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|  | Office of IRB Administration (OIA) **Biomedical Non-Intervention 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. | |
| 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** | |
| State the specific aims and hypotheses that are the basis for this protocol. | |
| **5. BACKGROUND AND SIGNIFICANCE** | |
| 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** | |
| Describe the research design and the procedures to be used to accomplish the specific aims of the study. Explain exactly what will be done to the research participants. Also list the locations where the project will be done and any specialized facilities (e.g., MRI, sleep lab) that the project will use.    This section should include a clear description of the procedures/activities associated with the study including the where the procedures/activities will be done, what will be done at each study “visit” (a study “visit” would include the participant visiting the research facility, phone interviews, self-monitoring at home, etc.), the study timeline for the visit(s), etc. as well as the participant’s time commitment for each study visit and the total duration of the participant’s involvement in the study. A table reflecting this information is encouraged. For studies that involve clinical procedures, this section must include a DISCRETE paragraph that clearly distinguishes procedures that are considered experimental, investigational and/or are carried out solely for research purposes versus those procedures that are considered standard treatment or therapy (i.e., procedures that participants would receive even if not taking part in research). Standard treatments, therapies and procedures done exclusively for research purposes should be clearly identified.  Describe the study procedures for obtaining research material, the sources of research material, and specifically what material will be collected from individually identifiable living human research participants in the form of specimens, records or data as well as indicate whether the material or data will be obtained specifically for research purposes. Also, indicate if there will be any identifiers associated with the specimens, records, or data or if they will be obtained anonymized.  If video and/or audio recording will be done as part of the study, a description of the study procedures associated with the recording should be provided including how the recording will be used. If questionnaires/surveys will be completed as part of the research, provide the name and reference for questionnaires/surveys that are standard. If the questionnaire/survey is not a standard assessment tool, provide a copy of the questionnaire/survey.  Provide a description of the planned data collection, data analysis and planned data interpretation. This should include criteria for determining statistical significance and sample size.  If UCSD will be a coordinating center or is the prime awardee of a grant, this section should include how information will be shared among all sites and appropriate agencies including safety updates, interim results, or other information that may impact risks to participants or others; modifications to the protocol and/or consent; etc. | |
| **7. RESEARCH PARTICIPANTS** | |
| Describe the proposed research participant population. State the inclusion and exclusion criteria for participants to be enrolled on this study including age, gender, cultural background and health status.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 the recruitment procedures. Explain how, when, where and by whom potential research participants are approached as well as how participants are identified such as data mining, physician referral. etc. 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.  If procedures for purposes preparatory to research (e.g., preparing a research protocol; assisting in the development of a research hypothesis, or identifying prospective research participants who meet the eligibility criteria for enrollment review) involve access to PHI, HIPAA authorization must be obtained, or a partial waiver of individual HIPAA authorization must be granted. In order for a partial waiver of HIPAA authorization to be granted, address the following:  1. A plan to a) protect identifiers from improper use and disclosure; and b) destroy identifiers at the earliest opportunity or provide justification for retaining the identifiers;  2. Justification as to why these procedures could not a) practicably be done without the waiver, and b) be done without access to, use, or disclosure of the PHI;  3. Justification that the privacy risk to individuals whose PHI will be used or disclosed is minimal and reasonable in relation to the anticipated benefit, if any, to the individuals; and  4. What PHI will be used and who will access, use or disclose the PHI. | |
| **9. INFORMED CONSENT** | |
| Describe the **process** for obtaining consent/assent/parental permission and HIPAA authorization. The details should describe:  1. The person(s) or position(s) who will obtain consent/assent/permission/authorization.  2. The circumstances under which consent/assent/permission/authorization will be obtained including location; any waiting period between informing the prospective participant and obtaining consent/assent/permission/authorization including sufficient time for the prospective participant to consider whether to participate; steps taken to minimize the possibility of coercion or undue influence.  3. The language used by those obtaining consent/assent/permission/authorization; the language understood by the prospective participant or the legally authorized representative.  4. The methods of documenting consent/assent/permission/authorization and that consent/assent/permission will be obtained before any study procedures are performed including screening procedures.  5. That the information being communicated to the participant/parent or legally authorized representative during the consent/assent/permission process will not include exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant’s legal rights or release or appear to release the Researcher, Sponsor, the University or its agents from liability for negligence.  If participants who cannot read or speak English may be enrolled, describe the procedures that will be done to obtain consent/assent/permission/authorization from these participants including the use of a document translated into the participant’s primary language, the use of an “official” translator, and how it will be ensured that **continued**, qualified interpretive services to the participant will be provided.  **Waiver of Consent, Waiver of Documented Consent, Waiver of Individual HIPAA Authorization**  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 subjects.  3.The research could not practicably be carried out without the waiver.  4.Whenever appropriate, the subjects 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 subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or b) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.  If a *waiver of individual HIPAA authorization* is being requested, this item must clearly and specifically describe how each of the following conditions will be satisfied:  1.The use of disclosure of PHI involves no more than minimal risk.  2.Granting waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.  3.The project could not practicably be conducted without a waiver.  4.The project could not practicably be conducted without the use of PHI.  5.An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.  6.An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.  7.The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.  8.Whenever appropriate, the subjects will be provided with additional pertinent information after participation.    **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.**  **BANKING OF INFORMATION/BIOSPECIMENS FOR FUTURE USES** | |
| If the study will maintain a database or biorepository for future uses (uses other than those specifically stated in this protocol), clearly state what information/biospecimens will be retained, what the potential future uses of the information/biospecimens are, how the information/biospecimens will be stored after the completion of the study for future use (i.e., identifiable, coded, or de-identified as well as physical location and access restrictions), and how, to whom, and under what circumstances such information/biospecimens might be released for future uses. ***NOTE:*** *IRB approval may be required for future research using the identifiable information/biospecimens collected for this study.]* | |
| **11. MINIMIZATION OF RISK** | |
| 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, use of a blood drawing IV instead of separate venipunctures, use of topical anesthetic, analgesics or sedation to minimize pain, and/or coding data and samples to conceal identifiers. 3. Combining research procedures with clinical care such as the timing research blood draws, X-rays or other procedures to occur at the same time as clinical procedures and/or limiting research MRI, PET, CT or other scans to those having a clinically indicated study, particularly when sedation or general anesthesia is required. 4. Incorporating adequate safeguards into the research design such as an appropriate data safety monitoring plan, the presence of trained personnel who can respond to emergencies, 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 of confidentiality. If so, no additional information is  required in this section. | |
| **12. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES** | |
| This section should describe each research team's responsibilities. Indicate which individuals are privileged/certified or licensed, and at what sites, to perform the procedures in the protocol. Examples include “Dr. ‘Z’ is a Ph.D. who will be conducting the data analysis for the study, Dr. ‘Y’ who is an M.D., has medical privileges at the UC Medical Centers and RCHSD to perform the biopsy.” “Dr. ‘X’ who is an M.D., will only be conducting the ‘abc’ procedure for which she has privileges for only at the UCSD Medical Center.” If individuals are not privileged, etc. to perform the procedures as described in the protocol, explain rationale and plan. This section must also clearly indicate by which entity each member of the research team is appointed/employed, such as UCSD. 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 NIH-grant-style bibliography. | |