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|  | Office of IRB Administration (OIA) **Social/ Behavioral/Educational Research (SBER)**  **Protocol**  Version Date: 12.08.21 |
| Detailed instructions are included for each section. All instructions must be removed, and all sections completed. “Not Applicable” is an acceptable response if the section does not apply to the research. In general, research protocols should be no longer than 8-10 pages, excluding attachments (e.g., questionnaires, consent/assent forms). | |
| 1. **STUDY TITLE** | |
| Enter the project title here. Be sure it matches the title in Kuali IRB. | |
| **2. PRINCIPAL INVESTIGATOR** | |
| Include Principal Investigator name, title and department. UCSD IRB only recognizes one PI per study. | |
| **3.** **STUDY RATIONALE** | |
| State the problem and the reason for conducting the research. | |
| **4.** **SPECIFIC AIMS/HYPOTHESES** | |
| Briefly state the specific aims and hypotheses that serve as the basis for this protocol. | |
| **5. BACKGROUND AND SIGNIFICANCE (2-3 paragraph maximum)** | |
| Provide a brief discussion of relevant background information including preliminary data to justify performing the study. Appropriate references should be included in Section 13. | |
| **6. RESEARCH DESIGN AND METHODS (1 page maximum)** | |
| Describe the research design and the procedures to be used to accomplish the specific aims of the project. Explain in  clear terms what precisely will be done to the human participants and how long they will be involved in the study.  Where appropriate, identify the sources of research material obtained from individually identifiable living human  participants in the form of records or data. Indicate whether new data will be obtained specifically for the purposes of  this research, or if existing records or data will be used.  In addition, this item of the Research Plan should include a precise, but brief, description of the methods for data  collection, data analysis and data interpretation. If video and/or audio recording will be done as part of the study, a  description of the study procedures associated with the taping should be provided including how the tapes will be  used, who will have access to the tapes, and the final disposition of the recordings.  If questionnaires/surveys will be completed as part of the research, please provide the name and reference for  questionnaires/surveys that are standard. If the questionnaire/survey is not a standard assessment tool, please  provide a copy of the questionnaire/survey.  If the research includes video and/or audio recording, explain that the taping may be stopped at any time and that portions and/or the entire tape may be erased at the participant’s request. In addition, describe how the tape recording will be used, when/whether the tape will be destroyed by the researchers, and any risk and risk management procedures associated with this taping including loss of confidentiality. This information should also be included in the informed consent/assent documents and a separate video and/or audio consent/assent document may also be required.  If it is reasonably foreseeable that the study will have access to or collection of information that Federal, State,  and/or local laws/regulations requires or may require to be reported to other officials (e.g., child or elder abuse) or  ethically requires actions (e.g., suicidal ideation), describe the reporting procedures/requirements including whether  the investigator is a “mandated reporter” and ensure the reporting requirements are described in the consent. | |
| **7. RESEARCH PARTICIPANTS (2-3 paragraph maximum)** | |
| Describe the characteristics of the proposed research participant population, including their age, gender, ethnic background and health status. Identify the criteria for inclusion/exclusion of participants to be enrolled in the study. Explain the rationale for using special participant populations, if any, such as those who are pregnant, children, or institutionalized individuals who are likely to be vulnerable. | |
| **8. RECRUITMENT** | |
| Describe how research participants will be contacted and by whom, what they will be told, and how they will be selected for participation. All recruitment materials (flyers, advertisements, letters, etc.) must be reviewed and approved by the IRB prior to use. Should participants vulnerable to coercion or undue influence be recruited for this study, such as those who are economically or educationally disadvantaged, mentally disabled, or students (undergraduate, graduate, and medical students) and employees of UCSD and RCHSD (administrative, clerical, nursing, lab technicians) describe the procedures to ensure the voluntary participation of these participants.  Further, if children are to be enrolled in the study, describe how possible undue influence for their participation will be addressed. | |
| **9. INFORMED CONSENT** | |
| Describe the consent procedures to be followed, including the circumstances under which consent/assent will be obtained, who will seek it, and the methods of documenting consent/assent.  **Waiver of Consent, Waiver of Documented Consent**  If a *waiver of consent* is being requested, provide a description of how each of the five criteria for granting waiver of consent will be satisfied. The criteria include the following:  1. The research is minimal risk.  2.The waiver will not adversely affect the rights and welfare of the participants.  3.The research could not practicably be carried out without the waiver.  4.Whenever appropriate, the participants will be provided with additional pertinent information after participation.  5.If the research involves the use of identifiable private information or biospecimens, the research could not be practicably carried out without the use of identifiers.  If *waiver of documented consent* is being requested, such as for the use of oral or video consent, provide justification for granting this waiver. Justification includes one of the following: a) that 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 confidentiality. Each participant will be asked whether they want documentation linking the participant with the research, and the participant’s wishes will govern; or b) that 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.  For research that involves video and/or audio recording, procedures for obtaining consent for such recording must also be described and the consent form must indicate that the recordings may be stopped at any time, and that portions and/or the entire audio/video may be erased at the participant's request. The consent should also state how the audio/video recording will be used by the researchers.  For research that involves participants under the age of 18 years, both a parent permission/consent form and adolescent assent (for children aged 13-17 years) and/or child assent (children 7-12 years of age) must be used. Note that both parent permission/consent and adolescent/child assent must be obtained before adolescent/children can be involved in a research study.  **Waiver of Assent**  If a *waiver of assent* is being requested, appropriate justification must be provided. The regulations provide three types of circumstances under which such a waiver may be justified:  1.The capability of some or all of the children is so limited that they cannot reasonably be consulted.  2. The intervention or procedure involved in the research holds out the prospect of direct benefit to the health and well-being of the children and is available only in the context of the research.  3. The research meets the same conditions of those for waiver or alteration of informed consent in research involving adults, as specified in the regulation 45 CFR 46.116(f). | |
| **10. PRIVATE, IDENITIFABLE INFORMATION ABOUT RESEARCH PARTICIPANTS** | |
| Indicate what personal identifying information (e.g., name, address, phone number, email, social media profiles, birthdate, photographs, biometrics identifier – fingerprints, voice), if any, about the research participants will be collected and/or received. | |
| **11. RISK MINIMIZATION** | |
| In this section describe how risks will be minimized in the research. Consider:   1. Eliminating unnecessary procedures such as collecting the minimum data necessary for the research, collecting the minimum number of identifiers, and/or performing only procedures that ate necessary for the study objectives. 2. Minimizing the risk of the procedures for example, coding data and samples to conceal identifiers. 3. Incorporating adequate safeguards into the research design such as the presence of trained personnel who can respond to emergent issues, and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords).   Also explain why the risks are reasonable in relation to be benefits to participants, if any, and the importance of the knowledge to be gained.  **\_\_\_** Check here if the **only risk** of the research is a breach in confidentiality. If so, no additional information is  required in this section. | |
| **12. QUALIFICATIONS, TRAINING, CULTURAL LITERACY AND RESEARCH TEAM RESPONSIBILITIES** | |
| Provide a detailed explanation outlining each member of the research team's  responsibilities as well as specifies each member's qualifications, training, cultural literacy, etc. as they relate to this study. Note: PI must have completed the appropriate CITI training in the last three years in order to submit a Kuali IRB application. Co-Is and key personnel must also have completed the appropriate CITI training in the past three years and have their completion report available for review upon the IRB’s request. | |
| **13. REFERENCES** | |
| List references noted in the Section 5. | |
| **14. BIBLIOGRAPHY** | |
| List up to five relevant articles that the IRB can use to provide necessary background for the protocol. Do not append an extensive grant-style bibliography. | |