Saint Mary's University OF MINNESOTA

Institutional Review Board

Application for Initial IRB Review - Instructions

This document is meant to guide researchers on how to fill in the application form correctly to minimize the risk for modification requests and promptly grant approval so that the researcher may begin the research. Please contact your research supervisor or the IRB Administrative Assistant at irb@smumn.edu with any questions.

In order for your submission to be reviewed, this application form, plus any necessary supporting documents and appendices, must be combined into one (1) PDF or Microsoft Word document and attached in an email to irb@smumn.edu.

Section 1: Researcher Information

1.1 Principal Investigator (PI): If there are multiple researchers, choose one to be the primary point of contact with the IRB.

1.2 Additional researchers:

1.3 Position at the University (select all that apply): ☐ Faculty ☐ Student ☐ Staff

1.4 SMUMN ID Number: List the ID numbers of all SMU-affiliated researchers on the project.

1.5 Academic Level (select all that apply):

☐ Undergraduate ☐ Bachelor's Completion ☐ Graduate

1.6 Program of Study: If you are conducting research as part of course activities, indicate the department of that course.

1.7 SMUMN Email: List the SMUMN email addresses for all researchers on the project.

Section 2: Research Advisor Information

You must complete this section if you are a student or staff member.

2.1 Research Advisor:

2.2 Department/Program:

2.3 SMUMN Email:

Section 3: Protocol Information

3.3 Protocol Title: The title of your project must be consistent throughout your documents.

Section 4: Protocol Design and Procedures

4.4 Briefly describe the purpose of the study: Briefly and concisely, describe the purpose, aims, or objectives of the study.

4.5 Study Design: Indicate the main method you will use to collect data. If multiple methods will be used, check all that apply.

☐ Behavioral Intervention

☐ Survey or Questionnaire

☐ Interview

☐ Observation of Public Behavior

☐ Research in an Educational Setting

☐ Focus Groups

☐ Secondary Data Analysis (archival)

☐ Clinical Study

☐ Collection of Biological Specimens

☐ Other:

4.6 What will the participants be asked to do? Explain the study design and describe the procedures being performed. Be as detailed as possible.

4.7 How will the end results be used? For example, results might be used in a course activity, shared in a presentation, analyzed as part of a larger project, etc. Be sure to describe if the results shared will be aggregated or individual.

4.8 What is the participant's time commitment? How long are subjects expected to participate in the study? For example, 3 sessions lasting 45 minutes, every week for 6 weeks.

Section 5: Participants

5.1 Does the study intentionally involve vulnerable populations?

☐ Children – The age of majority varies by state. For example, "children" in Minnesota are those under the age of 18.

☐ Wards

☐ Persons who are pregnant

☐ Human fetuses

☐ Neonates

☐ Prisoners

☐ Students of the PI/Researchers – If your potential participants will be your own students, be sure to check this box.

☐ Employees of the PI/Researchers – If your potential participants are your own employees, or work under your supervision in some capacity, be sure to check this box.

☐ Persons with mental disabilities/cognitive impairment

☐ Persons of color or indigenous persons

☐ Economically disadvantaged persons

☐ Socially disadvantaged persons

☐ Educationally disadvantaged persons

☐ Illiterate persons

☐ Individuals with speech impairments

☐ Persons who are terminally ill/very sick

☐ Institutionalized persons

☐ Individuals with therapeutic associations with the PI/Researchers

☐ Soldiers or other members of the military

☐ Immigrants

☐ Other:

5.2 If you selected any of the above vulnerable populations, what safeguards will you use to ensure they are protected? Vulnerable populations require additional safeguards in order to ensure their protection, such as consent monitoring, translators, legally authorized representatives, consultations, etc. See the worksheets available on the IRB website (irb.smumn.edu) for more information.

5.3 Explain your inclusion and exclusion criteria: Describe the criteria that define who will be included in your study sample. For example, students currently enrolled in a psychology class.

5.4 How will you identify potential participants?

5.5 How will participants be screened? This will be how you use your inclusion and exclusion criteria to determine eligibility for the study. For example, participants might be asked to indicate their age before the study begins.

