaborators. Consult guidance regarding inter-institutional projects.

Do the PI and Advisor have human subjects training documentation on file? (required) ☐ yes

Do all other key personnel have human subjects training documentation on file? ☐ yes ☐ no, some are pending

B. Purpose of Research

B1. Why is this research important and what are its primary purposes?

B2. What questions or hypotheses is this research designed to answer?

B3. How will the results be used or disseminated to others?

B4. If the research will involve or add onto an existing program or class activity (e.g. in action research), explain which activities are proposed as research and which already exist as normal training, class, or program activities. Clearly differentiate these in consent documents as well. Enter "Not Applicable", if this is not relevant to your study.

C. Participants

C1. List each participant group (e.g., K-12 students, UNI students, Facebook users, employees, etc.) and the number of each you hope will participate. See guidance on definition of "Participants" if needed.

C2. Will the study include any of the following special populations? (Check all that apply.)

- ☐ Persons in other countries
- ☐ Pregnant or nursing mothers
- ☐ Persons with limited literacy or ability to understand English
- ☐ Persons with cognitive impairments
- ☐ Persons with substance abuse or mental health problems
- ☐ Day care or K-12 students
- ☐ Adults who are incarcerated or in involuntary hospital confinement
- ☐ Youth in foster, residential and/or hospital care

C3. What characteristics (inclusion or exclusion criteria) must participants have to be in this study? (Answer for each participant group, if different.)

C4. How and when will you learn if the participants meet these criteria (if applicable)? Attach any screening instruments or tools to be used for this purpose.

D. Study Locations

D1. Check the types of locations where recruitment, data collection, or other study procedures will be carried out?

- ☐ UNI
- ☐ Other universities
- ☐ K-12 schools or day care centers
- ☐ Privately owned businesses
- ☐ Public libraries, parks, or similar sites
- ☐ Online or telephone only

D2. List each off-campus physical location where procedures will take place.

D3. List each additional organization, team, or entity that will provide assistance or permissions for the project and what will be provided (e.g., mailing lists, permission to access information, permission to post invitation, etc.)

Consult guidance on Letters of Cooperation, which are required from most external study locations and/or cooperating organizations.

E. Study Recruitment (Inviting Participation)

E1. Check all recruitment procedures to be used, and attach the text for each. If you will use the same text for more than one method, indicate that in the title of the attached materials.

- ☐ in person or phone recruitment (attach script or bullet points)
- ☐ email/text invitations sent by the PI or research team (attach email/text)
- ☐ email/text invitations forwarded by others (attach emails)
- ☐ letter invitation (attach letters)
- ☐ online posting (attach texts)
- ☐ flyers or handouts (attach flyers)
- ☐ reminder invitations (attach texts)

E2. Explain how these recruitment procedures will be implemented (e.g., in which order they will occur and for how long or how many times, for each group of participants). Also explain how individuals will communicate their interest in participating.

E3a. Will you invite potential participants to be in the study when others may be nearby?

☐ yes ☐ no

E3b. If yes, indicate **w**hether or not it is necessary to keep private the individual's decision about whether or not to participate (eg., because they are members of a stigmatized group or because they may feel uncomfortable for any reason saying yes or no). If this is a concern, explain what procedures you will use to keep the decision private.

E4a. What relationship, if any, is there between the potential participants and the PI and/or any other members of the research team?

☐ no relationship

☐ personal friends or family

☐ students

☐ employees

☐ other (describe below)

E4b. If applicable, how will you reduce any perceived pressure to participate resulting from this relationship? See guidance on indirect recruitment methods. (Note: Third party recruitment no longer required in K-12 action research.)

F. Data Collection

F1. Check all data collection procedures to be used:

- ☐ paper questionnaires, surveys, or tests (attach instruments)
- ☐ online questionnaires, surveys, or tests (attach instruments)
- ☐ in-person interviews or focus groups (attach initial questions)
- ☐ phone or online interviews (attach initial questions)
- ☐ collection of artifacts (e.g. photos, worksamples or essays)
- ☐ review of existing datasets or records
- ☐ collection of analysis of biological samples
- ☐ behavior observation
- ☐ physical activities or interventions

F2. Explain how these procedures will be implemented step by step (e.g., in which order they will occur and how long they will take, for each group of participants). Numbering or bullet points are encouraged. If you are accessing records, explain what is in the records, how you will obtain them, and how you will use the data.

F3. Check each type of compensation that will be provided to participants.

- ☐ no compensation will be offered
- ☐ cash or gift cards
- ☐ food or gifts
- ☐ low or no cost services
- ☐ course credit (non-research alternatives must also be offered)
- ☐ other

F4. Explain how, when, and how much compensation will be provided (e.g., will all participants receive it, by lottery, or after completion of specific tasks). University business procedures may apply. Consult guidance on Compensation for Participants.

