Please note that instructions are in blue text and are only to assist you in creating your protocol. Once you've finished creating your protocol, please delete all blue text and update your Table of Contents.

IF NOT A SPONSORED STUDY OF AN INVESTIGATIONAL DRUG OR DEVICE, DELETE ROWS FROM THE CHART BELOW THAT ARE NOT APPLICABLE

Clinical Research Protocol

Protocol Name:	
Protocol Number:	
Protocol Version Number:	
Protocol Date:	
Investigational Product: *(if not applicable, please delete this row)*	
IND/IDE Number: *(if not applicable, please delete this row)*	
Development Phase: *(if not applicable, please delete this row)*	
Sponsor:	Name (please note – for investigator-initiated studies, the sponsor is the Investigator) Address: City, State: Telephone: Fax: E-mail:
Principal Investigator:	Name: Telephone: Fax: E-mail:
Medical Monitor: *(if not applicable, please delete this row)*	Name: Telephone: Fax: E-mail:
CRO: *(if not applicable, please delete this row)*	*Name (please note – for academic studies, the sponsor is the Investigator, not the funding agency.)* *Address* *City, State*

PROTOCOL AGREEMENT

I have read the protocol specified below. In my formal capacity as Principal Investigator, my duties include ensuring the safety of the study subjects enrolled under my supervision and providing the Sponsor with complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in a manner consistent with accepted GCP principles and to abide by the terms of this protocol.

Protocol Title: *Title*

Protocol Version Number: *Number*

Protocol Date: *Date*

_____ _____

Investigator Signature Date

_____

Print Name and Title

TABLE OF CONTENTS

1 LIST OF ABBREVIATIONS

Add all other abbreviations referenced in the protocol and delete any not referenced in the protocol. Please sort into alphabetical order.

AE	Adverse Event
CFR	Code of Federal Regulations
CRF	Case Report Form
DMC	Data Monitoring Committee
DSMB	Data Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
OHRP	Office of Human Research Protections
PHS	Public Health Service
PI	Principal Investigator
SAE	Serious Adverse Event
UADE	Unanticipated Device Effect
UPIRSO	Unanticipated Problem Involving Risks to Subjects or Others (a.k.a. Unanticipated Problem)

2 PROTOCOL SYNOPSIS

Provide a brief 1-2 page synopsis of the study, including the design, objective, test products used, etc.

TITLE	
SPONSOR	
RATIONALE	*This should be a very brief – 1-2 paragraphs - highlighting the rational and clinical need(s) for the proposed research.*
STUDY DESIGN	*In 1-2 sentences, describe the general study design. For example, "This is a randomized, double-blind, placebo-controlled phase 2 study…."*
PRIMARY OBJECTIVE	*Summarize the primary study objectives. Note this is not the specific endpoints to be detailed later.*
SECONDARY OBJECTIVES	*Summarize the secondary study objectives. Note this is not the specific endpoints to be detailed later.*
NUMBER OF SITES	*Provide the total number of research sites where this study will be conducted.*
NUMBER OF SUBJECTS	*Provide the total number of subjects to be included in this study.*
SUBJECT SELECTION CRITERIA	Inclusion Criteria: • Exclusion Criteria: •
INVESTIGATIONAL ARM	*Provide a brief summary of what is being investigated in the experimental arm. For drugs/devices, provide the test article, dose/frequency, route of administration, etc.*
CONTROL ARM	*Provide a brief summary of what is being used in the control arm.*
DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	*Provide a summary of the:* • *Duration of time each subject will participate in the study* • *Well the overall duration of the entire study. Delineate this as the expected time for recruiting/enrollment, active participation, long-term follow up, etc.*
PRIMARY ENDPOINT(S)	• *List the specific endpoints that will be used to assess the study outcomes*

SECONDARY ENDPOINT(S)	• *List the specific endpoints that will be used to assess the study outcomes*
SAFETY EVALUATIONS	*List the measures/metrics that will be used to monitor the safety of subjects participating in the study.*
PLANNED INTERIM ANALYSES *(if not applicable, please delete this row)*	*Fill in the details of the data-monitoring plan, data monitoring committees and/or safety plans, and the specifics of any planned interim analyses to assess for efficacy, futility, safety, etc.* ***Example: When approximately 50% of patients have completed the study through Visit X, an interim analysis for safety will be conducted by an independent data monitoring committee consisting of XX with expertise in… (clinical, statistical, etc.) Serious adverse events will be monitored by the committee on an ongoing basis throughout the study.***
STATISTICS **Primary Analysis Plan**	*Describe plan for analyzing the primary endpoint.*
Rationale for Number of Subjects	*Describe the scientific basis for including the proposed number of subjects in the study.*

