**How To Use This Template**

It is important to incorporate all sections of the template into your protocol and to do so in the same order. If a particular section is not applicable to your trial, include it, but indicate that it is not applicable.

This template contains two types of text: instruction/explanatory and example.

**Instruction/explanatory text** are indicated by *italics* and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included. It also notes if a section should be left blank. For example, many headings include the instruction, “*No text is to be entered in this section; rather it should be included under the relevant subheadings below.*”

**Example text** is included to further aid in protocol writing and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted. Example text is indicated in [regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>.

Instruction/explanatory text should be deleted. Example text can be incorporated as written or tailored to a particular protocol. If it is not appropriate to the protocol, however, it too should be deleted. The section headers include formatting to generate a table of contents.

**RESOURCES**

Remove **Resources** before finalizing and distributing the clinical trial protocol.

Center for Medicare & Medicaid Services (CMS)

* [Clinical Laboratory Improvement Amendments](http://publicaccess.nih.gov/policy.htm?redirect=/clia/)

Code of Federal Regulations (CFR)

* [21 CFR Part 11: Electronic Records, Electronic Signatures](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html?SID=007006046b07c9fc5244ec13ef4a77bb&mc=true&node=pt21.1.11&rgn=div5)
* [21 CFR Part 50: Protection of Human Subjects](http://grants.nih.gov/grants/policy/coi/?SID=6d82202a67ba5bd44148d99f4aaf7198&mc=true&node=pt21.1.50&rgn=div5)
* [21 CFR Part 54: Financial Disclosure by Clinical Investigators](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html?SID=bae2d66180fd49cb11f40a935cd760a7&mc=true&node=pt21.1.54&rgn=div5)
* [21 CFR Part 56: Institutional Review Boards](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?SID=64724709940d94a34270c77fdb8d307f&mc=true&node=pt21.1.56&rgn=div5)
* [21 CFR Part 58: Good Laboratory Practice for Nonclinical Laboratory Studies](http://www.ecfr.gov/cgi-bin/text-idx?SID=90f8b344173d4c43e0c515d0a0cbc4de&mc=true&node=pt21.1.58&rgn=div5)
* [21 CFR Part 210: Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs; General](http://www.ecfr.gov/cgi-bin/text-idx?SID=90f8b344173d4c43e0c515d0a0cbc4de&mc=true&node=pt21.4.210&rgn=div5)
* [21 CFR Part 211: Current Good Manufacturing Practice For Finished Pharmaceuticals](http://www.ecfr.gov/cgi-bin/text-idx?SID=90f8b344173d4c43e0c515d0a0cbc4de&mc=true&node=pt21.4.211&rgn=div5)
* [21 CFR Part 312: Investigational New Drug Application](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/vulnerable-populations/?SID=27a0c0825d11663283856731fb14c8d2&mc=true&node=pt21.5.312&rgn=div5)
* [21 CFR Part 812: Investigational Device Exemptions](http://www.ncbi.nlm.nih.gov/books/NBK7256/?SID=0f8fa3b740966b3d21d5501233e2b493&mc=true&node=pt21.8.812&rgn=div5)
* [42 CFR Part 11: Clinical Trial Registration and Results Information Submission](https://gds.nih.gov/03policy2.html)
* [45 CFR Part 46: Protection of Human Subjects Research](http://www.hhs.gov/ohrp/policy/consentckls.html)

Food and Drug Administration (FDA)

* [Compliance Actions and Activities](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html)
* [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](https://www.ecfr.gov/cgi-bin/text-idx)
* [Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs – Improving Human Subject Protection](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html)
* [Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees](http://grants.nih.gov/grants/funding/women_min/women_min.htm)
* [Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance](https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf)
* [Guidance for Industry: Electronic Source Data in Clinical Investigations](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf)
* [Guidance for Industry: Multiple Endpoints in Clinical Trials](http://www.consort-statement.org/)
* [Guidance for Industry: Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)
* [Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](https://www.ecfr.gov/cgi-bin/text-idx)
* [Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Standardized Study Data](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292334.pdf)
* [Guidance for Industry: Safety Assessment for IND Safety Reporting](https://www.ecfr.gov/cgi-bin/text-idx)

Department of Health and Human Services (HHS)

* [The HIPAA Privacy Rule](https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol1/pdf/CFR-2016-title42-vol1-part11.pdf)
* [HIPAA Privacy Rule: Information for Researchers](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

