**PROTOCOL TEMPLATE: RETROSPECTIVE DESCRIPTIVE STUDY**

**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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**1 BACKGROUND AND RATIONALE**

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

* 1. **Introduction**

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

* 1. **Potential Risks and Benefits**

**1.3 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 (outcomes, prevalence, complications) of ….”**

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

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

**Type of design: (cohort study, descriptive, case control, etc.)**

* 1. **Study Duration, Enrollment and Number of Subjects**
  2. **Study Population**

**-Inclusion and Exclusion Criteria**

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

**Describe review of existing medical records and/or use of existing biological specimens.**

* 1. **Sources**
  2. **Data elements abstracted**

1. **STATISTICAL CONSIDERATION**

**Ensure that data is coded in such a way that it can be readily analyzed and ensure that sample size will be appropriate.**

* 1. **Primary Endpoint**
  2. **Secondary Endpoint**
  3. **Statistical Methods**
  4. **Measures to Avoid Bias**
  5. **Sample Size and Power**
* **Sample size should be justified based on study objectives.**
* **If sample size is limited, determine the effective size that you can reasonably expect to detect.**

1. **DATA COLLECTION AND MANAGMENT**

**-Case report forms?**

**-How will confidentiality be maintained?**

**-Anonymization, de-identification or destruction after publication?**

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**
3. **APPENDIX**