**Behavioral Research Protocol Template**

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| --- | --- |
| **Template Version Date** | **June 9, 2021** |
| Replaces Version Date | August 31, 2020 |

General Instructions for using the HDFCCC protocol template

* Guidance for completing the template is included within the document:
	+ *Blue italic text:* Instructions for completing the protocol sections. **As you fill in the template, please delete all blue italic text.**
	+ <<Red text>>: Placeholders to fill in study-specific information. Please add the appropriate information and format to plain black protocol text when completed.
	+ Black text: “Boilerplate” HDFCCC protocol language.
* Please use the built-in styles for section headings and protocol text (located in the ‘Home’ tab). Appropriate use of these styles allows for automatic updates to the Table of Contents.

 

* Please delete this instructions page from the protocol document.

Instructions for merging an existing protocol or sponsor protocol template with the HDFCCC template

Investigators who have drafted a study protocol or are using a sponsor template must incorporate the following sections of this template into the existing/sponsor protocol document:

* HDFCCC Cover Page
* HDFCCC logo, protocol version date, and CC# on every page
* [Protocol Signature Page](#_Protocol_Signature_Page) (multi-center studies must include the signature page for [UCSF and participating sites](#_Protocol_Signature_Page_1))
* [Study Objectives and Endpoints](#_Study_Objectives_and) – Provide distinct endpoint(s) and time frame(s) for measuring each objective, per [ClinicalTrials.gov requirements](https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf)
* [Inclusion of Women and Minorities](#_Inclusion_and_Recruitment)
* [Inclusion Across the Lifespan](#_Inclusion_Across_the)
* [Primary Completion](#_Primary_Completion)
* [Study Completion](#_Study_Completion)
* [Participant Registration](#_Participant_Registration)
* [Study Procedures and Assessments](#_Study_Procedures_and)
* [Adverse Events Monitoring](#_Adverse_Events_Monitoring)
* [Study Management](#_Study_Management)
* [Protection of Human Subjects (for multicenter studies)](#_Protection_of_Human)
* [Data and Safety Monitoring Plan](#DSMP) (for greater than minimal risk studies monitored by HDFCCC DSMC)

Study Title

Protocol Number: CC #

Protocol Version Number:

Protocol Version Date:

Study Intervention:

IND Number:

NCT Number:

Principal Investigator (Sponsor-Investigator)

PI Name

University of California, San Francisco

UCSF Address

San Francisco, CA 94143

Telephone: 415-

E-mail:

Statistician

**Revision History**

|  |  |
| --- | --- |
| Version        | Date  |

# Protocol Signature Page

1. I agree to follow this protocol version as approved by the Institutional Review Board (IRB).
2. I will conduct the study in accordance with Good Clinical Practices (ICH-GCP) and the applicable IRB, ethical, federal, state, and local regulatory requirements.
3. I certify that I, and the study staff, have received the required training to conduct this research protocol.
4. I agree to maintain adequate and accurate records in accordance with IRB policies and federal, state and local laws and regulations.

|  |  |  |
| --- | --- | --- |
| **UCSF Principal Investigator**  |  |  |
| Printed Name |  |  |
| Signature |  | Date |

# Protocol Signature Page – Participating Sites

***For multicenter trials only.***

* ***Include this page for participating site to fill in and sign.***
* ***Do not enter participating site Principal Investigator or institution directly into the protocol. This page should be left blank for distribution to participating sites. The site Principal Investigator completes and signs this page.***
* ***Delete this page if the study will be conducted at UCSF only***

I have read this protocol and agree to conduct the protocol in accordance with Good Clinical Practices (ICH-GCP) and the applicable IRB, ethical, federal, state, and local regulatory requirements.

***Instructions to the investigator****: Please* ***SIGN*** *and* ***DATE*** *this signature page.* ***PRINT*** *your name and the name of the facility in which the study will be conducted. Scan and email the completed form to UCSF Helen Diller Family Comprehensive Cancer Center and keep a record for your files.*

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Principal Investigator |  | Date |
| Name of Principal Investigator (Printed) |  |  |
| Name of Facility |  |  |

# Abstract

|  |  |
| --- | --- |
| Title | *Cross-reference Study Title* |
| Study Description | *Provide a short description of the protocol and study design, including a brief statement of the study hypothesis. This section should be 3-5 sentences.*  |
| Study Intervention | *Cross-reference Section 5*  |
| Study Population | *Specify gender, age, race/ethnicity, and general health status* |
| Primary Objective | *Cross-reference Section 2.1* |
| Secondary Objectives | *Cross-reference Section 2.2* |
| Recruitment Methods | *Cross-reference Section 4.2* |
| Sample Size | *State planned number of participants to be enrolled/receive the study intervention. This number can be a range with minimum and maximum projections, depending on protocol design. Information provided here should be consistent with Section 3.2.* |
| Duration of Study Participation | *Describe the amount of time (e.g., in months) it will take for each participant to complete all of the study-related tasks, including administration of the intervention and follow-up. This section should be consistent with Section 5.1 and Section 6.2.* |
| Unique Aspects of this Study | *Optional, for example: “This study is the first to....”* |

| List of Abbreviations*Add/Remove abbreviations as applicable to the study protocol* |
| --- |
| AE | adverse event |
| CRF | case report form |
| CTCAE | Common Terminology Criteria for Adverse Events |
| CTMS | Clinical Trial Management System |
| DSMCDSMP  | Data and Safety Monitoring CommitteeData and Safety Monitoring Plan |
| GCP | Good Clinical Practice |
| HDFCCC | Helen Diller Family Comprehensive Cancer Center |
| HIPAA | Health Insurance Portability and Accountability Act |
| ICF | informed consent form |
| ICH | International Conference on Harmonization |
| IRB | Institutional Review Board |
| PRMC | Protocol Review and Monitoring Committee (UCSF) |

