Application for Review of Human Subjects Research

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Section 1: Researcher Information

Principal Investigator Information

The principal investigator (PI) is responsible for the direction and conduct of the research activities during the project. The PI is also responsible for selecting and supervising project sta and all requirements necessary to maintain compliance with applicable institutional and/or sponsor/funder rules and regulations.

PI Name: _____ PI Email: _____

PI College and Department: _____

PI O ce Address: _____ PI Telephone: _____

IF PI is a student

Advisor Name: _____ Advisor Email: _____

Advisor College and Department: _____

Advisor O ce Address: _____ Advisor Telephone: _____

Co-PI Information

The co-PI is a senior member of the research team whose role is similar to the PI. However, the co-PI defers to the PI as the individual with ultimate responsibility for the conduct of the research project. The co-PI is obligated to ensure the project is conducted in compliance with applicable institutional and/or sponsor/funder rules and regulations.

Co-PI Name: _____ Co-PI Email: _____

Co-PI College and Department: _____

Co-PI O ce Address: _____ Co-PI Telephone: _____

Co-PI Name: _____ Co-PI Email: _____

Co-PI College and Department: _____

Co-PI O ce Address: _____ Co-PI Telephone: _____

If there are more than two co-PIs for this project, please provide the information requested above for all PIs.

Application for Review of Human Subjects Research

Other Research Personnel

Other research personnel are individuals who have a role on the research project (e.g., interacting with participants, assisting with data collection and/or analysis) but are not responsible for the research project as a whole. This could include people such as student Research Assistants.

If your project has Other Research Personnel, please list these individuals either by name OR by

Application for Review of Human Subjects Research

Section 2: Problem, Purpose, and Research Questions

Brie y (100 words or less) describe the purpose of the proposed study.
Include all research questions, hypothesis, and/or evaluation questions. Include a brief summary of related information from the published literature on this topic in a language understandable to someone who is not familiar with your area of study. Your response in this section will enable the reviewers to determine whether the project meets the criteria of research with human participants and also the extent to which the research may produce new generalizable knowledge that may bene t the participants and/or society.

How will the results of this project be used? (Check all that apply.)

‰Presentation ‰Publication ‰Thesis ‰ Dissertation

‰Other (please specify):

Section 3: Participants, Sampling, and Recruitment Information

Describe the target participants of this study.

Within the population of potential participants, are there any criteria that would exclude someone from qualifying as a participant in your study?

‰ No ‰Yes

If yes, please explain.

Are there any participants in this study under 18 years of age?

‰ No ‰Yes

If yes, please describe how you will comply with special regulations for having children as participants in research studies.

[redacted]

Application for Review of Human Subjects Research

Section 4: Data Collection Procedures

Will any existing data sets be accessed for information for this study?

‰ No ‰Yes

If yes, please describe the existing data set, how it will be accessed by the researcher and what identi able information will be included in the data set.

Which of the following will data collection involve? Check all that apply.
Attach permission letters and/or letters of support in Appendix E of this application if needed.

‰Educational Tests (cognitive, diagnostic, aptitude)
‰Biological Specimen(s)
‰Photographs and/or Artifacts
‰Interview Procedures - In Person
‰Focus Group Procedures - In Person
‰Survey(s)/Questionnaire(s) - Paper
‰Observation - Participatory
‰Audio Recording
‰Self-Health Monitoring
‰Food Consumption Procedures
‰Research in/with P-12 Schools/Students
‰
‰Psychological Tests
‰Use of Social Networking Sites
‰Anthropomorphic Measures
‰Interview Procedures - Phone/Online
‰Focus Group Procedures - Phone/Online
‰Survey(s)/Questionnaire(s) - Phone/Online
‰Observation - Non-Participatory
‰Video Recording
‰Electronic Devices
‰Educational Records/Materials

Application for Review of Human Subjects Research

Describe the location where the research will take place (e.g., online, physical location, etc.).
Attach permission letters and/or letters of support with your application.

Describe the calendar time frame for gathering the data using human subjects.
This should include approximate dates of data collection. PLEASE NOTE THE IRB CANNOT UNDER ANY CIRCUMSTANCES RETROACTIVELY APPROVE A RESEARCH PROPOSAL. Your initial dates of contacting participants must be AFTER IRB appr

Will any incentives be o ered to the participants for their participation?
NOTE: If course credit or extra credit is o ered, describe the alternative means for obtaining credit available to those students who do not wish to participate in the research project (whether the alternative is o ered by the researcher or instructor of the course).

‰ No ‰Yes

If yes, please explain.

Application for Review of Human Subjects Research

Section 5: Risks and Bene ts

From the list below, please select all the potential risks that are involved in this proposed study.