Please use the following template protocol sections below to document your research protocol and study plan, bearing in mind that no single protocol template will suit every clinical research study protocol. This is intended to serve as a general framework to help guide development of your protocol in sufficient detail for the IRB to make a determination and for the research to be conducted without errors or safety concerns. Feel free to modify this template as needed to clearly explain your study. If a particular section, or specific subsection, is not applicable to your study, then it may be deleted. Similarly, if you would like to add additional sections or sub-sections to better describe the research protocol, then feel free to do so. If you add or delete sections:

1. ***Please use the Heading 1, 2 and 3 styles above to place your additions as new sections, subsections, or sub-subsections, respectively. This will ensure that all new sections are properly numbered and appear in the Table of Contents.***

2. ***Please remember to re-generate the Table of Contents so that the all of the protocol sections are present and the page numbers are correct in the Table. This greatly facilitates efficient protocol review by the IRB. You can update the Table of Contents by clicking on the "Reference" tab above in the ribbon above, and on the left side near "Table of Contents", click on "Update Table". If you need assistance, please contact the Office of Research at 512-544-5478.***

Reminder: Be as complete and detailed in the description of your protocol. It is imperative that the Board have the most complete understanding of the research possible, otherwise there may be delays in the review process while the Board gathers the additional information requested.

3 BACKGROUND

Identify the product (drug, device) or clinical question to be studied, and describe it briefly. If applicable, provide a brief summary of any pre-clinical data (e.g. animal or lab data) that have clinical significance to your study. Similarly, provide a brief summary of any clinical data that are relevant to your study. For investigations involving approved products, summarize the product, approved indications, etc.

4 STUDY RATIONALE

Describe why it makes sense to study this product in this patient population or in the event of an observational study and why the information is needed.

4.1 Risk / Benefit Assessment

If applicable, describe how the specific risks of the product will be mitigated in the study and why the potential benefits outweigh the risks.

5 STUDY DESIGN

5.1 Study Overview

Insert a very short description of the study. For example:

This study is a multicenter, outpatient, double-blind, active placebo-controlled study with equal-sized strata based on mean of XXX and on pre-study YYY. Approximately 1200 patients will be randomized to 1 of 3 treatment groups: (1) AAA; (2) BBB; or (3) CCC. Subject will followed for one-year (12 months) with primary endpoints being mortality and 30-day hospital readmissions.

6 CRITERIA FOR EVALUATION

6.1 Primary Efficacy Endpoint

Detail the primary endpoint(s) - generally whatever data points the study was powered on. If necessary, include a brief statement about why the endpoint is appropriate. Include the time course for which the endpoint will be assessed (i.e. from baseline to end of treatment)

6.2 Secondary Efficacy Endpoints

Detail all secondary efficacy endpoints (ditto on why endpoints are appropriate). If there are no secondary endpoints, then delete this section.

6.3 Safety Evaluations

Enter the specific data and measures used to evaluate the safety of the subjects in this study. For drug/device studies, these may include specific clinical measures (labs, radiation dose, disease progression, etc.). Other safety data may include incidence of outcomes such as death, adverse events, etc.

6.4 Other Evaluations

Please detail any other research endpoints that may be used to evaluate the study. Other endpoints may include items such as PK analyses, subject feedback, etc.

7 SUBJECT SELECTION

7.1 Study Population

Describe the specific clinical population to be studied.

7.2 Inclusion Criteria

Describe the specific criteria to evaluate patients for inclusion in the study. This is usually provided as a numbered list.

7.3 Exclusion Criteria

Describe the specific criteria to evaluate patients for exclusion from the study. This is usually provided as a numbered list.

8 CONCURRENT MEDICATIONS

If necessary, document how your study will impact the medication management for patients. Provide details on any allowed or prohibited medications and/or treatments, as necessary.