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# Introduction

## Background on <<condition, symptom, behavior, or other primary study focus>>

* *Describe the applicable clinical, epidemiological, or public health background.*
* *Provide a context for the clinical trial issue/focus*
* *Reference citations should be listed in Section 11, References*

## Background on <<study intervention>>

* *Summarize relevant basic and clinical research related to the study intervention, including research conducted in other countries*
* *Discuss important literature and data that are relevant to the trial intervention and that provide background for the trial (reference citations should be listed in Section 11, References)*
* *Describe any relevant gaps, issues, or controversies.*

## Study Rationale

*This section should connect the background information to indicate why the study will provide valuable information/advance knowledge.*

* *Why is the study being done?*
* *What is the intent of the research?*
* *Provide background rationale for evaluating the intervention for this condition or problem.*
* *Indicate why this information is valuable and how will advance knowledge.*

## Risk/Benefit Assessment

*Identify known potential risks from either clinical or nonclinical studies. This information should come from published literature or product information.*

* *Describe any physical, psychological, social, legal, economic, or any other risks to participants who participate in the study that the Principal Investigator (PI) foresees.*
* *If risk is related to proposed procedures included in the protocol, describe alternative procedures that have been considered and explain why alternative procedures are not included.*

*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 a non-coercive inducement to participate or as compensation for time and inconvenience, is not considered a “benefit.” Provision of incidental care is not to be considered a benefit.*

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

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

# Study Objectives and Endpoints

*A study objective is a statement of purpose (e.g., to determine, to evaluate) for a scientific question to be answered about the study’s intervention.*

*A study endpoint is a specific measure or observation (e.g., clinical assessment, condition status, behavior or health outcome) that will be used to address the study objective.*

## Primary Objective

* *The primary objective is the main question. This objective generally drives statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing).*
	+ *Generally, there should be one primary endpoint that will provide a clinically relevant, valid, and reliable measure of the primary objective.*
	+ *Examples of Primary Objectives are included below. Please add/remove/modify as applicable to the study.*
* *Each endpoint should specify:*
	+ *One measure*
	+ *How it is being measured*
	+ *Time frame for the measurement (this information should be included in the ‘Time Frame’ column of the table.*
* *HDFCCC recommends that PIs state objectives and endpoints align with ClinicalTrials.gov registration and reporting requirements.*
	+ *For more information, see Outcome Measures:* [*https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf*](https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf)

| **Primary Objective** | **Endpoint(s)** | **Time Frame** |
| --- | --- | --- |
| 1. <<e.g., To assess the feasibility of…. >>
 | * <<e.g., proportion of individuals who enroll in the study, proportion of participants who complete the study.>>
 | <<e.g., from time of recruitment to the end of study recruitment, from time of enrollment to study completion.>> |

## Secondary Objective(s)

* *The secondary objective(s) are goals that will provide additional information about the study intervention. Secondary objectives can provide supportive information about the study intervention’s effect on the primary endpoint or demonstrate additional effects on the condition or behavior.*
	+ *Examples of Secondary Objectives are included below. Please add/remove/modify as applicable to the study.*
* *Each endpoint should specify:*
	+ *One measure*
	+ *How it is being measured*
	+ *Time frame for the measurement (this information should be included in the ‘Time Frame’ column of the table.*
* *HDFCCC recommends that PIs state objectives and endpoints align with ClinicalTrials.gov registration and reporting requirements.*
	+ *For more information, see Outcome Measures:* [*https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf*](https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf)

| **Secondary Objective** | **Endpoint(s)** | **Time Frame** |
| --- | --- | --- |
| 1. <<e.g., To evaluate the efficacy of…. >>
 | * <<e.g., participant-reported outcomes, change in validated survey score, condition status >>
 | <<e.g., from time of enrollment to study completion. >> |
|  |  |  |

## Exploratory Objective(s)

* *Exploratory objectives aim to explore other effects for new hypotheses or clinically important outcomes that are expected to occur too infrequently to show an effect.*
* *Each endpoint should specify:*
	+ *One measure*
	+ *How it is being measured*
	+ *Time frame for the measurement (this information should be included in the ‘Time Frame’ column of the table.*
* *HDFCCC recommends that PIs state objectives and endpoints align with ClinicalTrials.gov registration and reporting requirements.*
	+ *For more information, see Outcome Measures:* [*https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf*](https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf)

| **Exploratory Objective** | **Endpoint(s)** |
| --- | --- |
|  |  |
|  |  |
|  |  |

# Study Design

## Characteristics

* *Briefly describe the study design and indicate, in general terms, how the design will answer the question posed by the study, as well as theory(ies) or guiding framework(s) on which the intervention(s) is/are based.*
* *Use diagrams to explain design complexities.*
* *A description of the trial design should include:*
	+ *Type/design of trial (e.g., randomized, attention-control, multiple baseline, A-B-A design, dismantling, adaptive, SMART design, optimization trials, repeated measures, group- or cluster-randomized, superiority or non-inferiority design, within-subjects)*
	+ *Method for assigning participants to study groups/arms (i.e., randomized, non-randomized (single-arm design), or N/A). If randomization is used, reference Section 3.3 – Randomization/Assignment to Intervention – for details.*
	+ *Number of study groups/arms*
	+ *Study location (e.g., inpatient or outpatient, clinic, community)*
	+ *Description of intervention and administration*
	+ *Duration of the study intervention and follow-up period(s)*
	+ *If appropriate, description of control group(s)/invention(s) used; attention-control or other comparison conditions. Provide a rationale for the selection of control group(s) and discuss limitations associated with it. Selection of control groups should be based on how best to address the research question. In some cases, subjects can serve as their own controls. If applicable, a statement that an interim analysis is planned and refer to details in Section 9.4.6, Planned Interim Analysis*
	+ *If applicable, a statement that the study includes any stratifications and if so, identify the stratification planned (e.g. sex, race/ethnicity, age, dose) and refer to details in Section 9.4.7, Sub-Group Analyses*
	+ *Other protocol specific details, such as centralization of evaluations (e.g., central laboratory or central reading center for clinical scans)*

