Title of the Research Study

Protocol Number

Protocol Number

Protocol Version

Version Date

Version #

Confidentiality Statement:

# Preface

**(Remove this Preface before finalizing the study protocol)**

* Use this protocol template for an-investigator initiated repository.
* Once completed, upload your protocol in the “Basic Information” screen in the IRES IRB system.
* Enter protocol specific text in the sections that are applicable. Put “Not Applicable or N/A” for the sections that do not apply.
* When making changes, update the version number and date in the header to ensure proper version control.
* Please refer all questions regarding the use of this protocol template to hrpp@yale.edu or 203-785-4688.

**How to Use This Template**

**Green text box: provides section-specific guidance to aid in protocol writing. This entire box should be deleted prior to finalizing the protocol.**

*Blue, italicized text = example text: This text is provided to assist in protocol writing and should be modified to suit your specific protocol. Example text is not available for all sections.*

# Synopsis

|  |
| --- |
| Study Purpose Describe the main purpose of the study and the impact this research could have on the stated problem, such as money savings or quality of life improvements. Identify any health conditions and gaps in current knowledge the repository addresses. Briefly describe planned analyses or anticipated analyses that might be performed in the future, such as whole genome sequencing. |
| Primary Objective State the main purpose for establishing the repository. Indicate if this repository bank data and/or specimens for future research, for current research proposals, or both. Provide a brief overview of the types of questions the repository will be used to answer. |
| General Design Description Provide a description of your study design that is appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g., prospective/retrospective/both) and any specific study design that will be used. Describe the repository in general terms for the synopsis. Consider addressing the following:   * Describe what types of data and specimens will be collected.   + leftover clinical specimens/data only   + additional data and/or specimens obtained from subjects for repository purposes only   + describe the sources of these specimens * Will subjects be consented? * Will the repository retain subject identifiers and if so, are codes with links to identifiers used? Who retains the links? * Who is the gatekeeper of the repository? * Briefly describe how data and specimens will be shared and with whom. |
| Study Date Range and Duration State the expected duration the repository will be in existence (how long the specimens/data will be stored and maintained, if applicable). If there is no time limit, note that storage is indefinite. |
| Number of Study Sites Include the number and location of all study sites. Address if sites will house their own specimens and/or data or will there be a central repository. Provide the location of the central repository. |
| Study Population Define the study population, source of the participants, specimen sources, e.g. sputum, urine, blood, tissue, and selection rationale. Study subjects should be representative of the population of interest.  Provide a brief description of the study population (e.g., healthy/sick, children/adult, inpatient/outpatient, demographic groups), the characteristics of different study groups, if applicable, and the source of participants. Do not list inclusion/exclusion criteria here, as these will be listed in the upcoming sections. |
| Number of Participants Include the number of subject's data and/or specimens that will be collected if this is known (finite). If this is an infinite number over a long period of time, include a statement of the estimated number of specimens to be collected. Include whether the collection is a one-time collection or occurs longitudinally, over time, during clinical or other follow-up for example and for how long. |

# Abbreviations

|  |  |
| --- | --- |
| **Abbreviation** | **Explanation** |

# Glossary of Terms

|  |  |
| --- | --- |
| **Glossary** | **Explanation** |

Table of Contents

[Preface 2](#_Toc31854375)

[Synopsis 3](#_Toc31854376)

[Study Purpose 3](#_Toc31854377)

[Primary Objective 3](#_Toc31854378)

[General Design Description 3](#_Toc31854379)

[Study Date Range and Duration 3](#_Toc31854380)

[Number of Study Sites 4](#_Toc31854381)

[Study Population 4](#_Toc31854382)

[Number of Participants 4](#_Toc31854383)

[Abbreviations 5](#_Toc31854384)

[Glossary of Terms 6](#_Toc31854385)

[Protocol Revision History 9](#_Toc31854386)

[1 Statement of Compliance 10](#_Toc31854387)

[2 Background 11](#_Toc31854388)

[2.1 Background/prevalence of research topic 11](#_Toc31854389)

[3 Rationale/Significance 12](#_Toc31854390)

[3.1 Problem Statement 12](#_Toc31854391)

[3.2 Purpose of Study/Potential Impact 12](#_Toc31854392)

[3.3 Potential Risks and Benefits 12](#_Toc31854393)

[3.3.1 Potential Risks 12](#_Toc31854394)

[3.3.2 Potential Benefits 12](#_Toc31854395)

[4 Study Objectives 13](#_Toc31854396)

[4.1 Primary Objective 13](#_Toc31854397)

