**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 observational study of an individual or a group.
* 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

|  |
| --- |
| 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. Briefly describe planned analyses or anticipated analyses that might be performed in the future, such as whole genome sequencing. |
| Primary Objective The primary objective is the main question. It should be the driver of the statistical or data analysis for the study.  State the main purpose for performing the study. It should be clear, detailed but limited in scope. Keep in mind the primary objective will help determine the sample size.  *The primary objective of this study is to determine whether the [insert intervention] reduces, increases, etc. outcome measure [insert outcome measure] in population [insert population description].* |
| Secondary Objective Secondary objectives are goals that will provide further information on the focus of the study.  Identify any secondary objectives, which may or may not be hypothesis driven or dependent on the primary objective.  *The secondary objective[s] of this study is [are] to [insert goal: determine, describe, understand, etc.] whether the [insert exposure, presenting sign, comorbidity, treatment option] reduces, increases, etc. outcome measure [insert outcome measure].* |
| Study Design Provide a summary description of your study design that is appropriate to answer the research question(s) under study. Describe the type of research proposed and specific study design that will be used.  Describe if your study is prospective or retrospective; research, conducted in established or commonly accepted educational settings or research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).  Do not put the details of the entire study into this Section. |
| Study Date Range and Duration State the expected length of the study from recruitment to any follow-up.  For observations of public behavior or instructional techniques state the date when observation will begin and for how long. |
| Number of Study Sites Include the number and location of all study sites. |
| Primary Outcome Variables Explain the variables that will used to assess the primary objective. They should be precise, accurate and reliable. Include any rationale. |
| Secondary and Exploratory Outcome Variables (if applicable) Explain the endpoints that will used to assess any secondary objectives. They should be precise, accurate and reliable. Include the rationale. |
| **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 How many subjects will be enrolled? What's the rationale for the number? |
| Study Schedule Specify total number of expected visits, including consent and screening, on study visits and follow-up. If possible, provide a reasonable time estimate for each visit. |

**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** |
|  |  |
|  |  |
|  |  |

# 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.

# Abbreviations

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

# Glossary of Terms

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

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# Background/Literature Review

## Background

**Guide**

This section should contain a background discussion of what is to be observed.

Include:

The name and description of what the study will observe

A summary of relevant research and gaps in the research literature

Discussion of important literature and data that are relevant to the study, explain the problem and the importance of the study (include key supporting reference citations)

## Prior Experience (if applicable)

**Guide**

Summarize previous experience, including any information about the study and data from prior studies.

# Rationale/Significance

## Rationale and Study Significance

**Guide**

* Describe why this research makes sense for this patient population or why the information is needed.
* Describe the significance of the research including potential benefit for individual subjects or society at large.
* Discuss how public health and social welfare might be enhanced.
* Discuss any relevant treatment issues or controversies

## Purpose of Study/Potential Impact

**Guide**

* Describe the main purpose of the study and the impact this research could have, such as collection of additional safety information, cost analysis or quality of life improvements.

## Potential Risks and Benefits

### Potential Risks

All studies have at least some risk, even if it is not greater than minimal.

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 Include any procedures to minimize risks.

Include a discussion of known potential risks, e.g. risk of breach of confidentiality. Relevant published literature can provide relevant risk information. Describe in detail any psychological, social, legal, economic, or any other risks to participants by virtue of participation in the study that the PI foresees, addressing each of the following:

* Immediate risks
* Long-range risks
* Rationale for the necessity of exposing human participants to such risks
* Why the value of the information to be gained outweighs the risks involved

Address in the Study Design section how the study design and data protection plan will minimize the risks of harm. If the study involves normal educational practices discuss whether the study would or would not be likely to adversely impact students' opportunity to learn required educational content or the assessment of the educators who provide instruction.

### 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 to an individual participant, this should be stated.

Address each of the following:

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

# Study Purpose and Objectives

## Hypothesis

Include a clearly defined hypothesis, if relevant, and list the key questions the study is expected to answer. Be detailed, clear and as specific as possible.

## Primary Objective

The primary objective is the main question. It should be the driver of the statistical or data analysis for the study.

State the main purpose for performing the study. It should be clear, detailed but limited in scope. Keep in mind the primary objective will help determine the sample size.

*The primary objective of this study is to determine whether the [insert intervention] reduces, increases, etc. outcome measure [insert outcome measure] in population [insert population description].*

## Secondary Objective (if applicable)

Secondary objectives are goals that will provide further information on the focus of the study.

Identify any secondary objectives, which may or may not be hypothesis driven or dependent on the primary objective.