## Sample Size

* *State the target number of participants to be evaluated under the study/enrolled in the investigational portion of the study (sample size for primary objective).*
* *If the study includes multiple arms/cohorts, specify sample size needed for each arm/cohort (provide ranges with minimum and maximum projections, if applicable to study design)*
* *State the total number of participants to be consented for the study in order to reach sample size needed- take into account:*
	+ *Screening failures*
	+ *Withdrawals*
* *If participants are to be replaced, this information should also be included in this section. For example:* Participants who do not <<criteria for replacement>> will not be evaluable and will be replaced.

## Primary Completion

The expected primary completion date is <<## months/years>> after the study opens to accrual.

* *The estimated primary completion date is the date that the last study participant will be examined or receive an intervention so that data collection for the primary outcome measure/endpoint is complete.*
* *In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection will be completed for all of the primary outcomes.*
* *For more information see:* <https://clinicaltrials.gov/ct2/help/glossary/primary-completion-date>

## Study Completion

The expected study completion date is <<## months/years>> after the study opens to accrual.

* *The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant’s last visit).*

# Selection and Enrollment of Participants

*Key components of the success of a clinical study are the selection and enrollment of participants who are reasonably representative of the populations or characteristics under investigation to allow for sufficient generalizability. This section should define and describe the study population.*

## Eligibility Criteria

### Inclusion Criteria

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

1. Age <<specify>>
2. Able to understand study procedures and to comply with them for the entire length of the study.
3. Ability of individual or legal guardian/representative to understand a written informed consent document, and the willingness to sign it.
4. <<Diagnosis, state whether diagnosis is self-reported or documented.>>
5. <<Required laboratory, diagnostic, or other testing results required within XXX days of initiation of study intervention.>>
6. <<*Prior therapy requirements or allowances, if any. Consider listing specific prior treatments. Consider listing the allowable duration of prior therapy for the specific population to be studied (e.g., treatment-naïve, treatment-experienced or prior-treatment-failed “salvage” participants).>>*
7. <<If men and women of reproductive capability will be enrolled, indicate whether contraception is necessary and required. If yes, include details of allowable contraception methods for trial.>>
8. <<Other protocol specific inclusion criteria>>

### Exclusion Criteria

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

1. Contraindication to any study-related procedure or assessment.
2. <<Any exclusion related to health status, clinical conditions or other characteristics.>>
3. <<Any exclusion related to pregnancy, lactation, or plans to become pregnant. Specify methods for assessing current status and willingness to use contraception, if applicable.>>
4. <<Any exclusion related to use of drugs or devices or behaviors within XX days of initiation of study intervention.>>

## Recruitment Methods

* *Describe the method for the identification and recruitment of participants for the trial.*
	+ *State how potential participants will be identified and approached.*
	+ *Indicate whether an interview or a run-in period will be used to identify eligibility.*
* *Identify planned recruitment strategies (e.g. university student research pool, patient advocacy groups, online recruitment services, community advisors, national newspaper, local flyers). Include rationale for why the strategy will be appropriate for reaching the targeted study population.*
* *When applicable, consider and include strategies adapted to the cultural context of the study or population.*
* *If recruitment or data collection procedures occur in a public setting, community-based outreach, or other similar settings, describe a plan for ensuring participants’ and study staff’s safety.*
* *For multi-site studies, description and number of recruitment sites (e.g., inpatient hospital setting, outpatient setting, student health service, community center), and anticipated number of participants to be recruited from each site*
* *Include a section to address participant incentives:*
	+ *Specify if participants will be compensated or provided any incentives (e.g. vouchers, gift cards,) for study participation. Describe the type of incentive, amount, and timing of such compensation in relation to study activities (include financial and non-financial incentives).*
	+ *Describe steps to minimize coercion or undue influence (i.e., whether appropriate level of incentive is used so not to be viewed as coercive).*
	+ *Describe who will receive incentives (if not the participant). For example, if participants are minors, state whether the minor or the parent/guardian will receive the incentive. If participants are incapacitated adults, state if payment will be provided to the participant or to a legally authorized representative or guardian.*

## Inclusion of Women and Minorities

### Eligibility of Women and Minorities

Individuals of any sex/gender, race, or ethnicity may participate. << Include specifics about the sex/gender, race, and ethnicity of the study’s target population as applicable.>>

* ***If inclusion of women or minority groups is not appropriate for the trial design, please alter the statement above and provide a clear rationale and justification in the context of the scientific goals of the study.*** *Cost to recruit certain groups is not considered an acceptable justification for limiting the inclusion of those groups, unless substantial scientific data pertinent to the population already exists. For more information, see* [NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research](https://grants.nih.gov/grants/funding/women_min/guidelines.htm)*.*

### Recruitment of Women and Minorities

The study recruitment strategy aims to achieve representation of minority groups that reflects the demographics of the affected population in the catchment area. << Include specifics about the study’s recruitment strategy as applicable.>>