‰Social or economic risks (e.g., reputation, employability, cultural, etc.

‰Breach of privacy of subject or subject's family members

‰Injury or bodily harm ‰Identi cation of illegal activity

‰Identi cation of child, spousal, or elder abuse

‰Presentation of materials which may be considered sensitive, o ensive, threatening, or degrading

‰Probing for personal or sensitive information in surveys or interviews (e.g., private behaviors, employer assessments, etc.)

‰Manipulation of psychological or social state such as sensory deprivation, social isolation, or psychological stress

‰Use of private records (e.g., educational or medical records

‰Use of deceptive techniques, including incomplete disclosure

‰Other risks (please specify):

‰For participants in this study, there are no risks of any kind that are greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.

Describe the nature and degree of risk or harm selected above.

All risks/harms must be disclosed in the consent form Appendix A. If using deception, please justify its use and describe how participants will be debriefed afterwards.

Describe the steps that will be taken to minimize risks and/or harms and protect the welfare of the subjects.

Include a description of how you will handle an adverse or unexpected outcome (e.g., referral to counseling services). If the study includes protected populations, identify each group and provide an explanation for how risks/harms will be minimized and handled for each group.

Application for Review of Human Subjects Research

Will medical clearance be necessary for subjects to participate because of tissue sampling, administration of substances (such as food or drugs), or physical exercise conditioning?

All risks/harms must be disclosed in the consent form in Appendix A. If using deception, please justify its use and describe how participants will be debriefed afterwards.

‰ No ‰Yes

If yes, please explain how clearance will be obtained.

What are the costs to participants?

This can include money, time (such as time to ll out questionnaires), etc. You should also consider the "cost" of participation

What will be done with the identi ers and/or any master keys/lists that link names to subject numbers after the study is completed? How will identi ers be removed? When is the latest date that identifying information or links will be retained?

Describe the steps you are taking to protect the con dentiality of the participants and how you are going to advise participants of these protections in the consent process.

Note: For focus groups, con dentiality may not be maintained because other participants are in the focus group itself. If your study includes focus groups, we recommend using the following language in the consent form (Appendix A) and in the verbal directions given during the focus group itself: The researcher(s) will keep your participation in this research study con dential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, since one of the elements of this study is a focus group, other people in the focus group will be aware of what is shared in the group. Each individual in the focus group is asked not to share the discussions of the group outside of the group, but the researcher(s) cannot guarantee con dentiality in that setting.

What con dentiality or security measures/precautions will be used to protect (or not collect) identi able data? Include protections used during the collection, transfer, and storage of data.

Where will data be stored and secured?

Application for Review of Human Subjects Research

How long do you intend to keep raw data and how will it be destroyed after that time period?
Note: Federal regulations require raw data (and any coding/identi er key sheets) to be kept for at least three (3) years. Typically, raw data is shredded or erased within ve (5) years, particularly if identi ers are attached. Anonymous data can be kept forever.

Will participation in this study be made part of any record available to a participant's supervisor, teacher, or employer?

‰ No ‰Yes

If yes, please describe.

Will tissue samples or specimens be collected?

‰ No ‰Yes

If yes, when will they be destroyed?

Will they be used for research other than what is described in the consent?

‰ No ‰Yes

Application for Review of Human Subjects Research

Section 7: Consent Procedures

Describe, step by step, the procedures to be used to obtain the consent/assent of participants.
Include the context, how, when, and how often (for multiple-phase studies) consent will be sought and who will be responsible for seeking consent. If there are any possible communication barriers involved (e.g., non-English speaking participants; physically disabled, blind, or hearing-impaired participants; participants with cognitive impairments or delays), explain in detail how these will be addressed. Provide copies of all consent documents (and parental permission (assent) documents if needed) in Appendix A.

Are you requesting a Waiver of Documentation of Consent (i.e., no signature on the consent/assent forms)?
If you are conducting an online survey or an anonymous survey (online or in paper form), check yes.

‰ No ‰ Yes

If yes, what is the justi cation for the waiver?

‰ The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of con dentiality.

‰ The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

‰ Other (please specify) (Example: The study is mixed methods with one part online and one part in person.)

Are you requesting to waive:

1. some elements of consent/assent or parental permission? ‰ No ‰ Yes

OR

2. the entire consent/assent or parental permission (assent) process? ‰ No ‰ Yes

If yes to either or both, provide how you will make sure ALL of the following criteria are met:

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely a ect the rights and welfare of the subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

How will you make it clear to the participants that their participation is voluntary and they may withdraw from the study at any time they wish without penalty?

Typically, this is stated in the consent (Appendix A). However, there may be situations where it is explained more than once. Cut and paste the relevant statement here.