* [Guidance for Industry, E6 (R2) Good Clinical Practice: Consolidated Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM464506.pdf)
* [Guidance for Industry, M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals](http://www.hhs.gov/ohrp/regulations-and-policy/index.html)
* [Guideline for Industry, E3 Structure and Content of Clinical Reports](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf)
* [Guidance for Industry, E9 Statistical Principles for Clinical Trials](http://www.hhs.gov/ohrp/assurances/)
* [Final Concept Paper E9(R1): Addendum to Statistical Principles for Clinical Trials on Choosing Appropriate Estimands and Defining Sensitivity Analyses in Clinical Trials](https://www.ecfr.gov/cgi-bin/text-idx)

International Organization for Standardization (ISO)

* [Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice (ISO 14155:2011)](http://www.fda.gov/ICECI/EnforcementActions/default.htm)

National Institutes of Health (NIH)

* [Certificates of Confidentiality (CoC) Kiosk](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
* [Clinical Trials Registration and Results Information Submission](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm477584.pdf)
* [Financial Conflict of Interest](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536750.pdf)
* [Inclusion of Children- Policy Implementation](http://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf)
* [Inclusion Of Women And Minorities As Participants In Research Involving Human Subjects- Policy Implementation Page](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf)
* [NIH Data Sharing Policies and Related Guidance on NIH-Funded Research Resources](https://www.ecfr.gov/cgi-bin/text-idx)
* [NIH Data Sharing Policy and Implementation Guidance](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/E9__R1__Final_Concept_Paper_October_23_2014.pdf)
* [NIH Genomic Data Sharing Policy](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)
* [NIH Grants Policy Statement, Section 8.2 Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](http://grants.nih.gov/grants/policy/coc/index.htm)
* [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf)
* [NIH Public Access Policy Details](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073113.pdf)
* [Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials](https://www.ecfr.gov/cgi-bin/text-idx)
* [Required Education in the Protection of Human Research Participants](https://grants.nih.gov/grants/funding/children/children.htm)

Office for Human Research Protections (OHRP)

* [Human Subject Regulations Decision Charts](https://www.iso.org/obp/ui/%20-%20iso:std:iso:14155:ed-2:v1:en)
* [Informed Consent Checklist](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm)
* [Informed Consent Tips](https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission)
* [IRBs and Assurances](http://www.hhs.gov/hipaa/for-professionals/privacy/)
* [Regulations & Policy Index](http://grants.nih.gov/policy/sharing.htm)
* [Unanticipated Problems Involving Risks and Adverse Events Guidance](http://www.hhs.gov/ohrp/policy/ictips.html)
* [Vulnerable Populations](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073137.pdf)

Other

* [Citing Medicine, 2nd edition: The NLM Style Guide for Authors, Editors, and Publishers](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)
* [CONSORT statement](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf)
* [International Committee of Medical Journal Editors (ICMJE): Recommendations](http://www.icmje.org/recommendations/)
* [Practical Aspects of Signal Detection in Pharmacovigilance: Report of CIOMS Working Group VIII](http://cioms.ch/shop/product/practical-aspects-of-signal-detection-in-pharmacovigilance-report-of-cioms-working-group-viii/)

**<Title>**

*The title should be easy to remember, recognizable by administrative support staff, and sufficiently different from other protocol titles to avoid confusion. Brevity with specificity and neutrality is the goal. If there is a “short title” (e.g., an abbreviation used to refer to the study title, include here and that can be used throughout this document in place of the full title).*

**National Clinical Trial (NCT) Identified Number: <Number, if available>**

**Principal Investigator:** **< Principal investigator>**

**<IND/IDE> Sponsor: <Sponsor name, if applicable>**

*Sponsor means an individual or pharmaceutical or medical device company, governmental agency, academic institution, private organization, or other organization who takes responsibility for and initiates a clinical investigation.*

**Funded by: < NIH Institute or Center (IC)>**

**Version Number: v.<x.x>**

**<Day Month Year>**

Table of Contents

[1 PROTOCOL SUMMARY 1](#_Toc501564698)

[1.1 Abbreviations 1](#_Toc501564699)

[1.2 Synopsis 1](#_Toc501564700)

[1.3 Schema 1](#_Toc501564701)

[2 INTRODUCTION 6](#_Toc501564702)