* *The study must include a recruitment strategy consistent with the guidelines set forth by the* [NIH Revitalization Act of 1993, Public Law 103-43](https://www.nap.edu/read/2304/chapter/12)*. This guideline requires consideration of outreach programs to conduct or support recruitment of women and members of minority groups as participants and design of the clinical trial to include a valid analysis plan of whether variables being studied in the trial affect women or minority groups. These recruitment programs should aim to achieve representation of minority groups that reflects the demographics of the affected population in the catchment area.*

## Inclusion Across the Lifespan

### Age Range of Participants

* Address the age range of study participants and justify any age-related exclusions
* The HDFCCC requires that individuals of all ages, including children and older adults, be included in the study population UNLESS there are scientific, ethical, or regulatory reasons not to include them. This requirement is in accordance with the [NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html).
* Acceptable reasons for excluding individuals based on age may include:
	+ The disease or condition does not occur in the excluded age group, or the research topic is not relevant to the excluded age group.
	+ The knowledge being sought in the research is already available for the excluded age group or will be obtained from another ongoing study, and an additional study will be redundant.
	+ A separate, age-specific study in the excluded age group is warranted and preferable. While this situation may represent a justification for excluding individuals based on age, consideration should be given to taking age differences into account in the study design, whenever feasible.
	+ The study will collect or analyze data on pre-enrolled study participants (e.g., longitudinal follow-up studies that did not include data on children, or analysis of an existing dataset) and data inclusive of individuals across the lifespan are not available to address the scientific question.
	+ There are laws or regulations barring the inclusion of individuals in a specific age group in research.
	+ The study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB or peer review.
* **In this section, use the appropriate protocol template language and instructions from A, B, or C below, as applicable to the study/population.**
1. Studies without age-related restrictions
2. Studies enrolling only individuals ages 18 and over
3. Studies enrolling specific age group(s) only (e.g., older adults, children, adolescents)
4. ***For studies without age-related restrictions:***

Individuals of any age are eligible for this study. <<Add any age-related cohorts or planned sub-analysis.>>

<<Provide evidence to support prospective benefit and sufficient justification of risk to children. If this information is stated elsewhere in the protocol, refer to the relevant protocol section(s) here.>>

* Note on inclusion of children (individuals under the age of 18):
	+ Investigators and all study collaborators are encouraged to discuss the inclusion of pediatric participants in the clinical trial early in the protocol development process.
	+ For studies that plan to include participants younger than age 18, a pediatric oncologist coinvestigator must be involved with the study.
	+ Pediatric-specific cohorts should be included in early-phase trials when there is strong scientific rationale for likelihood of benefit, based on molecular pathways or histology as well as preclinical data.
	+ See [FDA Guidance for Industry - Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM633138.pdf?utm_campaign=SBIA%3A%20FDA%20Announces%20a%20Series%20of%20Draft%20Guidances%20Regarding%20Cancer%20Clinical&utm_medium=email&utm_source=Eloqua)
1. ***For studies enrolling only individuals ages 18 and over:***

Individuals ages 18 and over are eligible for this study. <<Add justification for excluding children. Use one of the justifications below if applicable to the study:

* Children are excluded from the study because insufficient data on prospective benefit and/or adverse events for a treatment that includes potentially fatal risks poses unacceptable risk to children.
* Children are excluded from the study because the disease/condition does not occur in children.>>
1. ***For studies enrolling a specific age group:***

Individuals ages <<study population age group>> are eligible for this study. The study population is restricted to this specific age group because <<explain the problem/question unique to this age group justifying research focus and age exclusions>>.

<<If the study population includes children, address the prospective benefit and anticipated risk to children. If this information is stated elsewhere in the protocol, refer to the relevant section(s) here>>.

### Study Design/Recruitment Considerations Related to Age Groups

The study design and recruitment strategy aim to achieve representation of age groups that reflect the demographics of the affected population. <<Include specifics about the age distribution of the affected population and detail the study design and recruitment strategies to ensure adequate representation across the age range of the affected population. If this information is stated above or elsewhere in the protocol, refer to the relevant section(s) here.>>

* To maximize generalizability of results, enrollment should reflect the age distribution of the affected population who is likely to use the investigational drug(s) in clinical practice.
* Therefore, the HDFCCC is committed to improving the underrepresentation of older adults in cancer clinical trials. While upper age limits are now less common in clinical trials, older adults remain underrepresented due to age-related biases in not offering clinical trial participation to potentially eligible patients, restrictive eligibility criteria (e.g., ECOG PS 0-1 only) and increased treatment burden from trial assessments with lack of social support to facilitate participation.
* Additional resources:
	+ *Hurria et al. Designing Therapeutic Clinical Trials for Older and Frail Adults With Cancer: U13 Conference Recommendations. J Clin Oncol 2014; 32: 2587-2594.* [*https://ascopubs.org/doi/10.1200/JCO.2013.55.0418*](https://ascopubs.org/doi/10.1200/JCO.2013.55.0418)
	+ *Kim et al. Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement. J Clin Oncol 2017; 35: 3737-3744.* [*https://ascopubs.org/doi/10.1200/JCO.2017.73.7916*](https://ascopubs.org/doi/10.1200/JCO.2017.73.7916)
	+ *Singh H, Beaver JA, Kim G, Pazdur R. Enrollment of older adults on oncology trials: An FDA perspective. J Geriatr Oncol 2017; 8: 149-150.* [*https://doi.org/10.1016/j.jgo.2016.11.001*](https://doi.org/10.1016/j.jgo.2016.11.001)

## Participant Registration

A written, signed, informed consent form (ICF) and a Health Insurance Portability and Accountability Act (HIPAA) authorization must be obtained before any study-specific assessments are initiated. A copy of the signed ICF will be given to the subject and a copy will be filed in the medical record. The original will be kept on file with the study records.

