**PROTOCOL TEMPLATE: INTERVENTIONAL STUDY**

**This template can be modified for a variety of interventional study designs. Sections that are not applicable can be deleted.**

**Complete Title:**

**Short Title:**

**Drug or Device Name(s):**

**FDA IND/IDE (if applicable):**

**Sponsor:**

**Protocol Date:**

**Amendment 1 Date:**

**Amendment 2 Date:**

**Amendment 3 Date:**

**Amendment 4 Date:**

|  |
| --- |
| **Sponsor** (IND or IDE holder, if applicable) Sponsor Name Address City, State, Zip Country |
| **Study Principal Investigator** (if multicenter study with UNC PI responsible) Office Address City, ST, ZIP Phone XXX-XXX-XXXX email: XXXXX@XXX.XXX |

EXAMPLE: Protocol Signature page for Multicenter research where the PI at UNC is the overall PI.

PROTOCOL TITLE: XXXXXX

Short Title: XXXXX

Lead Investigator:

XXX XXXX, M.D.

University of North Carolina at Chapel Hill

Protocol Version: XX.XX

Version Date: XXX XX, 201X

I confirm that I have read this protocol and understand it.

Principal Investigator Name:

Principal Investigator Signature:

Date:

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# Abbreviations and Definitions of Terms

|  |  |  |
| --- | --- | --- |
|  |  | Insert and delete terms as relevant |

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| --- | --- |
| **Abbreviation** | **Definition** |
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# Protocol Synopsis

**LIMIT SYNOPSIS to no more than 2 - 3 pages. The synopsis should provide an overview of the study.**

**Keep brief and use bullet points.**

|  |  |
| --- | --- |
| **Study Title** |  |
| **Funder** | **Grant Agency, Pharmaceutical company, or Departmental funds** |
| **Clinical Phase** | **(Phase I, II, III or IV - if applicable)** |
| **Study Rationale** | **No more than ½ page** |
| **Study Objective(s)** | **Primary**   * **To determine (obtain, evaluate, verify, etc.) …**   **Secondary**   * **To determine (obtain, evaluate, verify, etc.) …** * **Etc.** |
| **Test Article(s)**  *(If Applicable)* | **Describe the study drug, device, diagnostic, diet or other intervention** |
| **Study Design** | **Overview of design. Explain the basic design such as parallel group randomized controlled trial, open-label single arm PK study, diagnostic test evaluation, etc.** |
| **Subject Population**  **key criteria for Inclusion and Exclusion:** | **Inclusion Criteria**   1. **Subjects age X – X** 2. **Include main criteria but does not need to be complete, etc.**   **Exclusion Criteria**   1. **Subjects with X or Y, etc.** |
| **Number Of Subjects** | **Total Number of Subjects** |
| **Study Duration** | **Each subject’s participation will last …**  **The entire study is expected to last….** |
| **Study Phases**  **Screening**  **Study Treatment**  **Follow-Up** | **(1) Screening: screening for eligibility and obtaining consent and (2) Intervention: study intervention/experimental treatment.** |
| **Efficacy Evaluations** | **Primary evaluation measurements that will be used to assess the efficacy of the intervention** |
| **Pharmacokinetic Evaluations** | ***(include only if applicable)*** |
| **Safety Evaluations** | **Primary measurements that will be used to assess safety** |
| **Statistical And Analytic Plan** | **Limit to discussion of analysis to primary endpoint and possibly main secondary endpoint** |
| **Data And Safety Monitoring Plan** | **Describe how is responsible for data quality management and ongoing assessment of safety: PI, independent medical monitor, internal safety committee, or DSMB** |

**1 BACKGROUND AND RATIONALE**

**(Can refer to the grant proposal.)**

* 1. **Introduction**

**Describe the setting and rationale for the study.**

* 1. **Name and Description of Investigational Product or Intervention**

**Provide the name and description of the study intervention (drug, device, diagnostic, diet, experimental psychological therapy, etc.).**

* 1. **Non-Clinical and Clinical Study Findings**

**Include information on human pharmacokinetics, and studies involving adults and children (if applicable). Include information on any known/expected risks.**