[5 Study Design 14](#_Toc31854398)

[5.1 General Design Description 14](#_Toc31854399)

[5.1.1 Study Date Range and Duration 14](#_Toc31854400)

[5.1.2 Number of Study Sites 14](#_Toc31854401)

[5.2 Study Population 15](#_Toc31854402)

[5.2.1 Number of Participants 15](#_Toc31854403)

[5.2.2 Eligibility Criteria/Vulnerable Populations 15](#_Toc31854404)

[6 Methods 16](#_Toc31854405)

[6.1 Study Procedures 16](#_Toc31854406)

[6.1.1 Screening 16](#_Toc31854407)

[6.1.2 Recruitment, Enrollment and Retention 16](#_Toc31854408)

[6.1.3 Removal of subjects 16](#_Toc31854409)

[7 Trial Administration 17](#_Toc31854410)

[7.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization 17](#_Toc31854411)

[7.1.1 Informed Consent or a Waiver for the Creation of a research repository or database 17](#_Toc31854412)

[7.1.2 Waiver of HIPAA authorization for the secondary research uses of identifiable private information or identifiable biospecimens 19](#_Toc31854413)

[7.2 Institutional Review Board (IRB) Review 20](#_Toc31854414)

[7.3 Subject Confidentiality 20](#_Toc31854415)

[7.4 Deviations/Unanticipated Problems 21](#_Toc31854416)

[7.5 Data Quality Assurance 22](#_Toc31854417)

[7.6 Study Records 22](#_Toc31854418)

[7.7 Access to Source 22](#_Toc31854419)

[7.8 Data or Specimen Storage/Security 22](#_Toc31854420)

[7.9 Retention of Records 23](#_Toc31854421)

[7.10 Study Monitoring 23](#_Toc31854422)

[7.11 Study Modification 23](#_Toc31854423)

[7.12 Study Discontinuation 23](#_Toc31854424)

[7.13 Study Completion 23](#_Toc31854425)

[7.14 Conflict of Interest Management Plan 23](#_Toc31854426)

[7.15 Funding Source 24](#_Toc31854427)

[7.16 Publication Plan 24](#_Toc31854428)

[8 Appendices 25](#_Toc31854429)

[9 List of Tables 26](#_Toc31854430)

**Protocol Revision History**

Include the IRB approved protocol version number and date for each revision of the protocol. All version history should remain in the table and never be deleted. The oldest IRB approved version of the protocol should be listed on the top row. The most recent IRB approved version should be listed on the bottom row.

|  |  |
| --- | --- |
| **Version Date** | **Summary of Substantial Changes** |
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|  |  |

# Statement of Compliance

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to the Common Rule at 45CFR46 (human subjects) and other applicable government regulations and Institutional research policies and procedures.

# Background

## Background/prevalence of research topic

This section should contain a background discussion of the condition to be observed.

Include:

* The name and description of the health problem that the repository will address.
* A summary of relevant research and gaps in the research literature the repository will address and the contribution of the repository in advancing the field of knowledge.
* Discussion of important literature and data that are relevant to establishing the repository.
* Explain the problem and the importance of the repository (include key supporting reference citations).
* Describe any applicable clinical, epidemiological, or public health background or context of the repository.

# Rationale/Significance

## Problem Statement

State the existing problem and main reason for establishing the repository.

## Purpose of Study/Potential Impact

Describe the main purpose of the study and the impact this research could have on the stated problem, such as money savings or quality of life improvements. Describe the main purpose of the repository, including health conditions and gaps in current knowledge the repository addresses. Include how the field of knowledge will be advanced.

## Potential Risks and Benefits

### Potential Risks

Describe potential risks (physical, psychological, distress due to study participation, social, economic, legal, issues with insurability, employability or breach of confidentiality, etc.) to subjects or others. Noting that risk may be to an individual or a class of individuals. For example, with genetic research the risks include harms to groups other than just the subjects such as stigmatization and insurability.

Discuss why the value of the information to be gained outweighs any potential risks involved and include any procedures to minimize risks. Describe how confidentiality will be protected and how this extends to repository data and/or specimens shared with research collaborators.

Address in the Study Design section how the study design and data protection plan will minimize the risks of harm. How will the operations of the repository and sharing of data and/or specimens minimize the risk of breach of confidentiality?

### Potential Benefits

Describe expected benefits to research subjects, society and/or science and their likelihood. Noting that benefits may be to an individual or a class of individuals. If there are no expected benefits, this should be stated.