9 STUDY TREATMENTS

9.1 Method of Assigning Subjects to Treatment Groups

Describe the randomization scheme, its rationale, and the procedures used to assure randomization (e.g. a database, Excel table, or drawing straws).

9.2 Blinding

If applicable, describe the procedures that will be used to blind subjects and/or research staff, and the controls to be put in place to maintain blinding throughout your study. Additionally, provide details about under what situations and how the blind may be broken to assure subject safety. Delete this section if your study does not incorporate blinding.

9.3 Formulation of Test and Control Products

For drug studies, use this section to identify the study drug product, both active and placebo or comparator. Provide as much detail as possible about the manufacturer, and specify the formulation of the test article and placebo or comparator, etc. If drug must be reconstituted or otherwise prepared, then provide those details here.

9.3.1 Formulation of Test Product

Identify the active study drug product, manufacturer; specify the formulation of the test article. If drug must be reconstituted or otherwise prepared indicate in this section.

9.3.2 Formulation of Control Product

Identify the placebo or comparator, manufacturer; specify the formulation of the placebo or comparator. If drug must be reconstituted or otherwise prepared indicate in this section.

9.3.3 Packaging and Labeling

This section should describe how the drug will be packaged and labeled and by whom. This section should also describe how labeling will maintain blinding for blinded studies. A label mock-up may be inserted here, if that will help clarify.

Packaging example: Study drug is supplied in cartons containing 32 single use ampules. The ampules will be packaged in sets of 4 enclosed within a laminated foil pouch. Eight pouches will be contained in each carton (1 extra pouch containing 4 ampules in the event of breakage).

Labeling example: Each carton (kit) of study drug will be labeled with the required FDA warning statement, the protocol number, a treatment number, the name of the sponsors, and directions for patient use and storage. Each ampule will be labeled with XXX and XXX.

9.4 Supply of Study Drug or Device at the Site

Describe when and how medication will be supplied to the site. Detail where the study drug will reside, how it will be dispensed, and procedures to maintain supplies over the course of the study. For example:

The Sponsor (or designee) will ship Study Drug to the investigational sites. The initial study drug shipment will be shipped after site activation (i.e., all required regulatory documentation has been received by the Sponsor and a contract has been executed). Subsequent study drug shipments will be made after site request for resupply.

9.4.1 Dosage/Dosage Regimen

This section should contain information of the doses to be tested, dosing schedule, the route of administration, optimal timing between doses, adjustments for weight, age, meals, and other pertinent information, and the treatment period(s).

9.4.2 Dispensing

This section should describe who has authority to dispense the drug (investigator, pharmacist, etc.) and any other significant dispensing requirements.

9.4.3 Administration Instructions

Include step-by-step instructions including order of other medications, chest physiotherapy, etc. Include how the subject should administer the study drug and/or how the study site should administer the study drug.

9.5 Supply of Study Drug/Device at the Site

Describe when and how study drug/device will be supplied to the site. Also if subjects who are randomized but withdraw from the study prior to treatment will be replaced describe how replacement kits will be provided.

9.5.1 Storage

Describe study drug storage conditions: temperature, light, moisture, etc. Note how the drug is to be stored in a secure location [such as the drug will be stored in the site pharmacy (or state other locations)].

9.6 Study Drug Accountability

Describe how an accurate and current accounting of the dispensing and return of study drug for each subject will be maintained.

9.7 Measures of Treatment Compliance

Indicate how subject compliance will be monitored.

10 STUDY PROCEDURES AND GUIDELINES

An example Schedule of Events is supplied in Appendix 1. You may use/modify this as necessary to create an overview of all study procedures to be performed on subjects during their participation in the study.

10.1.1 Screening/Recruiting

Do not delete the following paragraph:

Prior to conducting any study-related activities, written informed consent and the Health Insurance Portability and Accountability Act (HIPAA) authorization must be signed and dated by the subject or subject's legal representative. If appropriate, assent must also be obtained prior to conducting any study-related activities.

Describe the procedures and location(s) to be used to identify and screen candidates. Describe how study staff will obtain informed consent from patients.

10.1.2 Baseline

Describe the procedures to be conducted (including labs, radiology, Quality of Life and outcomes surveys, research-specific tests, etc.) on subjects at their baseline visit. Provide information about the location where there procedures will take place and how the data will be obtained.