5.6 Expected number of participants:

5.7 Age or age range of participants, if known: Be as specific as possible. Some example answers may include: "3rd graders ages 7-9", "a diverse age range of adults", "youth ages 12-18"

Section 6: Recruitment

6.1 What is your source of participants? Describe the source of potential participants. For example, "my third grade classroom at X elementary school in X city."

6.2 What is your recruitment process? Describe how you will recruit participants to join the study. Recruitment refers to any communication asking someone to participate, from asking your classroom of students as part of normal educational coursework, to handing out flyers at a local mall.

6.3 Will the participants receive any type of compensation? Compensation may involve a giftcard or a refund for the costs to participate.

6.4 May participants be withdrawn or terminated without their consent? Describe what might happen that would lead you to withdraw or terminate the participant from the study without their consent. Some examples may include failure to show up for designated interview times or an unexpected absence from class during the planned period of behavioral intervention.

6.5 What are the procedures for participants who wish to be withdrawn or terminated from the study? If a participant wishes to leave the study, describe what steps they will go through in order to leave, what will happen to data that has already been collected, and if there will be any follow-up procedures for withdrawn participants.

6.6 Is there a point in the study at which participants cannot withdraw? For example, after submitting an anonymous survey, participants cannot withdraw because there is no way to identify which results belong to them.

Section 7: Consent Procedures

7.1 Which consent process and documentation will you use?

☐ Parental Permission (Permission Form)

☐ Assent (Assent Form for Minors Age 6-10)

☐ Assent (Assent Form for Minors Age 11-17)

☐ I request the IRB waive the need for consent - I will use a Notification of Classroom Research Form

☐ Implied Consent (Cover Letter for an Anonymous Survey)

☐ Informed Consent (Consent Form)

☐ Other:

7.2 Describe your process of assessing your participants' ability to consent or assent: How will you ensure that the participants' consent is freely given? This is especially important if the study involves vulnerable populations such as children, adults with diminished capacity to consent, people with impaired decision-making capabilities, non-English speakers, etc.

7.3 Does your study involve any of the following populations? Select all that apply.

☐ Non-English speakers

☐ Speech impaired participants

☐ Participants who are not yet adults

☐ Adults w/ diminished capacity to consent

☐ Cognitively impaired adults

☐ Adults unable to consent

☐ Illiterate

7.4 If your study involves any of the above populations, explain how you will know they fully understand the study and make an informed decision to participate? Some participants in the above categories might require a translator, witness, legally authorized representative, or other measures to help them understand the consent process and to provide consent. If so, explain your method for obtaining consent.

Section 8: Risks

8.1 What are the potential risks to the participants? Explain any physical, mental, or emotional risks related to participating in the study. See the Assessing Risk worksheet for more information.

8.2 What are the potential risks to others, if any? If the study might put any non-participants at risk, describe those here.

8.3 Does the study involve the use of deception or incomplete disclosure? If yes, justify why the study requires it. Briefly justify your use of deception or incomplete disclosure. Indicate whether or not your participants will be informed that the study uses deception and if they will be given the opportunity to agree to the use of deception. You must also provide a description and documentation of the debriefing process, if appropriate, that will be participants aware of the deception and their right to voluntary withdrawal.

Section 9: Benefits

9.1 What are the direct or indirect benefits to participants in the study, if any? Describe any potential befits that the subject might receive from participating in the research that those in a control group would not receive. Do not include benefits to society or others. If there are no distinguishable benefits to participants, you may use the following statement: There are no direct benefits for participating in the study.

Section 10: Data Collection

10.1 What type of data will be collected? Describe the data that will be collected about the participants, if there are different types of data to be collected, and any source records that will be used for data collection (attach all surveys, scripts, and data collection forms to the appropriate appendices).

10.2 Describe any long-term follow-up data, if applicable. Describe if there is any data that will be collected in the long-term as a follow-up to the data originally collected in the study.

10.3 How will you store the data collected? Describe how and where the data will be stored.

10.4 Who will have access to the data? Describe who will have access to the data, including the researchers and anyone outside the research study, such as transcribers, translators, second-coders, etc.