[2.1 Study Rationale 6](#_Toc501564703)

[2.2 Background 6](#_Toc501564704)

[3 STUDY DESIGN 6](#_Toc501564705)

[3.1 Overall Design 6](#_Toc501564706)

[4 STUDY PROCEDURES 7](#_Toc501564707)

[5 SUB-STUDY PROCEDURES 7](#_Toc501564708)

[6 STUDY POPULATION 7](#_Toc501564709)

[6.1 Inclusion Criteria 8](#_Toc501564710)

[6.2 Exclusion Criteria 8](#_Toc501564711)

[6.3 Lifestyle Considerations 8](#_Toc501564712)

[6.4 Recruitment and Consenting Procedures 9](#_Toc501564713)

[7 STUDY INTERVENTION(s) 10](#_Toc501564714)

[7.1 Study Intervention(s) Administration 10](#_Toc501564715)

[7.1.1 Study Intervention Description 10](#_Toc501564716)

[7.1.2 Dosing and Administration 10](#_Toc501564717)

[7.2 Preparation/Handling/Storage/Accountability 10](#_Toc501564718)

[7.2.1 Interventionists Training and Accountablity 11](#_Toc501564719)

[7.2.2 Formulation, Appearance, Packaging, and Labeling 11](#_Toc501564720)

[7.2.3 Product Storage and Stability 11](#_Toc501564721)

[7.2.4 Preparation 11](#_Toc501564722)

[7.3 Concomitant Therapy 11](#_Toc501564723)

[7.4 Discontinuation of Study Intervention 12](#_Toc501564724)

[7.5 Participant Discontinuation/Withdrawal from the Study 12](#_Toc501564725)

[8 RISKS AND BENEFITS 12](#_Toc501564726)

[8.1 Known Potential Risks 12](#_Toc501564727)

[8.2 Known Potential Benefits 12](#_Toc501564728)

[8.3 Assessment of Potential Risks and Benefits 12](#_Toc501564729)

[8.4 Subject Safety and Data Monitoring 13](#_Toc501564730)

[8.5 Adverse Event Reporting 13](#_Toc501564731)

[8.5.1 Reporting Events to Participants 13](#_Toc501564732)

[8.6 Reporting of Pregnancy 14](#_Toc501564733)

[8.7 Protocol Deviations 14](#_Toc501564734)

[9 PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY 14](#_Toc501564735)

[10 STATISTICAL CONSIDERATIONS 14](#_Toc501564736)

[11 REFERENCES 14](#_Toc501564737)

# PROTOCOL SUMMARY

*No text is to be entered in this section; rather it should be included under the relevant subheadings below.*

## Abbreviations

*List any abbreviations used in protocol document here.*

## Synopsis

|  |  |
| --- | --- |
| **Title:** | <Full title> |
| **Study Description:** | *Provide a short description of the protocol, including a brief statement of the study hypothesis. This should be only a few sentences in length.* |
| **Objectives:** | *Include the primary and secondary objectives. These objectives should be the same as the objectives contained in the body of the protocol. These align with Primary Purpose in clinicaltrials.gov[[1]](#footnote-2).* |
|  | <Primary Objective: |
|  | Secondary Objectives: > |
| **Study Population:** | *Specify the sample size, gender, age, demographic group, general health status, and geographic location.* |
| **Description of Sites/Facilities Enrolling Participants:** | *Provide a brief description of planned facilities/participating sites enrolling participants. Indicate general number (quantity) of sites only and if the study is intended to include sites outside of the United States.* |
| **Description of Study Intervention:** | *Describe the study intervention. If the study intervention is a drug or biologic, include dose and route of administration. For devices, provide a description of each important component, ingredient, property and the principle of operation of the device.* |
| **Study Duration:** | *Estimated time (in months) from when the study opens to enrollment until completion of data analyses.* |
| **Participant Duration:** | *Time (e.g., in months) it will take for each individual participant to complete all participant visits.* |
| **Key Roles:** | *List names and role of key study personnel.* |
|  |  |

## Schema

*This section should include a diagram that provides a quick “snapshot” of the study and ideally be limited to 1 page. Below are examples, revise with study-specific information.*

*Allowable windows should be stated for all visits. To determine the appropriate windows, consider feasibility and relevance of the visit time points to study endpoints (e.g., pharmacokinetic (PK) studies may allow little or no variation, with required time points measured in minutes or hours, whereas a 6-month follow-up visit might have a window of several weeks). Keep in mind that violations of these study windows are considered protocol deviations; multiple protocol deviations suggest the need to modify the study protocol which needs to be approved by the IRB.*

***Example #1 Flow diagram*** *(e.g., randomized controlled trial)*

Prior to

Total N: Obtain informed consent. Screen potential participants by inclusion and exclusion criteria; obtain history, document.

