**Purpose:** This template may be used to record and document information about the study.

**Responsibility:** To be used by Principal Investigator and study team members who are delegated to document information about the study.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

**Study Identification Template**

**Title:**

**Principal Investigator (PI):**

**PI Phone Number:**

**PI Email Address:**

**IRB Number:**

**Sponsor:**

**Sponsor Protocol Number:**

**IND/IDE Number:**

**Study State Date:**

**Study End Date:**

**Sponsor Contact (Protocol):**

**Sponsor Contact (Test Article):**