Font
• Red Font: Provides instructions for the body of the section. Remove all text in red font before finalizing document.
• Blue Font: Provides suggested text or text content that may be helpful for the author(s). Remove all text in blue font before finalizing document.
• Black Font: Text that should be included. This language should be read, understood, used if possible, and changed only if necessary or if not applicable.
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[Full Protocol Title]

List the Amendment Number if applicable, or, identify as the Original Protocol.

Remove row that is not applicable.

Amendment [X] or Original Protocol

**Sponsor Name**

**PROTOCOL SUMMARY**

|  |  |
| --- | --- |
| Study Title | [Insert Full Protocol Title] |
| Original ProtocolAmendment [X]: | Remove row that is not applicable. |
| Sponsor |  [Insert address]  |
| Study Design | Provide an overview of the study design. May include description of study type, study arms, randomization scheme if applicable, etc. |
| Study Objective | Present the study objective statement. May be broken into primary and secondary. Language regarding hypothesis may be included. |
| Study Endpoint(s) | Present the study endpoints. May be separated into Primary and Secondary. Not necessary to include all secondary endpoints. May separate into Safety and Efficacy. |
| Subject Population | Describe eligible population and total expected enrollment. Include descriptions of test and control groups if applicable, and include the number in each group or ratio |
| Number of Sites | Include number of sites, and include potential for geographic distribution. Sample language: Up to XX Sites in the U.S., Europe and Asia. |
| Expected Time to Complete Enrollment  | *e.g.*, Number of months |
| Schedule of Events | Include screening, treatment, and follow up schedule |
| Additional Information | Information regarding name of CRO contracted to do monitoring, Core Lab, DSMB, CEC, etc |