Enrollment

Randomize

Perform baseline assessments.

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Administer initial study intervention.

Visit 1

Time Point

Repeat study intervention (*if applicable*).

Visit 2

Time Point

Follow-up assessments of study endpoints and safety

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Visit 3

Time Point

Follow-up assessments of study endpoints and safety

<list specimens to be collected, examinations or imaging or laboratory assays to be performed, questionnaires to be completed OR refer to **Section 1.3, Schedule of Activities**>

Visit 4

Time Point

**Final Assessments**

<list analyses to be performed OR refer to **Section 1.3, Schedule of Activities**>

Visit X

Time Point

***Example #2*** ***provided as a guide, customize as needed: Process diagram*** *(e.g., randomized controlled trial)*

***Example #3*** ***provided as a guide, customize as needed: Timeline diagram*** *(e.g., randomized controlled trial)*

Day -7 to Day -1

Screening

Day 1

Randomization

Week 1

Titration

Weeks 2 - 25

Maintenance

Week 26

Dose Taper

Week 27

End of Study Assessments (EOS)

Week 28-29

Follow-up Phone Call

Study Intervention N=

Placebo N=

# in-clinic visits and

# telephone contacts

# INTRODUCTION

## Study Rationale

*Describe why this research project will be done. Clearly state the overall objectives, specific*

*aims, hypotheses and rationale for performing the study. Indicate the Primary and Secondary Study Endpoints. Also indicate the Primary Safety Endpoints (unless the study is a safety study).*

<Insert text>

## Background

* State the purpose of the research and describe the related theory/data supporting the intent of

the study.

* Describe what is considered standard care (approved and/or customary) for the medical

condition being studied, if applicable.

* Explain how the new treatment or procedure may improve standard care, if applicable. Clearly

delineate what is considered research study items from the “standard care”.

* Provide a short statement concerning the status of the drug, drug combination, delivery

method, device, or other interventions/concepts to be studied, if applicable.

* Indicate whether the research is confirming or an extension of previous work, or whether it is

pioneering with little prior information.

* Include an evaluation of existing knowledge and identify

the information gaps that the project intends to address.

* Describe published research with animals and/or humans that supports the study hypothesis

or objectives. If applicable, include information regarding toxicity.

# STUDY DESIGN

## Overall Design

* *Provide a brief description of the study design. If applicable, describe the treatment arms, use*

*of placebo or comparison drug/device and randomization.*

* *Include a brief description of outcome variables and study endpoints, as appropriate.*
* *Indicate the maximum number of local subjects to be consented on this protocol, including*

*projected screen failures and early withdrawals. Include subjects who will receive interventions as well as controls, if applicable. For multi-center research, indicate the total sample size for the entire project across all sites.*

* *If the study involves use of existing charts, records, or specimens, specify the maximum*

*number that will be reviewed to compile the data or the sample population necessary to*

*address the research question.*

* *Provide the total number of subjects to be studied at this site and approximately how long the*

*study will last.*

<Insert text>

# STUDY PROCEDURES

* This section should match figure in Section 1.2
* Provide a chronological description of all study procedures. If applicable, divide procedures

into pilot, screening, and procedures performed at each regular visit. Indicate how many total

visits and approximately how long visits will last. For studies that are providing medication(s),

give the name(s), dosage, and route of administration. For studies that have more than one

arm/part, provide the above information for each.

* Indicate the timing of all study procedures and the anticipated duration of the subject’s

involvement.

* As applicable, include the amount and blood to be drawn, tissue samples to be collected,

radiation exposure, questionnaires, or other interventions.

* Note if the subject will be responsible for any research-related costs and estimate the amount

of these costs, if applicable.

* If applicable, describe end-of-study procedures, including transition of the subject to alternative care

<Insert text>

# SUB-STUDY PROCEDURES

* For any sub-studies that may be a part of the research, please provide a subsection title and

include information about the procedures that will be performed and whether subjects have the

option to participate or not (e.g., pharmacokinetics, biomarkers).