*The secondary objective[s] of this study is [are] to [insert goal: determine, describe, understand, etc.] whether the [insert exposure, presenting sign, comorbidity, treatment option] reduces, increases, etc. outcome measure [insert outcome measure].*

# 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 and specific study design that will be used.

Describe if your study is prospective or retrospective; research, conducted in established or commonly accepted educational settings or research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

### Study Date Range and Duration

State the expected length of the study from recruitment to any follow-up.

For observations of public behavior or instructional techniques state the date when observation will begin and for how long.

### Number of Study Sites

Include the number and location of all study sites.

## Outcome Variables

### Primary Outcome Variables

Explain the variables that will used to assess the primary objective. They should be precise, accurate and reliable. Include any rationale.

### Secondary and Exploratory Outcome Variables (if applicable)

Explain the endpoints that will used to assess any secondary objectives. They should be precise, accurate and reliable. Include the rationale.

## 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, inpatient/outpatient, demographic groups, adult/children), 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 people that will be screened and the number of participants that will be selected. For multi-center protocols, identify both overall total for study and numbers for each site

### 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 study.

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.

If the study intends to enroll children, pregnant women, prisoners, or other vulnerable populations, refer to applicable section of 45 CFR Part 46 Subpart B — Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research (45 CFR Part 46.201-46.207); Subpart C — Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (45 CFR Part 46.301-46.306); Subpart D — Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46.401-46.409).

*In order to be eligible for inclusion in the study, 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.].</li><li>*

*• Documentation of a [insert condition] as evidenced by one or more features consistent with the [insert phenotype] phenotype and one or more of the following criteria:<ul><li>*

*o [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 condition]*

1. **Study Methods/Procedures**

## Study Procedures

Investigators are required to perform research as written in the protocol, so this section should be written carefully to minimize deviations.

• Identify all procedures performed exclusively for research purposes and those that would occur regardless of the research (i.e. standard of care).

• Include Study Schedule listing study procedures (visit by visit) with timing intervals to provide a summary for study team.

• Explain in detail the procedures for recruiting subjects, obtaining informed consent and collecting data and specimens.

### Data Collection

Describe how and where the data will be recorded and identify all sources of data. This description should be specific but not over-detailed. However, you must make sure that data collected supports the objectives and endpoints stated above. Indicate whether:

• The information obtained will be recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; OR

• If any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

• If the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Specify any assessments being used including methods and timing for assessing, recording and analysis.

Include any questionnaire administration and identify the questionnaire to be used for the study related assessment. State how these assessments contribute to the overall study aims. Include as appendices copies of each questionnaire.

### Adverse Events Definition and Reporting

Specify how adverse events will be defined and assessed for causality, graded for severity and reported to the IRB.

## Study Schedule

Specify total number of expected visits, including consent and screening, on study visits and follow-up. If possible, provide a reasonable time estimate for each visit.

## Informed Consent

If Informed Consent will be obtained confirm that provisions are in place for seeking IRB-approved informed consent of participants or legally authorized representatives (LAR), and that the process will minimize undue influence or coercion and offer sufficient time for review. If a waiver of informed consent is being requested indicate that here as well.

*Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol:*

*• [insert list]*

### Screening (if applicable)

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

### Recruitment, Enrollment and Retention (if applicable)

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 study
* How will the process take place, including obtaining consent in relation to the start of the study procedures
* Use of third parties (call centers/centralized screening centers)

Include as appendices or attachments to this protocol any documents that will be used (letters, telephone scripts, in person introduction scripts, advertisements, emails, letters to the patient's physician or other healthcare provider known to the patient, etc.)

### Study Visits (is applicable)

Describe what study procedures will be conducted during each study visit as a bulleted itemized list. Include timing and approximate length of the visits.

## Statistical Method

### Statistical Design

This section defines the statistical approach to the study. Consult a biostatistician for assistance if needed.

Provide the overall statistical approach to the data analysis. If the study is purely descriptive in nature, state that the data will be summarized in descriptive measures.

If applicable, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g., specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.

Include any adjustments that will be made for confounding variables.

### Sample Size Considerations

Describe the statistical methods for determining the sample size and power calculations for the study.

### Planned Analyses

Explain how data will be analyzed to evaluate the stated study objective.

### Analysis of Subject Characteristics (if applicable)

Specify descriptive analysis to define subject population(s).

### Interim Analysis (if applicable)

If an interim analysis will be done, explain the rationale, timing, and impact to the study. Include any stopping rules that would determine if the study should be discontinued.

### Handling of Missing Data

Describe how missing outcome data will be handled in regards to analysis.

# Trial Administration

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

This section should include any applicable ethical considerations. They should also be addressed in the Informed Consent form, including if informed consent and/or HIPAA authorization will be obtained or a waiver of informed consent and/or HIPAA authorization will be requested. The Informed Consent form should be included as an attachment to the protocol.