**- Potential Benefits**

**-Risk /Benefit Assessment**

**1.4 Relevant Literature and Data**

**Include literature and data that provide background for the study and established validity for scales and evaluation tools.**

1. **STUDY OBJECTIVE**

**Example: “The purpose of the study is to determine the (efficacy, pharmacokinetics, safety, etc.) of ….”**

* 1. **Primary Objective**
  2. **Secondary Objective**

1. **INVESTIGATIONAL PLAN (brief overview)**
   1. **Study Design**

**Type of design: (randomized, controlled, cross-section, parallel, open-label, etc.?)**

**Provide brief overview of the study phases:**

* **Screening/Baseline**
* **Intervention/Treatment**
* **Follow up**
* **Unscheduled Visits**
  1. **Allocation to Treatment Groups and Blinding (if applicable)**
  2. **Study Duration, Enrollment and Number of Subjects**
  3. **Study Population**

**-Inclusion and Exclusion Criteria**

1. **STUDY PROCEDURES (what will be done)**

**Provide a list of procedures, observations, measures, etc., at each study visit (such as medical history, examinations, study drug administration or other interventions).**

* 1. **Screening/Baseline Visit procedures**
  2. **Intervention/Treatment procedures (by visits)**
  3. **Follow- up procedures (by visits)**
  4. **Unscheduled visits**
  5. **Concomitant Medication documentation**
  6. **Rescue medication administration ( if applicable)**
  7. **Subject Completion/ Withdrawal procedures**
  8. **Screen failure procedures**

1. **STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)**

* **List variables that will be abstracted from medical charts**
* **Describe baseline evaluation**
* **Describe how measurements will be taken.**
* **Describe rating scales, tests, psychological tools, laboratory evaluations, etc.**
  1. **Efficacy Evaluation ( if applicable)**
  2. **Pharmacokinetic Evaluation ( if applicable)**
  3. **Safety Evaluations**

1. **STATISTICAL CONSIDERATION**

**Provide sufficient detail to permit assurance that the sample size is justified and the statistical methods are sufficient and appropriate for the research question(s).**

* 1. **Primary Endpoint**

**Ensure it serves as the basis for justification for the sample size.**

* 1. **Secondary Endpoint**

**Include evaluation of safety and tolerability (if not primary endpoint) of drug.**

**-include evaluation of adverse events**

* 1. **Statistical Methods**
* **Baseline Data**
* **Efficacy Analysis**
* **Pharmacokinetic Analysis ( if applicable)**
* **Safety Analysis**
  1. **Sample Size and Power**
  2. **Interim Analysis**
* **Include description of rules for stopping the study (if applicable) per interim efficacy or safety analyses.**

1. **STUDY INTERVENTION (drug, device or other intervention details)**

* **Description**
* **Receipt/Storage**
* **Packaging/Labeling**
* **Dosing**
* **Treatment compliance and Adherence**
* **Drug Return/Destruction**
* **Drug Accountability**

1. **STUDY INTERVENTION ADMINISTRATION(if applicable)**

* **Randomization procedures**
* **Blinding procedures**
* **Unblinding procedures**

1. **SAFETY MANAGEMENT**

**-Adverse Event/Serious Adverse Event monitoring procedures**

**- Adverse Event/Serious Adverse Event reporting procedures**

**-Medical Emergency procedures?**

**-Data Safety Monitoring Plan?**

1. **DATA COLLECTION AND MANAGMENT**

**-Monitoring Plan?**

**-Case report forms?**

**-How will confidentiality be maintained?**

1. **RECRUITMENT STRATEGY**
2. **CONSENT PROCESS**

**Describe the procedure that will be used to obtain informed consent/HIPAA authorization and assent (if applicable).**

**-Who will obtain consent/assent?**

**-Where will consent /assent process take place?**

**-How will investigator assure that subjects comprehend the nature of the study, procedures, the risks and benefits?**

1. **PLANS FOR PUBLICATION**
2. **REFERNECES**

**15 APPENDIX**

**-Study diagrams and tables**