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**PROTOCOL TEMPLATE**

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| --- |
| **Full study title** |
| **Name(s), Title(s),Department of Principal Investigator, contact number(s), email address(es)** |
| **Collaborators (institutions and departments), if any** |
| **Sponsor(s), if any** |
| **Funding source(s), if any** |
| **Protocol version number and version date** |

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| --- | --- | --- |
| **Revision History** | | |
| **Version No.** | **Version Date** | **Description/Summary** |
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**PROJECT OVERVIEW**

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| --- | --- |
| **Project Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/Interactions** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |

**INTRODUCTION**

Introduce the project by providing a summary of the primary hypothesis, purpose, scholarly rationale, and prior literature. State and elaborate on the hypotheses to be tested as a part of the research.

**OBJECTIVES**

Describe the specific intent and aims of the research proposal. Outline the primary and secondary aims, outcome measures, and study timelines (for the research and participant).

**PARTICIPANT SELECTION**

Describe your target population and specifically state whether you will include or exclude any of the following special populations:

* Adults unable to consent
  + If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.
* Individuals who are not yet adults (infants, children, teenagers)

If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), consider the applicable regulations found at 45 CFR 46 Subpart D NOTE: The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a)

* Pregnant women

If the research involves pregnant women, human fetuses, or neonates of uncertain viability or non-viable neonates consider the regulations found at 45 CFR 46 Subpart B

* Prisoners

If the research involves prisoners consider the regulations found at 45 CFR 46 Subpart C.

* Cognitively impaired or Individuals with Impaired Decision-Making Capacity

If the research involves cognitively impaired adults, describe procedures to be followed to ensure consent and continuing consent is properly obtained.

* Individuals who are not able to clearly understand English (If you indicated you will exclude, please provide a rationale.)

Indicate the total number of participants to be accrued locally (and study-wide, when applicable). If possible, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)

**SUBJECT RECRUITMENT PLAN**

* Describe when, where, and how potential participants will be recruited, who will make initial contact and how, and if physicians or staff refer participants.
* Describe the source of participants.
* Describe the methods that will be used to identify potential participants.
* Describe materials that will be used to recruit participants. Copies of these materials must be included in the submission for IRB review.
* Describe the screening for eligibility process.

**STUDY DESIGN AND METHODS**

* Describe the procedures to be performed (distinguish between the procedures performed for diagnostic or treatment purposes and those for research) – include a table of study visits and their procedures, if helpful. Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.
* Describe procedures performed to lessen the probability or magnitude of risks.
* Indicate the source records that will be used to collect data about participants.(i.e diaries, surveys, etc… - copies of each must accompany the submission for IRB review.
* If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.
* 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 holder of the IND/IDE/Abbreviated IDE.
  + Explain procedures followed to comply with sponsor requirements for FDA regulated research.
* Describe the randomization and blinding scheme, if any.
* Describe wash outs or dose escalations, if any.
* Outline the risks/discomforts and potential benefits if any to subjects. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to the participant's participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not participants.

Describe the potential benefits that individual participants 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.

* State what type of information will be collected.
* State what specimens will be collected, if any.
* Describe if and how data/samples collected for this study will be saved/banked/archived for future use Indicate who may use the material, and for what purposes.
* Outline the sample size determination and power.
* Describe any interim monitoring and early stopping plans.
* Describe the analysis plan and statistical methods.
* Describe the procedures when a subject withdraws from a study:
  + Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
  + Describe any procedures for orderly termination.
  + Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

**PARTICIPANT REMUNERATION**

Describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit, etc.). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Indicate if payments will be pro-rated if a participant withdraws early.

**RESEARCH SETTING**

Describe the sites or locations where your research team will conduct the research.

* Identify where your research team will identify and recruit potential participants.
* Identify where research procedures will be performed.

**INFORMED CONSENT PROCESS**

* Describe the process for how will you obtain consent from participants or their legally authorized representatives, if applicable (in person, online, via phone, etc…)
* If you are requesting a waiver of signed documentation of informed consent, describe how will you document consent.
* Interaction consenting:
  + Describe where will the informed consent discussion take place.
  + Indicate who will conduct the discussion and obtain consent.
  + Outline the steps to be taken to ensure participant understanding.
  + Describe the process to ensure ongoing consent.
  + Describe the process to determine whether an individual is capable of consent. Consider the cognitively impaired.
  + For adults unable to consent, list the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.)
  + For inclusion of minors, describe the process for the assent of the participants.
    - Indicate whether:
      * Assent will be required of all, some, or none of the participants.
      * If some, indicated, which participants will be required to provide assent and which will not.
      * If assent will not be obtained from some or all participants, an explanation of why not.
  + Describe the steps that will be taken to minimize the possibility of coercion or undue influence.

**RESULTS SHARING**

* Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the participant’s primary care physicians) and if so, describe how the results will be shared If applicable.
* Describe the plan for managing the types of findings that might arise. This should include any secondary findings that are being sought actively, findings that might be anticipatable, and findings that might be un-anticipatable.
* Describe the plan for recognizing, analyzing, and handling incidental findings and how incidental findings will be communicated to participants during the consent process. If the plan is not to disclose any findings, then this should be included. This plan might include the option for participants to opt-out of receiving incidental findings.

**DATA MANAGEMENT AND CONFIDENTIALITY**

* Describe the data/biospecimens management plan. Describe the steps that will be taken to secure the data and specimens (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for the quality control of collected data
* Describe how data/biospecimens will be handled locally and study-wide (if applicable):
  + What information will be included in the data/biospecimens?
  + Where and how will the data/biospecimens be stored?
  + How long will the data/biospecimens be stored?
  + Who, in general, will have access to the data/biospecimens?
  + Will any data be shared with an external entity or non-Piedmont collaborator? If so, clarify what identifiers will be included with the data.
  + Who is responsible for receipt or transmission of the data/biospecimens?
  + How will data/biospecimens be transported?

**SAFETY AND MONITORING REPORTING**

Describe the of plan for notifying the IRB of reportable events. See PHCIRB policy #6421 and #6422 for reporting requirements for unanticipated problems, deviations and violations.

**COLLABORATIVE RESEARCH**

List external collaborators on the first page of this protocol including whether external collaborators are seeking IRB approval from PHCIRB or their own IRBs. If there are any external collaborators seeking approval from the PHCIRB, please so indicate in the New Protocol Application Form\* to accompany the materials submitted for IRB review. Include language to address/clarify/confirm the following:

* Anticipated study wide number of participants to be included in the research
* If participants will be recruited by methods, not under the control of the local site (e.g., call centers, national advertisements) describe those methods.
* Describe the processes to ensure communication among sites. All sites have the most current version of the protocol, consent document, and HIPAA authorization. All required approvals (initial, continuing review, and modifications) have been obtained at each site (including approval by the site’s IRB of record).
* All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data, including the secure transmission of data, as required by local information security policies.
* All local site investigators conduct the study following applicable federal regulations and local laws.
* All non-compliance with the study protocol or applicable requirements will be reported following local policy

Describe the method for communicating to engaged participating sites:

* Problems (inclusive of reportable events).
* Interim results.
* Suspension or closure of a study.

**REFERENCES/BIBLIOGRAPHY**

**\*IRB submission forms and templates found at:** [**https://www.piedmont.org/research/research-eforms-and-systems**](https://www.piedmont.org/research/research-eforms-and-systems)