All participants consented to the study will be registered in OnCore®, the UCSF Helen Diller Family Comprehensive Cancer Center Clinical Trial Management System (CTMS). The system is password protected and meets HIPAA requirements.

*For multicenter studies only:* Each participating site is responsible for OnCore® registration of study participants consented at the site.

## Randomization/Assignment to Intervention

*Describe the randomization or assignment process for assigning participants to different interventions or study groups. Can reference this section to describe randomization in Section 3.1. Remove this section if not applicable to the study.*

* *Include a description or a table that describes how study participants (at the individual or group level) will be assigned to study arms, without being so specific that blinding or randomization may be compromised (e.g., the ratio between intervention and control or comparison groups may be stated).*
* *Specify allocation ratio, unit of randomization, and when in the study timeline randomization will occur (e.g., after enrollment assessment).*
* *In addition, details regarding the implementation of procedures to minimize bias should be included in this section. Do not include details that might compromise these strategies.*
* *The timing and procedures for planned and unplanned breaking of randomization codes should be included.*

## Blinding

*For blinded studies, describe blinding and unblinding methods. Address the following points:*

* *Procedure for retaining the blind (including specific procedures for protecting the blind should data collected in the study offer evidence of a participant’s assignment to a particular study arm)*
* *Individuals authorized to break the blind*
* *Circumstances for breaking the blind*
* *Procedures for breaking the blind.*

# Study Intervention

## Administration and/or Delivery of Study Intervention

* *Indicate each study intervention, and the following information:*
	+ *how it is administered (e.g., to individual participants, to groups of participants)*
	+ *who or how will the intervention be delivered*
	+ *the frequency/schedule*
	+ *where the intervention will be administered (e.g., outpatient, at the participant’s home, exercise laboratory).*
	+ *If information for this section is located in an Intervention Manual included in the protocol as an Appendix, please reference the Appendix here.*

## Interventionist Training and Tracking

* *If protocol objectives depend on consistent administration of study interventionist(s) or experimental manipulation(s), describe a plan for monitoring and ensuring consistent administration (fidelity of delivery).*
* *If the protocol objectives relate to understanding variability in delivery (e.g., an objective of comparing different intensities of an intervention or an objective of examining effects of intervention delivered by a person versus internet-based), describe a plan for how variability will be monitored.*
* *If one or more study interventions will be delivered by interventionists, state how success of training will be assessed (e.g., will supervisors be used for quality assurance of the interventionists?).*
* *If information for this section is located in an Intervention Manual included in the protocol as an Appendix, please reference the Appendix here.*
* *Delete this section if it is not applicable to the study.*

## Modifications to Administration of the Intervention and/or Supportive Care

*Describe modifications to administration of the intervention, if relevant, and guidelines for use of appropriate supportive care or treatments.*

* *Include when administration of the intervention may be modified and instructions for modifications to the study interventions, if appropriate.*
* *Describe the criteria for discontinuing the study intervention, including any monitoring testing/assessments and associated clinical decision points.*
* *Include reasons for temporary discontinuation of the study intervention (e.g., details and quantity of specific adverse events/serious adverse events or clinical worsening), clearly stating the length of time, if applicable.*
* *Identify individuals responsible for determining whether study interventions should be discontinued (e.g., independent clinician or ombudsman) and the specific instruments used to make these determinations. Also describe any approaches for restarting administration of study intervention(s).*
* *If information for this section is located in an Intervention Manual included in the protocol as an Appendix, please reference the Appendix here.*
* *Delete this section if it is not applicable to the study.*

## Adherence Assessment

*Adherence to a study regimen is generally defined as the extent to which participants follow the study regimen or comply with other study requirements as prescribed by the investigators.*

* *Define adherence (e.g., at least 85% of exercise sessions attended).*
* *Provide details as to how adherence to study intervention will be assessed (e.g., pill counts, electronic monitoring devices, attendance at visits, exposure to intervention materials)*
* *In the section on Statistical Analysis (Section 8.3 Analyses Plans), describe how this information will be incorporated into the statistical analysis of the study results.*

## Concomitant Therapy

*In the sections below, describe allowed, required, and prohibited medications, supplements, therapies, non-pharmacologic interventions, and/or procedures for study participants.*

*This information should be consistent with the medications and interventions restrictions in the inclusion/exclusion criteria.*

### Allowed Therapy

*List all drugs and/or treatments/interventions that are allowed on study, including rescue medications and other non-pharmacologic interventions.*

### Required Therapy

*For example, if in weight loss study, vitamin pills may be required.*

### Prohibited Therapy

*Include classes of medications, devices, etc. from the exclusion criteria (Section 4.1.2* Exclusion Criteria*) if they are also prohibited while the participant is on study. If necessary, provide a list of prohibited medications in appendix.*

## Participant Discontinuation/Withdrawal from the Study

* *Provide a list of reasons participation may be discontinued from the study.*
* *Note that participants may withdraw voluntarily from the study or the study intervention at any time.*

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

* Unacceptable adverse event(s)
* Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
* Lost-to-follow up; unable to contact participant (see Section 5.7 - Lost to Follow-Up)
* Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
* The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

## Lost to Follow-up

A participant will be considered lost to follow-up if he or she fails to return for <<specify number of visits>> scheduled visits and study staff are unable to contact the participant after at least 3 attempts. Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a letter to the participant’s last known mailing address or local equivalent methods). These contact attempts will be documented in the participant’s study file. Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