Describe in detail any potential benefits to participants, science or society that the PI foresees, addressing each of the following:

* Immediate potential benefits (and likelihood)
* Long-range potential benefits (and likelihood)

# Study Objectives

## Primary Objective

State the main purpose for establishing the repository.

# Study Design

## General Design Description

Provide a description of your study design that is appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g., prospective/retrospective/both) and any specific study design that will be used. Provide more detail here as compared to the synopsis.

* What data and/or specimens will be collected, and from whom?
* Will the collection be limited to left over clinical specimens/data only or will additional data and/or specimens also be obtained from subjects for repository purposes only?
* What are the sources of the data and/or specimens and how will they be collected (medical records, subject questionnaires, pathology, physicians performing tumor biopsies, etc.)?
* Will subjects be consented?
* Will repository retain subject identifiers and if so, are codes with links to identifiers used and who retains the links?
* Who is the gatekeeper of the repository?
* Describe in detail how data and/or specimens will be shared and with whom. If NIH funded, describe plans for NIH data sharing.
* Describe types of analyses or potential analyses that will be performed on the specimens, e.g. whole genome sequencing, cell cultures, etc.

### Study Date Range and Duration

State the expected duration the repository will be in existence (how long the specimens/data will be stored and maintained, if applicable). If there is no time limit, note that storage is indefinite.

### Number of Study Sites

Include the number and location of all study sites. Indicate the following:

* Is this a single site repository or a central repository with multiple sites?
* If there are multiple sites, what data and/or specimens will be contributed to the central repository and what data and/or specimens will be housed locally at each site?
* Who is responsible for determining how data and/or specimens are shared and how is this determined?

## Study Population

Define the study population, source of the participants, and selection rationale. Study subjects should be representative of the population of interest.

Provide a brief description of the study population (e.g., healthy/sick, children/adult, inpatient/outpatient, demographic groups), the characteristics of different study groups, if applicable, and the source of participants. Do not list inclusion/exclusion criteria here, as these will be listed in the upcoming sections.

*Participants with [insert condition] of [insert level of severity] severity and [other symptoms/disease specific criteria] and/or healthy volunteers aged [insert age].*

### Number of Participants

Include the number of subject's data and/or specimens that will be collected if this is known (finite). If this is an infinite number over a long period of time, include a statement of the estimated number of specimens to be collected.

### Eligibility Criteria/Vulnerable Populations

Identify who determines eligibility, and inclusion/exclusion criteria. List only the eligibility criteria absolutely necessary for the study as a bulleted or numbered list. Describe any vulnerable populations specifically and rationale for including or excluding them from the repository.

Children, pregnant women and prisoners are considered vulnerable populations under federal regulation. Individuals with impaired decision-making capacity or economically or educationally disadvantaged persons, elderly, students, and employees are also often considered vulnerable subjects and in need of greater protection.

*In order to be eligible for inclusion in the repository, an individual must meet all of the following criteria:*

* *Male or female ≥\_\_\_ years of age at [qualifying event: i.e. visit, date or date range, etc.].*
* *Documentation of a [insert diagnosis] diagnosis as evidenced by one or more clinical features consistent with the [insert phenotype] phenotype and one or more of the following criteria:*
  + *[insert criteria]*

*Any individual who meets any of the following criteria will be excluded from participation in this study:*

* *Documented history of [insert pre-existing conditions]*
* *Documented [insert diagnosis]*
* *Concomitant use of another medication [insert diagnosis being treated*

# Methods

## Study Procedures

Explain in detail the procedures for recruiting subjects, obtaining informed consent and collecting data and/or specimens. Describe how the investigators intend to:

1. Use or disclose PHI (data and/or specimens) to create a research database or repository, and
2. Subsequently use or disclose PHI (data and/or specimens) in the database for a particular research protocol.

### Screening

Describe the screening process including who will perform screening procedures. Include specific procedures to be completed and timeframe.

### Recruitment, Enrollment and Retention

This section must address the strategies for Recruitment and Retention including:

* How potential subjects will be identified
* Approaching subjects about participation
* Who will enroll subjects in the repository
* How the process will take place, including obtaining consent prior to collecting data and/or specimens.
* Use of third parties (call centers/centralized screening centers), e.g. use of JDAT to screen for potential subjects.

**Upload appendices or attachments** to this protocol as supporting documents in IRES IRB (letters, telephone scripts, in person introduction scripts, advertisements, emails, letters to the patient's physician or other healthcare provider known to the patient, etc.).

### Removal of subjects

State criteria, procedures and documentation instructions for withdrawing a subject from the study. Note that subjects may withdraw voluntarily at any time for any reason.