Describe the following:

* Any possible deception
* Rationale if payment will be provided for participation.
* Any sensitive data that may be collected and how it will be protected.
* Any possibility that a previously unknown condition (disease, genetic disposition, etc.) will be discovered as the result of the study procedures and how this will be handled.
* Any information that may be added to the subject's permanent medical records with rationale.
* 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 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.

*Consent forms will be Institutional Review Board (IRB)-approved and the participant/legally authorized representative (LAR) will be asked to read and review the document. The [list who] will explain the research study to the participant and answer any questions that may arise. This conversation will take place in a private room.*

*Participants/LAR will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants/LAR should have the opportunity to discuss the study with their family or surrogates, or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants/LAR must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants/LAR for their records*

**Additional text if applicable:**

*<Assent [will/will not] be conducted. A verbal explanation will be provided in terms suited to the participant’s comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants.*

## 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

• Study team updates

• Reportable events

• Unanticipated problems

Indicate whether the study is prospective or retrospective research, conducted in established or commonly accepted educational settings or research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

*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 determine 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

State the provisions to protect the privacy of participants. This may be institution or sponsor specific. This section should describe provisions in place to maintain subject confidentiality and should include the following:

• Who will have access to the study data and for what purposes

• Where data will be stored

• Specify who will have access to study data

• 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

• Describe how study data (both paper and electronic) will be stored (e.g., in a locked cabinet in PI's office, RedCap, managed network drive…)

• How data will be secured.

*Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. 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 of the sponsor.*

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

*The study monitor, representatives of the Institutional Review Board (IRB), or regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the participants in this study. The clinical study site will permit access to such records.*

*The study participant's contact information will be securely stored at each clinical 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, or, if applicable, sponsor 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].*

## Deviations/Unanticipated Problems

The reporting of UPs applies to non-exempt human subjects research conducted or supported by HHS. Provide the definition of an UP being used for this clinical trial. An incident, experience, or outcome that meets the definition of an UP generally will warrant consideration of changes to the protocol or consent in order to protect the safety, welfare, or rights of participants or others. Other UPs may warrant corrective actions at a specific study site. Examples of corrective actions or changes that might need to be considered in response to an UP include:

• Modification of inclusion or exclusion criteria to mitigate the newly identified risks

• Implementation of additional safety monitoring procedures

• Suspension of enrollment of new participants or halting of study procedures for enrolled participants

• Modification of informed consent documents to include a description of newly recognized risks

• Provision of additional information about newly recognized risks to previously enrolled participants.

Describe the UP reporting procedures, including timeframes. Further details should be included in a SOP including a description and a flow chart of when events are reported to various oversight (e.g., DSMB, safety monitoring committee, independent safety monitor) and regulatory groups, and what study staff are responsible for completing and signing off on the UP report forms.

Institutions engaged in human subjects research conducted or supported by Department of Health and Human Services (DHHS) must have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and any supporting department or agency head of any unanticipated problem involving risks to subjects or others. Furthermore, for research covered by an assurance approved for federal wide use by OHRP, DHHS regulations require that institutions promptly report any unanticipated problems to OHRP.

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.

*A protocol deviation is any noncompliance with the study 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.*

*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.*

*The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB) and to the study sponsor. 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 that are serious adverse events (SAEs) will be reported to the IRB and study sponsor, if applicable within [insert timeline in accordance with of the investigator becoming aware of the event.*
        + *Any other UP will be reported to the IRB and study sponsor within [insert timeline in accordance with policy] of the investigator becoming aware of the problem.*
        + *All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within & [insert timeline in accordance with policy] of the IRB's receipt of the report of the problem from the investigator.*

## 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 (subject diaries, regulatory documents, protocols, consents forms, case report forms, subject medical records, surveys, specimens, etc.).

## Access to Source

Describe the source documents and how data will be collected from them and incorporated into the database. Specify who will have access and how it may be transferred to any collaborators.

*Source data will be maintained per Medical Records policy in a password protected, secure, Health Insurance Portability and Accountability Act (HIPAA) compliant, web-based electronic database with a built-in audit trail.*

*Only Institutional Review Board (IRB) approved research team members who have current HIPAA and Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (GCP) and human subjects protection training will be authorized to access records.*

## Data or Specimen Storage/Security

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

## 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.). Describe when the master list linking the unique subject number to the research data will be destroyed.

## 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.

## Study Modification

Describe how any study modifications will be handled. State how and when the protocol will be updated and when the change will be implemented into the study.

## Study Completion

State the completion date of the study and specific instructions for notifying IRB.

## 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].*

## Conflict of Interest Policy

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.*

*Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the [specify committee] with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All investigators will follow the applicable conflict of interest policies.*

## 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