# Study Procedures and Assessments

*The Schedule of Activities below should include all study procedures and evaluations. Use an ‘X’ in a cell to indicate that a particular evaluation is to be performed at a particular study visit. The evaluations listed and their order in the table are only examples. The activities listed should reflect the protocol and should be arranged for clearest presentation. Additional columns may be needed to specify evaluations at intervention failure, at early discontinuation of study interventions, or at other special time points that require a different set of evaluations. In complicated studies with multiple study steps or multiple randomization points, it may be useful to include in the table the time of each step/randomization and the time that study intervention is given to the participant.*

## Schedule of Activities

*Note: If the study involves multiple cohorts/arms, consider creating a schedule for each cohort/arm in order to more clearly identify cohort/arm-specific activities.*

| **Assessments/Procedures** | **Screening** |  |  | **Study Intervention Period** |  |  | **End of Study Intervention** | **Follow-up** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Visit / Day** **(Window, # Days)** | **Visit -1 (D-# to D1)** | **Visit 1 / D1****(+/-#)** | **Visit 2 / D#****(+/-#)** | **Visit 3 / D#****(+/-#)** | **Visit 4 / D#****(+/-#)** | **Visit 5 / D#****(+/-#)** | **Visit 6 / D#****(+/-#)** | **<<Frequency of F/U>>** |
| Informed Consent[[1]](#footnote-2) | **X** |  |  |  |  |  |  |  |
| Inclusion/Exclusion Criteria | **X** |  |  |  |  |  |  |  |
| Medical Record Review | **X** |  |  |  |  |  |  | **X** |
| Concomitant Medications | **X** | **X** | **X** | **X** | **X** | **X** | **X** |  |
| Adverse Events  | **X** | **X** | **X** | **X** | **X** | **X** | **X** | **X** |
| <<Randomization/Assignment to Intervention>> | **X** |  |  |  |  |  |  |  |
| <<Administration of Study Intervention>> |  | **X** | **X** | **X** | **X** | **X** |  |  |
| <<Protocol-Specific Assessments/Procedures>> | **X** | **X** |  |  |  |  | **X** |  |

*Use footnotes to provide more details, such as denoting assessments that may be done remotely via telephone or specific windows/timing for certain activities.*

## Study Procedures and Assessments

*HDFCCC DSMC requires that the schedule of activities be listed in the section below in addition to the calendar marked above.*

### Screening Period / Visit -1 (Day -# to Day 1)

After an individual provides informed consent, the following activities will be performed during the Screening Period:

* Inclusion/exclusion criteria review
* Medical record review - <<specify data collected>>
* Review of concomitant medications
* Adverse Events assessment
* <<Protocol-specific assessments/procedures>>
* <<Randomization/Assignment to Intervention>>

### Study Intervention Period

#### Visit 1 (Day 1 +/- #)

* Review of concomitant medications
* Adverse Events assessment
* <<Administration of Study Intervention>>
* <<Protocol-specific assessments/procedures>>

#### Visit 2 (Day # +/- #)

* Review of concomitant medications
* Adverse Events assessment
* <<Administration of Study Intervention>>
* <<Protocol-specific assessments/procedures>>

### End of Study Intervention / Visit X (Day # +/- #)

* Review of concomitant medications
* Adverse Events assessment
* <<Administration of Study Intervention>>
* <<Protocol-specific assessments/procedures>>

### Follow-up

Participants will be followed *<<* frequency >> for up to << timeframe >> after discontinuing the study intervention. The following procedures will be performed at each follow-up time point:

* Medical record review
* Adverse Events assessment

# Reporting and Documentation of Results

## Measures and Instruments

*Identify and describe any surveys, scales, validated questionnaires, instruments, or other methods use for evaluating safety or other study endpoints. Be sure to include:*

* *What the instrument intends to measure*
* *Is it validated?*
* *Who completes the measure (e.g., participant, practitioner, etc.)*
* *How the measure is completed (e.g., paper, electronic, via telephone)*

# Adverse Events and Serious Adverse Events

*Depending on the nature of the intervention, it may not be necessary to collect adverse events, except those that are considered to be unanticipated problems. Please use or modify the language below for the specific study.*

## Definition of Adverse Event

An adverse event (AE) is defined as any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention related.

## Definition of Serious Adverse Event

An AE that results in any of the following outcomes is defined as a Serious Adverse Event:

* Death,
* Life-threatening adverse experience\*,
* Inpatient hospitalization or prolongation of existing hospitalization,
* Persistent or significant disability/incapacity,
* Congenital anomaly/birth defect, or cancer, or
* Any other experience that suggests a significant hazard, contraindication, side effect or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above,
* Event that changes the risk/benefit ratio of the study.

\*A life-threatening adverse experience is any AE that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.

## Classification of Adverse Events

### Severity

Adverse events are graded according to the Common Terminology Criteria for Adverse Events (CTCAE) as developed and revised by the Common Therapy Evaluation Program (CTEP) of the National Cancer Institute.

### Attribution

Adverse events are further given an assignment of attribution or relationship to study intervention or procedure. Attribution categories are:

* **Definite** – The adverse event is clearly related to the study intervention or procedure.
* **Probable** – The adverse event is likely related to the study intervention or procedure.
* **Possible** – The adverse event may be related to the study intervention or procedure.
* **Unrelated** – the adverse event is clearly not related to the study intervention or procedure.

### Expectedness

An adverse event is considered unexpected if it is not listed in the investigator brochure or package insert(s), or is not listed at the specificity or severity that has been observed, or, if an investigator brochure is not required or available, the event is not consistent with the risk information described in the general investigational plan or elsewhere in the current application.

## Adverse Events Monitoring

*Please include one of the two options below after consultation with the HDFCCC DSMC:*

1. *If the study is considered minimal-risk and will not be monitored by the HDFCCC DSMC, please include the following language:*

This study is a minimal risk level study that does not require monitoring by the HDFCCC Data and Safety Monitoring Committee (DSMC) as per the National Cancer Institute-approved Data and Safety Monitoring Plan. Ultimately, the PI is responsible for the safety and conduct of this study.

