## SUBSTUDY SUBMISSION FORM

**Title of the Substudy:** [Short descriptive title of the substudy]

**Principal Investigator (PI) for the Substudy:** [Name, Affiliation and Contact information]

**Co-Investigators/Collaborators:** [Names, Affiliations, and Contact Information]

**Date of Submission:** [MM/DD/YYYY]

**Background and Rationale:** [Explain the significance of the substudy, the knowledge gap it aims to fill, and its relation to the main study]

**Objective of the Substudy:** [Brief description of what the substudy aims to achieve or investigate]

**Methods:** [Briefly outline the study design, statistical analyses, and any other relevant methodologies you plan to employ]

**Study Population:** [Are you proposing a subset of the main cohort or the entire cohort? Specify details.]

**Observational nature:** [Is the substudy strictly observational? Be advised that additional Ethics Committee approval and informed consent might be necessary if the substudy is not strictly observational]

**Ethical Considerations:** [Highlight any ethical concerns and how you plan to address them, including whether additional IRB/Ethics Committee approval is required]

**Expected Outcomes:** [Describe the potential results, insights, or information the substudy hopes to produce]

**Data Variables Required:**

| Variable Name | Timepoint (Baseline, Follow-up, etc.) | Reason for inclusion |
| --- | --- | --- |
|  |  |  |

**Workload:** [Describe how much extra time is asked of the local investigators for the substudy]

**Duration of the Substudy:** [Describe for how long the substudy will run]

**Potential Conflicts of Interest:** [Any financial, personal, or other relationships with other people or organizations that could inappropriately influence this research]

**Funding Source(s) for the Substudy (if applicable):** [Provide details about any external funding or grants]