* For studies that collect blood and/or tissue for DNA analysis where the genetic portion is

described in the Master Protocol provide a genetic subsection to include information about the

procedures that will be performed and whether subjects have the option to participate in the

sub-study.

# STUDY POPULATION

No text is to be entered in this section; rather it should be included under the relevant subheadings

* The eligibility criteria should provide a definition of participant characteristics required for study entry/enrollment.
* If participants require screening, distinguish between screening participants vs enrolling participants. Determine if screening procedures will be performed under a separate screening consent form.
* The risks of the study intervention should be considered in the development of the inclusion/exclusion criteria so that risks are minimized.
* The same criterion should **not** be listed as both an inclusion and exclusion criterion (e.g., do not state age >18 years old as an inclusion criterion and age ≤18 years old as an exclusion criterion).
* Identify specific laboratory tests or clinical characteristics that will be used as criteria for enrollment or exclusion.
* If reproductive status (e.g., pregnancy, lactation, reproductive potential) is an eligibility criterion, provide specific contraception requirements (e.g., licensed hormonal or barrier methods).
* If you have more than one study population, please define the common inclusion and exclusion criteria followed by the specific inclusion and exclusion criteria for each subpopulation.

## Inclusion Criteria

Example text provided as a guide, customize as needed:

[In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Male or female, aged <specify range>
4. In good general health as evidenced by medical history or diagnosed with <specify condition/disease> or exhibiting <specify clinical signs or symptoms or physical/oral examination findings>
5. <Specify laboratory test> results between <specify range>
6. Reasonable expectation of being available for the duration of the study
7. Willingness to adhere to the <study intervention> regimen
8. For females of reproductive potential: use of highly effective contraception for at least 1 month prior to screening and agreement to use such a method during study participation and for an additional <specify duration> weeks after the end of <study intervention> administration
9. For males of reproductive potential: use of condoms or other methods to ensure effective contraception with partner
10. Agreement to adhere to Lifestyle Considerations throughout study duration]

<Insert text>

## Exclusion Criteria

Example text provided as a guide, customize as needed:

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

1. Current use of < specify disallowed concomitant medications*>*
2. Presence of <specific health conditions contraindicated for study procedures>
3. Presence of <specific devices (e.g., cardiac pacemaker)>
4. Treatment with another investigational drug or other intervention within *<*specify time frame*>*
5. < Specify any condition(s) or diagnosis, both physical or psychological, or physical exam finding that precludes participation>]

<Insert text>

## Lifestyle Considerations

*Include content in this section if applicable, otherwise delete. Describe any restrictions during any parts of the study pertaining to lifestyle and/or diet (e.g., food and drink restrictions, timing of meals relative to dosing, intake of caffeine, alcohol, or tobacco, or limits on activity), and considerations for household contacts. Describe what action will be taken if prohibited medications, treatments or procedures are indicated for care (e.g., early withdrawal).*

*Example text provided as a guide, customize as needed:*

[During this study, participants are asked to:

* Refrain from consumption of red wine, Seville oranges, grapefruit or grapefruit juice, [pomelos, exotic citrus fruits, grapefruit hybrids, or fruit juices] from [X days] before the start of <study intervention> until after the final dose.
* Abstain from caffeine- or xanthine-containing products (e.g., coffee, tea, cola drinks, and chocolate) for [x hours] before the start of each dosing session until after collection of the final pharmacokinetic (PK) and/or pharmacodynamic sample.
* Abstain from alcohol for 24 hours before the start of each dosing session until after collection of the final PK and/or pharmacodynamic sample.
* Participants who use tobacco products will be instructed that use of nicotine-containing products (including nicotine patches) will not be permitted while they are in the clinical unit.
* Abstain from strenuous exercise for [x hours] before each blood collection for clinical laboratory tests. Participants may participate in light recreational activities during studies (e.g., watching television, reading).
* Minimize interactions with household contacts who may be immunocompromised.]