10.1.3 Visit 1 – X

Describe the procedures to be conducted (including labs, radiology, Quality of Life and outcomes surveys, research-specific tests, etc.) on subjects at each study visit. Provide information about the location where the procedures will take place and how the data will be obtained.

Use the "Heading 3" style above to create new correctly numbered sub-subsections.

11 ADVERSE EVENT REPORTING AND DOCUMENTATION

11.1 Adverse Events

11.2 Serious Adverse Events (SAE)

In 10.1 and 10.2, describe how AEs and SAEs, respectively, will be monitored and tracked, how severity will be established, and how relationship to participation in the research will be determined.

11.2.1 Serious Adverse Event/Unanticipated Problem Reporting

Describe how SAEs/Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs)/Unanticipated Adverse Device Effects (UADEs) will be reported to the sponsor and to the IRB.

Example for Drug Studies:
All Adverse Events or other events affecting safety will be reported to the IRB and Sponsor within 5 business days of becoming aware of the event.

Any Adverse Event or other type of event that appears to be a risk to subjects or others and is related to the research will be assessed. The Principal Investigator will determine whether or not he/she feels the event meets

the criteria to be considered an Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO). To be considered to be a UPIRSO, the event must meet all three of the following criteria:

- It is **unexpected** (in terms of nature, severity, or frequency) given: (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol, informed consent document, or Investigator's Brochure/product information; and (b) the characteristics of the subject population being studied,
- It is **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 research (e.g. including procedures that are done in support of the research that would not have been done absent the research), and
- The event suggests that the research **places subjects or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the Principal Investigator or study staff becomes aware of any Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO), the Principal Investigator will submit a report of the event to the IRB for review **within 5 business days**.

Furthermore, the PI will determine whether any Serious Adverse Event or UPIRSO indicates that an immediate hazard exists to human subjects. In such situations, the PI will notify the IRB Chairperson by telephone immediately in addition to filing the written report.

If additional information on the event comes to light that affects or could potentially affect safety, or if causality of the event is determined after the initial report is submitted to the IRB, a follow-up report will be submitted to the IRB for review.

11.3 *Protocol Defined I*mportant Medical Findings Requiring Real Time Reporting

This is a special section that should be deleted if not needed. This section should define events that are to be reported in real time that may or may not meet the definition of serious. The SAE section should not be changed, because SAE is a regulatory term with regulatory implications. If events in addition to SAEs are being requested to be reported in real time, they should be described here.

11.4 Medical Monitoring

If applicable, insert the name and contact information for the medical monitor providing oversight of your study. Also, detail any specific scenarios where the medical monitor must be consulted. For example,

The Medical Monitor should be contacted directly at these numbers to report medical concerns or questions regarding safety.

Phone: (XXX) XXX-XXXX
Pager: (XXX) XXX-XXXX

12 DISCONTINUATION AND REPLACEMENT OF SUBJECTS

12.1 Early Discontinuation of Study Drug

Describe any reasons or situations where subject may be withdrawn early from the study for safety or other reasons.

12.3 Replacement of Subjects

Describe whether dropped or withdrawn subjects will be replaced, and a rationale for replacement or non-replacement of subjects.

13 PROTOCOL VIOLATIONS

A protocol violation occurs when the subject, investigator, or Sponsor fails to adhere to significant protocol requirements affecting the inclusion, exclusion, subject safety and primary endpoint criteria.

Describe a plan for ongoing monitoring for protocol deviations, as well as how they will be reported to the IRB providing oversight of the site(s) engaged in the study.

14 DATA SAFETY MONITORING (OPTIONAL SECTION – INCLUDE IF APPROPRIATE)

Describe how the safety data from the study will be monitored. If the plan includes a formal DSMB or DMC, then provide information about the constituents, review processes, and reporting methodology to be used by the DSMB/DMC to ensure subject safety. If an independent DSMC/DMC is not planned, then provide additional details about how the PI and site investigators will ***objectively*** *monitor the data to protect current and future subjects.*

15 STATISTICAL METHODS AND CONSIDERATIONS

Provide a detailed Statistical Analysis Plan (SAP) describing all analyses that will be performed. The SAP will contain any modifications to the analysis plan described below.