G. Risks and Benefits

G1. Check all potential risks that may be associated with your project at some level:

- ☐ inconvenience or time (all studies have this)
- ☐ emotional discomfort, stress, or distress
- ☐ risks to privacy or dignity
- ☐ risks to social reputation
- ☐ legal risks
- ☐ financial risks
- ☐ physical injury or illness
- ☐ other (describe below)

G2. Explain how likely or serious each of the risks are, and if possible, what steps you will take to minimize them, including how to address any negative impacts that do happen to occur during or after participation. (It is not generally possible to remove all risk or inconvenience from study participation, so the goal is simply to minimize risks to the extent possible and otherwise inform the participants about them.) For studies involving physical activity, describe and attach emergency action plan.

G3. If the project includes any special populations (as noted in item C2), discuss special risks and procedures for mitigating them. Also explain any special procedures to ensure consent will be fully understood and voluntary.

G4. Sometimes in your research, you might discover information about your participants that are a potential problem for them or others (e.g, substance abuse, suicidal behavior, abuse). UNI policy and Iowa law may require that you report any child abuse, and you may need to report other types of abuse or behavior based on your status as a mandatory reporter and/or your personal ethics. How will you handle these types of information?

G5. In some studies, participants cannot be told in advance what the study is about, or there may be other elements of deception or omission that are necessary. If this item is not applicable, indicate that below. If this project does require some type of deception or omission, please explain a) why this is needed; and b) how, when, and by whom participants will be fully informed. Attach debriefing script or text.

G6. Describe the anticipated benefits of this research for individual participants. If none, state "None". Note: study compensation is not a benefit.

G7. Describe the anticipated benefits of this research for the field or society, and explain how the benefits outweigh the risks.

H. Confidentiality

In most studies, confidentiality of participant identities or data is necessary and appropriate, but not always. How you handle such information will depend on your study design and the risks/benefits to participants. What IS necessary is that this information be clearly described in your consent documents (except in cases of deception or omission).

H1. Check all types of identifying information that will be collected in this study:

- ☐ Direct IDs such as name, address, phone/email, student ID, SSN, etc.
- ☐ Indirect IDs such as race, gender, grade in school, etc.
- ☐ IP addresses (collected by online survey programs - indicate below if you will remove them)
- ☐ Photographs or videos
- ☐ Audio recordings
- ☐ No direct or indirect identifiers will be obtained or recorded - study will be entirely anonymous (*Skip to Question H4.*)

H2. If identifiers are involved, will they be shared with anyone outside of the research team, and if so, with whom? Indicate which information, and how and when this will occur. For example, it may be appropriate to report results by grade, gender, or county of residence.

H3. If it is important to keep identifying information and study data confidential, how will that be done? (This might include procedures such as keeping the identifiers separate from the data, using password protected files, destroying identifying data or tapes at the end of the study, disguising faces on videos, etc.)

H4. How long will you keep the study data or artifacts?

H5. Is it possible that the study data might be analyzed in new studies in the future, by you or others?

☐ yes (include this in consent documents) ☐ no

I. Consent Process

Consent that is fully informed and voluntary is a basic standard for research and thus a waiver of consent is uncommon. In most cases, it is also important to document the consent process on a form with signatures. However, in some studies, such as phone or online surveys, or with special populations, obtaining signatures is not appropriate and the IRB will waive *documentation* of consent. Important: Consult the Informed Consent Checklist to ensure all required items are included. If the study involves children, see Research with Children and Youth and Research in K-12 Educational Settings.

I1. Which consent process(es) will be used in this study? (Check all that apply.)

☐ written signed consent form for adults

☐ written signed student assent

☐ written signed parental permission forms

☐ waiver of signatures is requested - oral consent or assent

☐ waiver of signatures is requested - consent text will be presented in a letter, email, or online (explain below)

☐ waiver of consent is requested (provide justification below)

I2. Describe how the consent procedures will be implemented - at which point in the recruitment process, by whom, and how the consent document(s) will be shared with participants. Also indicate how participants will communicate their consent (initially and ongoing) and what will occur if they decline.

J. Application and Attachment Checklist

All questions are answered	☐ yes	
Training is on file for PI and Advisor	☐ yes	
Training is on file or pending for other key personnel	☐ yes	☐ not applicable
All applicable items on the Informed Consent Checklist are included in consent document(s)	☐ yes	☐ not applicable

ATTACHMENTS INCLUDED

Recruitment materials - text is included for each item listed in Question E1. If the same text is being used for more than one method, the attachment(s) indicate that.	☐ yes	☐ not applicable
Consent materials - text is included for each item listed in Question I1. If the same text is being used for more than one method, the attachment(s) indicate that.	☐ yes	☐ not applicable
Screening tools or instruments are attached.	☐ yes	☐ not applicable
Data collection instruments and/or *interview questions* are attached.	☐ yes	☐ not applicable
Debriefing script or text is attached, when deception or omission is involved, or when sharing resource info	☐ yes	☐ not applicable
Emergency action plan is attached, if physical activity is involved	☐ yes	☐ not applicable
Letters/emails of cooperation are attached or will be forwarded	☐ yes	☐ not applicable