For repository studies this should include procedures for return or disregarding of any remaining specimens and/or data should a subject choose to withdraw from the study.

# Trial Administration

## Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

*To create the repository informed consent and HIPAA authorization or a waiver of informed consent and HIPAA authorization are required. In the sections below describe process of obtaining consent/assent and HIPAA authorization from subjects.*

### Informed Consent or a Waiver for the Creation of a research repository or database

**Example ethical or scientific rationales to justify the practicability standard referenced above in bullet (ii) could include:**

* Scientific validity would be compromised if consent were required because it would introduce bias to the sample selection by limiting the review to those individuals who consented to use of their data or samples when researchers may need to understand the experience of all experienced what is under study.
  + For example, a study assessing flu outbreaks and its relationship to vaccination rates needs to understand the health and vaccination status of all individuals in a region.
  + For example, a data repository aims to collect data about individuals who survive a ruptured Abdominal Aortic Aneurysm (AAA ) and those who do not and compare risk and protective factors for death. The individuals who do not survive obviously are unable to provide consent and consenting only survivors would render the study invalid. This study could not be done without obtaining a waiver of consent.
* The consent procedure would itself create additional threats to privacy that would otherwise not exist, by identifying an individual as having or experiencing what is being studied by virtue of their signature on a consent form identifying the condition or event.
* There is risk of inflicting significant psychological, social or other harm by contacting individuals or families
* Finally, once the IRB has determined that the waiver or alteration does not adversely impact the ethical nature or scientific rigor of the research, logistical issues (e.g. cost, convenience, speed) may be considered

Note: a request for a waiver of HIPAA authorization will also need to be requested and granted for prospective observational studies involving PHI.

Describe whether informed consent and HIPAA authorization will be obtained, or a waiver of informed consent and/or HIPAA authorization will be requested.

**If informed consent/assent and HIPAA authorization will be obtained, the following should be addressed:**

* Who will obtain consent/authorization
* When and where will the consent/authorization discussion occur
* How will subject privacy be assured
* How will consent/authorization be documented
* How will subject understanding of the study be assessed
* What steps are in place to avoid subject coercion

**If a Wavier of Informed Consent will be obtained, the following criteria from 45 CFR 46.116 (f)(3) must be met for the IRB to waive consent:**

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

If your study involves children, additional information should be provided to describe:

* How parental permission will be obtained
* From how many parents will parental permission be obtained
* Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided
* Whether or not assent will be obtained from the child
* How will assent be documented
* Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects
* If requesting waiver of parental consent, provide a compelling rationale for why it is not practicable to consent parents.

### Waiver of HIPAA authorization for the secondary research uses of identifiable private information or identifiable biospecimens

There are two separate activities to consider: (1) The use or disclosure of PHI for creating a research database or repository and (2) The subsequent use or disclosure of PHI in the database for a particular research protocol.

A covered entity's use or disclosure of PHI to create a research database or repository, and use or disclosure of PHI from the database or repository for a future research purpose, are each considered a separate research activity under the Privacy Rule. In general, the Privacy Rule requires Authorization for each activity, unless, for example, an IRB or Privacy Board waives or alters the Authorization requirement.

A covered entity also could use or disclose a limited data set to create a research repository or database under conditions set forth in a data use agreement. If a Waiver of HIPAA Authorization needs to be obtained, the following elements from 45 CFR 164.512 (i) (1) (i) must be met for the IRB to waive the requirement:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

* An adequate plan to protect the identifiers from improper use and disclosure
* An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
* Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart
* The research could not practicably be conducted without the waiver or alteration
* The research could not practicably be conducted without access to and use of the protected health information.

**Example ethical or scientific rationales to justify the practicability standard referenced above could include:**

* Scientific validity would be compromised if authorization were required because it would introduce bias to the sample selection by limiting the review to those individuals who consented to use of their data when researchers may need to understand the experience of all experienced what is under study.
  + For example, a study assessing flu outbreaks and its relationship to vaccination rates needs to understand the health and vaccination status of all individuals in a region.
* There is risk of inflicting significant psychological, social or other harm by contacting individuals or families
* Finally, once the IRB has determined that the waiver or alteration does not adversely impact the ethical nature or scientific rigor of the research, logistical issues (e.g. cost, convenience, speed) may be considered

## Institutional Review Board (IRB) Review

Provide a statement in regard to the study being approved by the IRB. Document how the IRB will be notified of the following:

* Protocol modifications
* Reportable events & Unanticipated problems

*The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol or study team will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.*

*A study closure report will be submitted to the IRB after all research activities have been completed.*

## Subject Confidentiality

This section should describe provisions in place to maintain subject confidentiality and should include the following:

* Specify who will have access to the repository data and/or specimens and for what purposes
* Describe how and where repository data (both paper and electronic) will be stored and secured (e.g., in a locked cabinet in PI's office, RedCap, MCIT-managed network drive…)
* Specify all identifiers that will be temporarily accessed/reviewed.
* Indicate if identifiers will be recorded for research purposes.
* Describe measures for minimizing risks to subjects and/or potential breach of confidentiality
* If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens
* List the information that will be stored with each specimen, including how specimens are labeled/coded
* Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.

*Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s)/funding agency. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval.*

*All research activities will be conducted in as private a setting as possible.*

*Representatives of the Institutional Review Board (IRB), regulatory agencies or study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.*

*The study participant's contact information will be securely stored at each study site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, regulatory, or sponsor/funding agency requirements.*

*Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the [insert location]. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number.*

*The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the [insert location]. All data will be transferred and stored on encrypted devices.*

## Deviations/Unanticipated Problems

*A protocol deviation is any noncompliance with the protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.*

Describe how the study team will monitor for and report unanticipated study problems to oversight bodies, including the IRB. The most common type of unanticipated problem in a repository study is a confidentiality breach or loss of samples.

This section should also address how Protocol Deviations will be managed during the study including plans for detecting, reviewing, and reporting deviations from the protocol.

*It is the responsibility of the site investigator to identify and report deviations within [specify number] working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.*

*Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:*

* *Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;*
* *Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and*
* *Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*

*If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by [insert mechanism].*

*The UP report will include the following information:*

* *Protocol identifying information: protocol title and number, PI's name, and the IRB project number;*
* *A detailed description of the event, incident, experience, or outcome;*
* *An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;*
* *A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.*

*To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:*

* *UPs will be reported to the IRB within <insert timeline in accordance with policy> of the investigator becoming aware of the event.*

## Data Quality Assurance

Describe the quality control and assurance for the conduct of the study to ensure that Good Clinical Practice is followed. Any steps that will be implemented as part of the study to ensure standardization of the collection of accurate, consistent, complete and reliable data, such as training sessions, monitoring of investigator sites, instruction manuals, use of central laboratory or reading center should be included.

## Study Records

Specify the documents considered study records (regulatory documents, protocols, consents forms, case report forms, subject medical records, surveys, etc.).

## Access to Source

Describe the format and the place where source documents and/or source specimens (e.g. electronic medical record, private practice office notes, lab samples) and case report forms (data collection tools) will be maintained. Define who will be responsible for maintaining the records and who will be authorized to access source documents.

## Data or Specimen Storage/Security

Describe method in which data/specimens will be collected, labeled, stored (digital, hard copy, etc.) and maintained in a secure manner (encryption, password protection, locked facility etc.).

Describe who will have access to stored data and/or specimens.

Explain procedures for handling or destroying data and or specimens at the end of the study and any plans for de-linking, coding, or de-identifying collected information.

## Retention of Records

Specify how long the study records will be retained. If permission is needed to move or destroy the records, identify the person who will need to be contacted (investigator, sponsor, etc.).

## Study Monitoring

Specify who will monitor the study (third party, sponsor, internal team, etc.), where monitoring will occur and frequency. Describe any related responsibilities and identify anyone who will review the study for accuracy and how often.

* Who is the gatekeeper of the repository?
* Where is the repository housed?
* Who will decide about secondary release of data and/or specimens for research purposes?

## Study Modification

Describe how any study modifications will be handled.

## Study Discontinuation

Explain the circumstances under which the study may be discontinued.

## Study Completion

Discuss whether there is an anticipated study completion date and instructions for notifying IRB. If there is no anticipated completion date, state so.

## Conflict of Interest Management Plan

This section should include a description of how the study will manage actual or perceived conflicts of interest.

*The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.*

*All investigators will follow the applicable conflict of interest policies.*

## Funding Source

Explain how the study will be funded but do not include specific dollar amounts.

*Salary support for this study is provided by [institution and department].*

## Publication Plan

Describe any plans for publication and presentation

Note that the inclusion of illustrative cases in such reports may result in disclosure of identifiable information. Consider this eventuality.

Describe the requirements and publication policy (of the sponsor, department, university, etc.) and specify who holds primary responsibility for publishing the study results.

# Appendices

|  |  |  |  |
| --- | --- | --- | --- |
| **Appendix #** | **Title** | **Section** | **Topic** |

# List of Tables