**ANCILLARY STUDY**

**PROPOSAL TEMPLATE**

**PART 1: Description of the Proposed Ancillary Study**

Please provide a brief (maximum 4 pages not including citations) description of the proposed ancillary study. Please include the following:

1. **Abstract**

Summarize background information and literature, and state how they lead to the question(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. End by stating the aim of the ancillary study and summarizing the method(s) that will be used to address the questions.

1. **Background and Rationale**

Explain in detail the background information summarized in the Abstract paragraph. Explain why this information is lacking with regard to the ancillary study question(s) of interest and how the proposed study will address that gap. Finally, explain how the methods and/or information will address the ancillary study question(s). Acknowledge any limitations or concerns related to the proposed methods and explain how they have been or will be dealt with.

1. **Specific Aims**

Detail the research questions or hypotheses to be addressed by the ancillary study.

1. **Methods**
2. **Study Population**

Describe the sample of interest (the entire cohort or certain subgroups). Include the anticipated time frame of participant involvement (if applicable).

1. **Data Collection**

Describe information to be collected and any methods or equipment to be used. Include detailed explanations and protocols for each method in the ancillary study. Explain how the information from the method or equipment will address the question(s) of the study. Attach copies of any study instruments (questionnaires and forms) that participants or administrators will be expected to complete. Include an estimate of the time necessary to complete them. Describe the data needed from the main study (including outcomes/events).

1. **Statistical Analysis**

Explain how each study hypothesis (from Section 3 – Specific Aims) will be analyzed. Include any current hypotheses or information that might influence the approach to the analysis or the question itself.

1. **Sample Size Calculations**
2. **Literature References**
3. **Is a letter of support being requested? If yes, list RFA and deadline**

**PART 2: Detailed Biospecimen Use (if applicable)**

**Table 1. Type, Amount, Timepoint, and Assays**

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| --- | --- | --- | --- | --- |
| **Sample Type (e.g., plasma, serum, etc.)** | **Number of Participants** | **Volume** | **Specifics (e.g., freeze-thaw issues.)** | **Proposed Assay(s)** |
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