15.1 Data Set Analysis

Define which subjects will be included in each analysis (e.g., all randomized subjects, all dosed subjects, all eligible subjects).

15.2 Demographic and Baseline Characteristics

Indicate which demographic and baseline characteristics will be summarized and the statistics to be used to assess the significance of observed differences.

15.3 Analysis of Primary Endpoint

Describe the statistical methods to be employed for each primary endpoint.

15.4 Analysis of Secondary Endpoints

Describe the statistical methods to be employed for each secondary endpoint.

15.5 Interim Analysis

Indicate the timing of any planned interim analyses, and how the interim analysis results may be used to modify or terminate the research activities.

15.6 Sample Size and Randomization

Specify the number of subjects planned to be enrolled and describe the reason for choice of sample size including reflections on (or calculations of) the power of the study and clinical justification. Prior studies or data that was used as rationale for the power calculations should be included.

16 DATA COLLECTION, RETENTION AND MONITORING

16.1 Data Collection Instruments

Describe in detail how the data will be collected. For example, paper CRFs, eCRFs, etc.

16.2 Data Management Procedures

Describe the procedures for managing the study data in accordance with procedural documentation, such as database management, data processing, data freezes, data analysis, data sharing (if applicable), and so forth.

16.3 Data Quality Control and Reporting

Describe the procedures to be used to ensure data quality, such as quality audits, data queries, etc. Describe the procedures used to generate reports from the study database, if required, such as reporting to the FDA or other regulatory agency.

16.4 Archival of Data

Describe procedures to be used to archive data to protect against loss due to database corruption. Describe how long data will be retained after the study has been completed.

16.5 Availability and Retention of Investigational Records

Describe the plans and procedures to make study data accessible to monitors, authorized representatives of the Sponsor (or designee), the IRB, and regulatory agency (e.g., FDA) inspectors upon request, as well as timeframe and procedures for records retention.

16.6 Monitoring

16.7 Subject Confidentiality

Describe the procedures to be used to protect the confidentiality of subjects.

17 ADMINISTRATIVE, ETHICAL, REGULATORY CONSIDERATIONS

Do not edit the sentence below:

The study will be conducted according to the principles outlined in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (aka, the "Belmont Report").

Outline any additional regulatory statutes that will govern this research, such as 21 CFR 50, 45 CFR 46, etc. Ask the IRB if you are uncertain whether there are additional regulatory obligations or laws that your research study must follow.

17.1 Protocol Amendments

Describe how protocol amendments will be implemented. Do not change or remove the sentence below:

Protocol amendments may not be implemented without prior written IRB approval, except as necessary to eliminate immediate safety hazards to patients. A protocol amendment intended to eliminate an apparent immediate hazard to patients may be implemented immediately, provided the IRB is notified within five working days.

17.2 Institutional Review Board

Describe how the protocol and consent documents will be overseen by the IRB. If this is a multi-center study, then describe whether single/central IRB will be used or local IRBs will provide oversight of their respective institutions.

Do not change or remove the paragraphs below:

The protocol will be conducted under the requirements of the IRB. The following items will be reported to the IRB for review:

- Modifications to the protocolwill be approved by the IRB prior to implementation. Protocol modifications will not be initiated without prior written IRB approval, except when necessary to eliminate immediate hazards to subjects.
- Modifications to the Informed Consent Form will be approved by the IRB prior to use. Subjects who are enrolled in the study will be consented with the most recent Informed Consent Form approved by the IRB.
- Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including Unanticipated Adverse Device Effects (UADEs) occurring during the study, will be reported to the IRB in accordance with the protocol, standard operating procedures, and policies of the IRB
- The following will also be reported to the IRB in accordance with the standard operating procedures of the IRB and the Institution:
    - New or increased risk that may adversely affect the safety of the patients or the conduct of the study
    - Protocol deviation that harmed a subject or placed subject at risk of harm
    - Audit, inspection, or inquiry by a federal agency
    - Written reports of federal agencies (e.g., FDA Form 483)
    -
    - Allegation or Finding of Noncompliance or other instances of research misconductBreach of subject confidentiality
    - Unresolved subject complaint
    - Suspension or premature termination by the sponsor, investigator, or institution
    - Incarceration of a subject in a research study to which the study subject is intended to continue in the study but the study is not approved to involve prisoners
    - Serious, unanticipated adverse events, device effects, or IND safety reports related to the research that require a change to the protocol or consent
    - State medical board actions
    - Information where the sponsor requires prompt reporting to the IRB
- Continuing Review Submissions will be submitted to the IRB prior to the expiration date to avoid gaps in IRB approval for this study
- The study will be formally closed with the IRB once the study has been completed

