**PROTOCOL TEMPLATE: REGISTRY\_REPOSITORY 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 NameAddressCity, State, ZipCountry |
| **Study Principal Investigator** (if multicenter study with UNC PI responsible)Office AddressCity, ST, ZIPPhone XXX-XXX-XXXXemail: 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

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| --- | --- | --- |
|  |  | 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**

**Provide background and rationale for developing a registry/repository including information about the disease or condition, the target population and the unmet need and value of the desired information /specimen for future research.**

* **Potential future use of registry/repository**
* **Any cooperating investigators or groups that will utilize the registry/repository**

**1.2 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 registry/repository is to provide a mechanism to store, data, specimens, etc. to support the conduct of future research about…..”**

* 1. **Primary Objective**
	2. **Secondary Objective**
1. **INVESTIGATIONAL PLAN (brief overview of registry/repository design )**
	1. **Description**

**Include a general description of the participating sites (if applicable), nature of the data and specimens and mechanisms for protection.**

* 1. **Data/Specimen Collection**

**Provide an overview of the methods that will be used for the data/specimen collection (database, interviews, physical examination, existing specimen sources, blood draws, biopsies, etc.)**

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

**-Inclusion and Exclusion Criteria**

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

**Data:**

* 1. **Research Data Sources: (Existing research data or prospective data collection)**
	2. **Data Collection procedures**
	3. **Data Elements to obtained**
	4. **Private Health Information (PHI) collected?**

**Specimens:**

* 1. **Collection Source**
	2. **Collection and Storage Procedures**
1. **REGISTY/REPOSITORY ADMINISTRATION**
* **Describe the overall organization and structure of the registry/repository.**
* **Policies and Procedures of how the registry/repository will be operated**
	+ **How access to the registry/repository will be granted?**
	+ **How data/specimens will be provided?**
		- **Limited data set?**
		- **With identifiers?**
1. **DATA COLLECTION AND MANAGEMENT**
* **Describe computer systems, facilities and equipment.**
* **Describe back- up and recovery plans.**
* **Describe password protection and data encryption systems**
* **Describe plan for restricting and controlling access to data**
* **Describe methods for ensuring privacy of subjects and confidentiality of data/specimens.**
* **Certificate of Confidentiality?**
1. **SPECIMEN COLLECTION AND MANAGEMENT**
* **Describe code/ID assignment to specimens**
* **Where will the specimens be stored**
* **Describe plans for controlling access to specimens and limiting use to the purposes outlined in the consent document**
1. **PROVIDING RESULTS TO SUBJECTS**

**-Describe the plans (if any) for reporting research results to subjects and results of any incidental findings that are clinically significant.**

1. **RISK ASSEMENTS/ POTENTIAL BENEFITS OF PARTICIPATION**

**-Risk/Benefit Assessment**

**-Summarize all anticipated risks and potential benefits from the study**

* **Direct and indirect benefits**
1. **SAFETY MANAGEMENT**

**-Describe monitoring and reporting for any (serious) adverse events that may occur during the collection of specimens**

1. **RECRUITMENT STRATEGY**

**-Include confidentiality statement stating all data and records generated will be kept confidential in accordance with institutional policies and HIPAA.**

**-Describe the safeguards to maintain subject confidentiality**

**12 CONSENTING PROCESS**

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

**-Study diagrams and tables**