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| Instructions and Notes:   * Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA”. * When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes. | |
| 1. **Protocol Title**   Include the full protocol title | |
| 1. Background and Objectives   Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.   * Describe the purpose, specific aims, or objectives. * State the hypotheses to be tested. * Describe the relevant prior experience and gaps in current knowledge. * Describe any relevant preliminary data. | |
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| 1. Data Use   Describe how the data will be used. Examples include:   * Dissertation, Thesis, Undergraduate honors project * Publication/journal article, conferences/presentations * Results released to agency or organization | * Results released to participants/parents * Results released to employer or school * Other (describe) |
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| 1. Inclusion and Exclusion Criteria   Describe the inclusion and the exclusion criteria for the study.  Describe how individuals will be screened for eligibility.  Indicate specifically whether you will target or exclude each of the following special populations:   * Minors (individuals who are under the age of 18) * Adults who are unable to consent * Pregnant women * Prisoners * Native Americans * Undocumented individuals | |
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| 1. Number of Participants   Indicate the total number of participants to be recruited and enrolled   * Provide a rationale for the proposed enrollment number * What percentage of screened individuals will likely qualify for the study? | |
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| 1. Recruitment Methods  * Describe when, where, and how potential participants will be identified and recruited. * Describe materials that will be used to recruit participants. (Attach copies of these documents with the application.) * Does any member have a dual role with the study population? | |
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| 1. Study Timelines   Describe:   * The duration of an individual participant’s participation in the study. * The duration anticipated to enroll all study participants. * The estimated date for the investigators to complete this study (up to and including primary analyses). | |
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| 1. Procedures Involved   Describe and explain the study design. Provide a description of all research procedures being performed and when they are performed. Describe procedures including:   * The documents/ measures / devices/ records /sampling that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms.) * What data will be collected including long-term follow-up? * All drugs and medical devices used in the research and the purpose of their use, and their regulatory approval status. * Describe the available compensation (monetary or credit that will be provided to research participants). * Describe any costs that participants may be responsible for because of participation in the research. | |
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| 1. Withdrawal of Participants   Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.  Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection. | |
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| 1. Risks to Participants   List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Reference this information when appropriate.   * If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant. * If applicable, describe risks to others who are not subjects. | |
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| 1. Potential Benefits to Participants   Realistically describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit. Do not include compensation or benefits to society or others. | |
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| 1. Setting   Describe the sites or locations where your research team will conduct the research.   * Identify where research procedures will be performed. * For research conducted outside of the ASU describe:   + Site-specific regulations or customs affecting the research.   + Local scientific and ethical review structures in place. | |
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| 1. Multi-Site Research   If this is a multi-site study where you are the lead investigator, describe the processes you will use to ensure communication among sites, such as:   * Each site has the most current version of the protocol, consent document, and HIPAA authorization. * Required approvals have been obtained at each site (including approval by the site’s IRB of record). * Describe processes you will use to communicate with participating sites. * Participating sites will safeguard data as required by local information security policies. * Local site investigators conduct the study appropriately. | |
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| 1. Resources Available   Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform your roles. When applicable describe knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.  Describe other resources available to conduct the research: For example, as appropriate:   * Describe your facilities. * Describe the availability of medical or psychological resources that participants might need as a result of any anticipated consequences of the human research. * Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. | |
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| 1. Prior Approvals   Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site, funding agency, laboratory, radiation safety, or biosafety approval.) | |
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| 1. Data Management and Confidentiality   Describe the data analysis plan, including procedures for statistical analysis.  Describe the steps that will be taken to secure the data during storage, use, and transmission.   * Training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data   Describe how data and any specimens will be handled:   * What personal identifiers will be included in that data or associated with the specimens? * Where and how data or specimens will be stored? * How long the data or specimens will be stored? * Who will have access to the data or specimens? * Who is responsible for receipt or transmission of the data or specimens? * How will data and specimens be transported? * If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens. * Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. | |
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| 1. Safety Monitoring   This is required when research involves more than Minimal Risk to participants. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Describe:   * The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. * What data are reviewed, including safety data, untoward events, and efficacy data? * How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants). * Who will review the data? | |
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| 1. Consent Process   Describe the process and procedures process you will use to obtain consent. Include a description of:   * Who will be responsible for consenting participants? * Where will the consent process take place? * How will consent be obtained? * If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved. | |
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| 1. Investigational New Drug or Devices   If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:   * Identify the hold of the IND/IDE/Abbreviated IDE. * Explain procedures followed to comply with FDA sponsor requirements for the following:  |  |  |  |  | | --- | --- | --- | --- | |  | ***Applicable to:*** | | | | **FDA Regulation** | **IND Studies** | **IDE studies** | **Abbreviated IDE studies** | | 21 CFR 11 | X | X |  | | 21 CFR 54 | X | X |  | | 21 CFR 210 | X |  |  | | 21 CFR 211 | X |  |  | | 21 CFR 312 | X |  |  | | 21 CFR 812 |  | X | X | | 21 CFR 820 |  | X |  | | |
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| 1. CITI   Provide the date that the members of the research team have taken the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: <http://researchintegrity.asu.edu/training/humans> | |
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