<Insert text>

## Recruitment and Consenting Procedures

* *If applicable, indicate if the potential subjects will be patients of the investigators.*
* *Describe and provide details of the recruitment process. Include when, where, by whom and how potential subjects will be approached.*
* *Indicate if non-English speaking subjects are being consented and if so, indicate how informed consent process will be conducted.*
* *Explain measures that will be taken to respect the privacy of the potential subjects.*
* *Explain what precautions will be taken to minimize the potential for undue influence or coercion.*
* *If you are requesting a waiver of informed consent, explain how the criteria for waiver are met.*

In addition, this section should address:

* If appropriate, include justification for inclusion of vulnerable participants and recruitment strategy. Vulnerable participants include, but are not limited to pregnant women, those who lack consent capacity, including the mentally ill, prisoners, cognitively impaired participants, children, and employee volunteers. Include safeguards for protecting vulnerable populations. Please refer to OHRP guidelines when choosing the study population. Note that these regulations apply if any participants are members of the designated population, even if it is not the target population (e.g., if a participant becomes a prisoner during the study).
* *If participants will be compensated or provided any incentives* (e.g. vouchers, gift cards,) *for study participation, describe amount, form and timing of such compensation in relation to study activities (include financial and non-financial incentives). Describe who will receive incentives (if not the participant). For example, if minors, state whether the minor or the parent/guardian will receive the incentive. If incapacitated adults, state if payment will be provided to the participant or to a legally authorized representative or guardian.*
* *If specimens or data are retained after the study is complete, include the provisions for consent and the options that are available for the participant to agree to the future use of his/her specimens, images, audio or video recordings.*

<Insert text>

# STUDY INTERVENTION(s)

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

*If multiple study interventions are to be evaluated in the trial, clearly differentiate between each intervention. Address attention-control and comparison conditions. If the control or comparison condition(s) is/are handled differently than the study intervention, be sure to state how they are each handled, separately. If the control or comparison condition(s) are handled the same as the study intervention, state as such. A****ll sections may not be relevant for your study. If not relevant, delete section.***

## Study Intervention(s) Administration

No text is to be entered in this section; rather it should be included under the relevant subheadings below. Delete or modify subheadings that are not relevant (e.g., dosing and administration may be deleted or may be changed to administration for a social behavioral intervention.

### Study Intervention Description

*Describe the study intervention(s) including any control or comparison intervention(s).*

<Insert text>

### Dosing and Administration

*Describe how the study intervention(s) will be administered, including whether there will be interventionists, the setting in which the intervention will be delivered, and the number of sessions constituting a complete intervention “dose”. Please describe all intervention/experimental conditions, including any comparison groups (e.g., attention-control, treatment as usual), if applicable. Also describe any planned variation in intervention frequency or schedule (e.g., for adaptive designs).*

<Insert text>

## Preparation/Handling/Storage/Accountability

*No text is to be entered in this section; rather it should be included under the relevant subheadings below.*

### Interventionists Training and Accountablity

*If applicable, state how study interventionists will be or their relevant credentials.*

<Insert text>

### Formulation, Appearance, Packaging, and Labeling

*This section is not applicable for most behavioral clinical trials.*

*Describe the formulation, appearance, packaging, and labeling of the study intervention and control product, as supplied. Information in this section can usually be obtained from the IB or the package insert, or device labeling. This section should include the name of the manufacturer of the study intervention and control product.*

<Insert text>

### Product Storage and Stability

*This section is not applicable for most behavioral clinical trials.*

*Describe storage and stability requirements (e.g., protection from light, temperature, humidity) for the study intervention and control product. For studies in which multi-dose vials are utilized, provide additional information regarding stability and expiration time after initial use (e.g., the seal is broken).*

<Insert text>

### Preparation

*This section is not applicable for most behavioral clinical trials.*

*Describe the preparation of the study intervention and control product, including any preparation required by study staff and/or study participants. Include thawing, diluting, mixing, and reconstitution/preparation instructions in this section, as appropriate, or within a MOP or SOP. For devices, include any relevant assembly or use instructions.*

<Insert text>

## Concomitant Therapy

Include content in this section if applicable, otherwise delete.

*This section should be consistent with any concomitant treatment restrictions in the inclusion/exclusion criteria previously listed. Describe the data that will be recorded related to permitted concomitant medications, supplements, complementary and alternative therapies, treatments, and/or procedures. Include details about when the information will be collected (e.g., screening, all study visits). Describe how allowed concomitant therapy might affect the outcome (e.g., drug-drug interaction, direct effects on the study endpoints) and how the independent effects of concomitant and study interventions could be ascertained.*

*Example text provided as a guide, customize as needed:*

[For this protocol, a prescription medication is defined as a medication that can be prescribed only by a properly authorized/licensed clinician. Medications to be reported in the Case Report Form (CRF) are concomitant prescription medications, over-the-counter medications and supplements.]