17.3 Informed Consent Form

Describe the procedures to be used to develop and secure appropriate approvals for the subject's informed consent form. Some of the following may require editing, as necessary, depending on the Sponsor (either a company or the PI for investigator-initiated studies). Additionally, depending on whether the study is FDA or PHS regulated, the governing regulations should be carefully reviewed to ensure the correct laws are being followed.

Informed consent will be obtained in a manner consistent with principles outlined in the Belmont Report, the Health Insurance Portability and Accountability Act (HIPAA), local regulations, and institutional policies. *Edit the following, as necessary:* If an FDA regulated study then consent will be obtained in accordance with 21 CFR 50, otherwise for other human subjects studies consent will be obtained in accordance with 45 CFR 46.

The Principal Investigator (or his/her designee) will prepare the informed consent form and HIPAA authorization. *Include if applicable:* These documents will be provided to the Sponsor or designee for approval prior to submission to the IRB. The consent form generated by the Investigator must be approved by the IRB. The written consent document will embody the elements of informed consent as described in 45 CFR 46 and 21 CFR 50, and will also comply with local regulations and institutional policies. *Edit/delete the following, as necessary:* The Investigator will send an IRB-approved copy of the Informed Consent Form to the Sponsor (or designee) for the study file.

Review and edit, as necessary, the paragraph below to ensure it's in accordance with your plans for conducting the study. For example, you will need to describe how consent will be obtained from non-English speaking subjects, if they are to be included in your study.

A properly executed, written, informed consent will be obtained from each subject prior to enrolling the subject into the study. Information about the study will be provided to subjects in both oral and written form, and subjects (or their legal representatives) will be given adequate time and opportunity to inquire about details of the study. If a subject is unable to sign the informed consent form (ICF) and the HIPAA authorization, a legally-authorized representative may sign the documents on behalf of the subject in accordance with local laws. A copy of the signed consent form (and assent form, if applicable) will be given to the subject or legal representative, a copy will be placed in the subject's medical record/chart, and the original will be maintained in the subject's study files.

17.4 Publications

Provide a summary of how the results of this research may be disseminated to the medical and scientific community.

17.5 Investigator Responsibilities

Do not alter the text below.

By signing the Agreement of Investigator form, the Principal Investigator agrees to:

- Conduct this study according to the protocol and in compliance with local, state, and federal laws and St. David's policies.
- Thoughtfully consider the potential risks and benefits of this research and determine that the risk/benefit ratio is acceptable and does not put an undue burden on potential research subjects.
- Abide by IRB requests.
- Report any adverse medical events, protocol violations, changes in the protocol or consent, and will obtain written approval from IRB for these changes prior to implementation.
- Submit a Continuing Review Submission Form or Closure Form for this research prior to the expiration of IRB approval.
- Ensure the research site(s) have the necessary emergency or safety equipment to conduct the study in accordance with the protocol.

APPENDIX 1. SCHEDULE OF EVENTS

	VISIT 1 (Day/Week/ Month #)[a]	VISIT 2 (Day/Week/Month #)[a]	VISIT 3 (Day/Week/Month #)[a]	VISIT 4 (Day/Week/Month #)[a]	VISIT 5 (Day/Week/Month #)
Informed Consent	X				
Medical History	X				
Complete Physical Exam	X				X
Abbreviated Physical Exam		X	X	X	
Height	X	X	X	X	X
Weight	X	X	X	X	X
Vital Signs	X	X	X	X	X
Oximetry	X	X	X	X	X
Spirometry	X	X	X	X	X
Randomization	X				
Dispensing or Administration of Study Drug	X	X	X	X	
Counting of Returned Study Drug		X	X	X	X
Initiate Subject Diary	X				
Subject Diary Review		X	X	X	X
Concomitant Medication Review	X	X	X	X	X
Adverse Events					

[a] ±2 day