1. *If the study is considered above minimal-risk and will be monitored by the HDFCCC DSMC, please add the following:*

Refer to the Data and Safety Monitoring Plan located in Appendix <<X>> for more information.

## Follow up of Adverse Events

All participants who experience adverse events will be followed with appropriate medical management until resolved or stabilized, as determined by the investigator.

## Documenting and Reporting of Adverse Events

*General template language is provided below, please use and/or adjust as applicable to the study.*

Adverse Events will be documented in the study Case Report Forms (CRFs) and reported to the IRB, HDFCCC DSMC, and collaborators in accordance with all applicable institutional and regulatory requirements.

*If the study is considered above minimal risk and includes monitoring by the HDFCCC DSMC, please add the following:*

Refer to the Data and Safety Monitoring Plan located in Appendix <<X>> for more information.

# Statistical Considerations

* *The statistical section should clearly outline how the data will be evaluated in relation to each objective. A biostatistician should write the information in the sections below.*
* *All trials must have a trained statistician who takes responsibility for the statistical aspects of the study. The HDFCCC provides statistical support during the protocol development process for UCSF-sponsored investigator-initiated trials, if needed. Contact the* [*HDFCCC Biostatistics Core*](http://cancer.ucsf.edu/research/cores/biostatistics/) *statistician assigned to your clinical/disease program.*

## Sample Size Considerations

### Sample Size and Power Estimate

* *State the total sample size and all relevant assumptions and calculations. All parameters (e.g., power) used in calculating the sample size should be specified*
* *If the sample size is justified by power, state the null and alternative hypotheses, the significance level and the power, and the method by which it was calculated. Otherwise comment on the expected precision of the estimates to be calculated. If there is uncertainty in the effect size or other aspects of the calculation, provide power for multiple plausible scenarios and explain.*
* *If this study has only a single arm (non-randomized), justify the historical control rate. Refer to the section that summarizes the literature on which it is based.*
* *If this study is a pilot, state what result would convince you to begin a fully powered study.*
* *A reviewer should be able to duplicate the calculations given the information provided.*

### Randomization and Blinding

* *If the study involves randomization, describe the randomization process. If described previously in the protocol, reference the appropriate section.*
* *Who (i.e., what role) will generate and implement the randomization schema.*
* *How randomization errors be handled.*
* *If the study involves blinding, note here whether statistician is/not blinded.*

*If the study does not involve randomization or blinding, remove this section.*

### Stratification Factors

* *Identify any stratification planned (e.g. sex, race/ethnicity, age, dose, etc.) and rationale for stratification. If the study does not involve stratification, remove this section.*

### Accrual Estimates

* *If not mentioned above, provide an estimate of the number of eligible participants yearly. Describe in detail how the estimate was calculated*

## Interim Analyses and Stopping Rules

* *If a statistical stopping rule is described previously, please refer to that section here.*
* *Describe any statistical interim analyses and stopping rules that are proposed, including timing and who reviews the interim analyses. In addition, if the interim analyses could result in an adjusted sample size, discuss the statistical algorithm to be used when evaluating results.*
* *Specify how the stopping rule will preserve the significance level coverage of confidence intervals, or other relevant aspects of inference.*

## Statistical Analysis Plans

* *In the sections below, describe how each objective (particularly the primary objective) will be addressed by a particular data analysis plan. Provide the details of each data analysis plan for each objective – stating what statistical methods will be used, and under which assumptions. Every objective, every study endpoint should have a plan associated with it.*
* *Confirm that plans analyze the assessments described in the protocol and satisfy the objectives stated in Section 2. referring to those sections as appropriate. Describe any plans for descriptive statistics and exploratory data analysis.*

### Analysis Populations

* *Describe defined subsets of enrolled participants who will be used for different kinds of statistical analysis, if applicable.*

### Primary Analysis (or Analysis of Primary Endpoints)

* *Describe in detail the statistical methods to be used to address the study’s primary objective. Define the participant cohort to be analyzed, state the primary endpoint(s), and explain how the results will be interpreted.*
* *This information should be consistent with objective(s) and endpoint(s) listed in* [Section](#_Primary_Objective_and) 2.1*.*

### Secondary Analysis (or Analysis of Secondary Endpoints)

* *If secondary endpoints are included in this study, please specify how they will be analyzed. If the analysis is inferential and not descriptive, the power for each endpoint to be analyzed should be discussed.*
* *This information should be consistent with objective(s) and endpoint(s) listed in Section 2.2.*

### Exploratory/Correlative Analysis/Assessments

*Should be consistent with objective(s) and endpoint(s) listed in Section 2.3.*

# Study Management

## Pre-study Documentation

Before initiating this trial, the PI will have written and dated approval from the Institutional Review Board for the protocol, written informed consent form, subject recruitment materials, and any other written information to be provided to participants before any protocol related procedures are performed on any participants.

The PI must comply with GCP/ICH guidelines and all applicable regulatory requirements.

## Institutional Review Board Approval

The protocol, the proposed informed consent form, and all forms of participant-facing materials related to the study (e.g., advertisements used to recruit participants) will be reviewed and approved by the IRB. The initial protocol and all protocol amendments must be approved by the IRB prior to implementation.

## Informed Consent

All participants must be provided a consent form describing the study with sufficient information for each participant to make an informed decision regarding their participation. Participants must sign the IRB-approved informed consent form prior to participation in any study specific procedure. The participant must receive a copy of the signed and dated consent document. The original signed copy of the consent document must be retained in the medical record or research file.