<Insert text>

## Discontinuation of Study Intervention

Describe the criteria for discontinuing the study intervention (e.g., halting rules).

<Insert text>

## Participant Discontinuation/Withdrawal from the Study

Provide a list of reasons participation may be discontinued.

# RISKS AND BENEFITS

## Known Potential Risks

* Describe the known risks and/or potential discomforts associated with each intervention or research procedure. Risks may be physical, psychological, social or economic.
* Estimate the probability (chance or likelihood of occurrence) that a given harm may occur and its severity (mild, moderate or severe) and define risks by percentages, when available, or by categorizing with the terms rare, unlikely, likely.
* Compare the risks of the research to standard of care. If placebo controls are used, justify their use over active or other kinds of controls.

<Insert text>

## Known Potential Benefits

* *Include a discussion of known potential benefits from either clinical or nonclinical studies*
* *Describe any physical, psychological, social, legal, or any other potential benefits to individual participants or society in general, as a result of participating in the study.*
* *Note that payment to participants, whether as an inducement to participate or as compensation for time and inconvenience, is not considered a “benefit.” Provision of incidental care is also not to be considered a benefit.*

<Insert text>

## Assessment of Potential Risks and Benefits

Include an assessment of known potential risks and benefits, addressing each of the following:

* *Rationale for the necessity of exposing participants to risks and a summary of the ways that risks to participants were minimized in the study design*
* *Justification as to why the risks of participation in the study outweigh the value of the information to be gained*

<Insert text>

## Subject Safety and Data Monitoring

* *Describe what measures have been taken and/or will be taken to prevent and minimize any risks or discomforts.*
* *If applicable, discuss provisions for insuring necessary medical or professional intervention in the event of adverse events.*
* *Describe the plan for monitoring study data collected to protect subject safety and data integrity.*
* *Note: investigator-initiated studies involving administration of an experimental (i.e. not FDA approved for the indication/population under study) drug, device or intervention must submit a Data Safety Monitoring Plan and may be required by the IRB to establish a Data Safety monitoring Board (DSMB).*

## Adverse Event Reporting

*Do not change the text below.*

The study investigator is responsible for conducting an evaluation of an unanticipated adverse event and shall report the results of such evaluation the Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of an adverse event and within 24 hours of first learning of a serious adverse event.

*If applicable Include additional reporting responsibilities particular to your study here.*

<Insert text>

### Reporting Events to Participants

*Include content in this section if applicable, otherwise delete.*

*Describe how participants will be informed about AEs and SAEs, and study-related results on an individual or aggregate level. In addition, describe plans for detecting and managing incidental findings associated with study procedures.*

<Insert text>

## Reporting of Pregnancy

*Include content in this section if applicable, otherwise delete. Pregnancy is not an adverse event, but some studies will require unique considerations if pregnancy was to occur during the study.*

*Provide appropriate modifications to study procedures (e.g., discontinuation of study intervention, while continuing safety follow-up, requesting permission to follow pregnant women to pregnancy outcome).*

<Insert text>

## Protocol Deviations

*Plans for detecting, reviewing, and reporting deviations from the protocol should be described.*

<Insert text>

# PROCEDURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY

*Describe how data/specimens will be collected and stored and the security methods in place. Note: the more sensitive the study data, the more sophisticated the methods should be to maintain confidentiality.*

*If data/specimens will be disclosed to outside persons or entities, list the entities and the method used to code or de-identify the data/specimens.*

*State if you intend to apply for a Certificate of Confidentiality from the NIH.*

*<Insert text>*

# STATISTICAL CONSIDERATIONS

*Omit this section for peer-reviewed for peer-reviewed research such as cooperative group, or NIH sponsored studies, and for industry-sponsored research which has been submitted to FDA.*

* *Describe the statistical methods to be used to answer the study question(s).*
* *Explain how the target sample size was determined. (Pilot studies also require a method of analysis, but the justification of the target sample size is not required)*

# REFERENCES

*Include a list of relevant literature and citations for all publications referenced in the text of the protocol.*

1. [↑](#footnote-ref-2)