10.5 For how long will you store the data? When will it be destroyed? Federal Common Rule requires data be kept for a minimum of 3 years, while HIPAA and APA guidelines suggest data be kept for a minimum of 5 years. Consult your Research Advisor to determine what is appropriate for your project.

10.6 Does the study involve individually identifiable health information?

☐ Yes ☐ No

If yes, explain: Describe how the study procedures follow HIPAA rules to protect the individually identifiable health information, if applicable. If any individually identifiable health information is being accessed, participants must sign a release statement that allows the researcher access to those records.

10.7 Will you share the results of the data with the participants?

☐ Yes ☐ No

If yes, explain how: Describe the method by which you will share the data with the participants, and who exactly the data will be shared with.

10.8 How will the data be analyzed? Describe the method by which you will analyze the data: variables to be analyzed, statistical tests or regression models to be used, etc. Describe how your analysis of the data will tell you whether or not. You have accomplished the purpose of your research.

Section 11: Confidentiality and Privacy

11.1 How will the confidentiality of the data be maintained? Describe the steps you will take to secure the data, such as authorization access, password protections, encryption, de-identified coding, certificates of confidentiality, statements of confidentiality, or physical controls. If the consent form will be placed with the participants' medical, employment, or educational records, explain why this is appropriate.

11.2 Will anyone besides the researcher have access to the participants (e.g., transcriber)?

☐ Yes ☐ No

If yes, explain the role of that person and the additional measures you will take to ensure confidentiality. Explain how you will ensure anyone with access to the participants will maintain confidentiality and privacy. Note: Every third-party person involved in the research study must sign a Statement of Confidentiality that needs to be submitted with the application.

11.3 How will the privacy of the participants be protected? Describe the steps you will take to ensure the participants' privacy interests are protected. Privacy interests refer to a person's desire to place limitations on with whom they interact or to whom they provide personal or sensitive information. Participants must feel comfortable with the research in what they will be asked to do. For example, if a participant wishes to keep their involvement in the study private, how will you set up the study so that no one knows they are being interviewed/surveyed?

Section 12: Research Sites

12.1 Will the study take place outside of Saint Mary's University of Minnesota?

☐ Yes ☐ No, it will take place at Saint Mary's.

If yes, does that external site have their own Institutional Review Board (IRB)? If a research site has its own IRB, an Authorization Agreement must be signed and included with your submission.

☐ Yes ☐ No

Required Documentation

If your protocol utilizes any of the following materials, these supporting documents must be included with your submission.

Appendix A: Recruitment Materials

e.g., recruiting posters, advertisements, emails, written/verbal announcements, and other communication used to recruit participants for the research study

Appendix B: Consent Documentation

e.g., consent form, permission form, assent form, cover letter for an anonymous survey

Appendix C: Documents Provided to Participants

e.g., written or verbal instructions, request for summary of results, or other documents given to research participants. These must include research protocol and procedures.

Appendix D: Data Collection Tools

e.g., surveys, questionnaires, tests, demographic information sheets, or other instruments designed by the researcher.

Appendix E: External Data Collection Tools

e.g., tests, measurement scales, or other instruments developed by another individual or agency). In addition, attach documentation to show that the instrument is in the public domain, that the researcher has the written permission of the author of the instrument to use for research, or that the researcher purchased the instrument (receipt).

Appendix F: **Research Cooperation Agreement**

Appendix G: **Conflict of Interest Statement**

Appendix H: **Archival Data**

Archival data is subject to regulations governing the use of health care data or student records. Please include how the use of the data complies with relevant HIPAA, FERPA regulations, or state statutes.

Appendix I: External Funding

Description of any external funding or copy of grant application/protocol

Appendix J: IRB Authorization Agreement

Review and approval of the cooperating agency/institution's IRB

Appendix K: CITI certificate

Certificate of Completion for CITI training dated no more than 3 years prior

Appendix L: Statement of Translation Accuracy

Appendix M: Statement of Confidentiality from Third Party Person

Appendix N: Review and Approval from Research Advisor

Insert appendices here