## Changes in the Protocol

Once the protocol has been approved by the IRB, any changes to the protocol must be documented in the form of an amendment. The amendment must be signed by the PI and approved by the IRB prior to implementation.

If it becomes necessary to alter the protocol to eliminate an immediate hazard to participants, an amendment may be implemented prior to IRB approval. In this circumstance, however, the PI must then notify the IRB according to institutional requirements.

*For multicenter studies add:* The Study Chair and the UCSF study team will be responsible for updating any participating sites.

## Case Report Forms (CRFs)

The PI and/or designee <<*for multicenter studies, add:* at each study site>> will prepare and maintain adequate and accurate participant case histories with observations and data pertinent to the study. Study specific Case Report Forms (CRFs) will document study data for safety monitoring and data analysis. All study data will be entered into <<OnCore® or other CTMS used for the study>> via standardized CRFs in accordance with the CTMS study calendar, using single data entry with a secure access account. Study personnel <<*for multicenter studies, add:* for each study site>> will complete the CRFs; the PI <<*for multicenter studies, add:* for the study site>> will review and approve the completed CRFs.

The information collected on CRFs shall be identical to that appearing in original source documents. Source documents will be found in the participant’s medical records maintained by study personnel. All source documentation should be kept in separate research files for each participant.

In accordance with federal regulations, the PI <<*for multicenter studies, add:* at each study site>> is responsible for the accuracy and authenticity of data entered onto CRFs. The PI will approve all completed CRFs to attest that the information contained on the CRFs is true and accurate.

All source documentation and CTMS data will be available for review/monitoring. <<*For multicenter studies where the HDFCCC DSMC is responsible for monitoring, add:* The DSMC performs remote review/monitoring for non-UCSF participating sites. Study personnel at non-UCSF participating sites must upload source documents into the PC console of OnCore (or an alternative HIPAA compliant repository) prior to scheduled DSMC remote monitoring or auditing. The source documents for review will need to be organized by the study team prior to uploading into OnCore. >>.

## Record Retention

The PI is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each study participant. Study documentation includes all CRFs, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed participant consent forms). Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study. The PI shall retain records for a period of 2 years following the conclusion of the study.

## Publications

*Template language is provided below. Modify or replace with specific processes regarding publication of study data.*

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the Sponsor-Investigator and collaborators.

## Multicenter communication *(for multicenter studies only – remove this section if the study will only be conducted at UCSF)*

The UCSF Coordinating Center provides administration, data management, and organizational support for the participating sites in the conduct of a multicenter clinical trial. The UCSF Coordinating Center will also coordinate, at minimum, monthly conference calls with the participating sites, at the completion of each cohort or more frequently as needed to discuss risk assessment. The following issues will be discussed as appropriate:

* Enrollment information
* Cohort updates
* Adverse events (i.e. new adverse events and updates on unresolved adverse events and new safety information)
* Protocol violations
* Other issues affecting the conduct of the study

## Regulatory Documentation (for multicenter studies only – remove this section if the study will only be conducted at UCSF)

Prior to implementing this protocol at UCSF or any participating site, the protocol, informed consent form, and any other information pertaining to participants must be approved by the UCSF IRB. Prior to implementing this protocol at the participating sites, approval of the UCSF IRB approved protocol must be obtained from the participating site’s IRB.

The following documents must be provided to UCSF HDFCCC before the participating site can be initiated and begin enrolling participants:

* Participating Site IRB approval(s) for the protocol, informed consent form, and HIPAA authorization
* Participating Site IRB approved consent form
* Participating Site IRB membership list
* Participating Site IRB’s Federal Wide Assurance number and OHRP Registration number
* Curriculum vitae and medical license for each investigator and consenting professional
* Documentation of Human Subject Research Certification training for investigators and key staff members at the Participating Site
* Participating site laboratory certifications and normal (if applicable).

Upon receipt of the required documents, UCSF HDFCCC will formally contact the site and grant permission to proceed with enrollment.

# Protection of Human Subjects *(for multicenter studies only – remove this section if the study will only be conducted at UCSF)*

## Protection from Unnecessary Harm

Each clinical site is responsible for protecting all participants involved in human experimentation. This is accomplished through the IRB mechanism and the process of informed consent. The IRB reviews all proposed studies involving human experimentation and ensures that the participant’s rights and welfare are protected and that the potential benefits and/or the importance of the knowledge to be gained outweigh the risks to the individual. The IRB also reviews the informed consent document associated with each study in order to ensure that the consent document accurately and clearly communicates the nature of the research to be done and its associated risks and benefits.

## Protection of Privacy

Participants will be informed of the extent to which their confidential health information generated from this study may be used for research purposes. Following this discussion, they will be asked to sign the HIPAA form and informed consent documents. The original signed document will become part of the participant’s medical records, and each participant will receive a copy of the signed document. The use and disclosure of protected health information will be limited to the individuals described in the informed consent document.

# References

Appendix 1: Data and Safety Monitoring Plan

*Only for studies categorized as greater than minimal risk according to the HDFCCC Data and Safety Monitoring Plan (DSMP): include the DSMC-approved Data and Safety Monitoring Plan here. Templates are available on the HDFCCC website, at:* <http://cancer.ucsf.edu/itr/itr-dsm>.

***Minimal-risk studies should delete this Appendix.***

*Consult with the HDFCCC DSMC regarding the study’s risk level.*

Appendix 2: Intervention Manual

*If the protocol uses a manual to describe detailed instructions for providing the study intervention, include the manual here.*

*Please remove this appendix if the study does not use an intervention manual.*

1. Informed consent must be obtained prior to any study-specific procedures and may be obtained prior to the screening window. [↑](#footnote-ref-2)