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| Instructions:   * The purpose of this document is to provide a structure or general guideline to help you create a concept submission for consideration. The following template is to be used as you see fit and is only a template to help guide synopsis development. * If you choose to use portions or the entire template, please remove any guiding language highlighted in grey before submission. * It is not mandated to use any of this document. |

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| Investigator-Sponsored Studies |
| Protocol Synopsis Template |
|  |

| **Item** | **Description** |
| --- | --- |
| **Study Title** |  |
| **Principal Investigator** | Name:  Telephone:  Fax:  E-mail:  Address: |
| **Co-Investigators** | *[If applicable]* |
| **Coordinating Center/s** | *[If applicable]* |
| **Date and Version** |  |
| **Rationale** | *[Provide a brief justification for the study]* |
| **Study Design** | *[Describe the overall study design e.g., double-blind, placebo-controlled, parallel design, open labelled, etc.]* |
| **Objectives & Hypothesis** | *[List all study objectives and a study hypothesis]* |
| **Endpoints** | *[Provide study endpoints]* |
| **Inclusion Criteria** | *[List all inclusion criteria]* |
| **Exclusion Criteria** | *[List all exclusion criteria]* |
| **Study Population & Enrollment** | *[State sample size and briefly describe the target population of the study]* |
| **Study Duration** | *[Describe the expected duration of the study, including enrollments, intervention and analysis]* |
| **Investigational Device / Interventional Procedure** | *[Describe any treatment procedures and any investigational devices involved]* |
| **Statistical Analysis** | *[Briefly describe analysis for all endpoints]* |
| **Publication** | *[Describe any plans for publication]* |
| **Budget Amount Request** | *[Provide the total budget amount to fund this proposed study. Add any level of detail that is currently available.]* |

Add any study flow diagrams or table of procedures, if available.

***Example #1 Flow diagram*** *(e.g., randomized controlled trial) (Credit: NIH/FDA Clinical Protocol Template)*

Prior to

Total N: Obtain informed consent. Screen potential participants by inclusion and exclusion criteria; obtain history, document.

Enrollment

Randomize

Perform baseline assessments.

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 1

Time Point

Visit 2

Study intervention

Time Point

Follow-up assessments of study endpoints and safety

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 3

Time Point

Follow-up assessments of study endpoints and safety

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 4

Time Point

**Final Assessments**

List analyses to be performed

Visit X

Time Point

***Example #2 Table of Procedures and Data Capture***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Assessment** | **Screening & Enrollment** | **Baseline** | **Pre-op** | **Intra-op** | **Post-Op** | | | **Follow-Up** |
|  |  |  |  | ***Day 0*** | ***Day 1*** | ***Day 2*** | ***Day 3*** | ***Day 30***  ***(+/- 5 Days)*** |
| Informed Consent | **X** |  |  |  |  |  |  |  |
| Inclusion/Exclusion Criteria | **X** |  |  |  |  |  |  |  |
| Demographics | **X** |  |  |  |  |  |  | **X** |
| Medical History | **X** |  |  |  |  |  |  |  |
| Physical Examination | **X** | **X** | **X** |  |  |  | **X** | **X** |
| Current Medications | **X** | **X** |  |  |  |  |  |  |
| Laboratory | **X** | **X** | **X** |  |  | **X** |  | **X** |
| Urine Analysis | **X** | **X** | **X** |  |  | **X** |  | **X** |
| Randomization |  | **X** |  |  |  |  |  |  |
| Adverse Event Assessment |  |  | **X** | **X** | **X** | **X** | **X** | **X** |