*Instructions in italics should be deleted from the final protocol.*

*This protocol template is designed for research studying a therapeutic intervention that does not require an IND or IDE from the FDA.*

*If your research requires an IND or IDE from the FDA, use a GCP protocol template. If you are not studying a therapeutic intervention, use a shorter protocol template. See the COMIRB website for* [*Protocol Templates*](https://research.cuanschutz.edu/comirb/home/forms/comirb-forms)*. Contact* *COMIRB@ucdenver.edu* *if you have questions about appropriate protocol templates or levels of review.*

**Study Title:**

**Protocol (COMIRB) Number:**

**Principal Investigator:**

**Version Number:**

**Version Date:**

**Sponsor (if any):**

**1. Study Rationale**

*State the problem or question (e.g., describe the population, disease, current routine care, and limitations of knowledge or current usual care). State the reason for conducting the clinical trial. State the name and the nature of the intervention. Identify the hypothesized target(s) of the intervention, and the clinical or social outcomes of interest.*

<Insert text>

**2. Background**

*Provide applicable background and/or context (e.g., clinical, social/behavioral, epidemiological, public health) for the topic. Summarize relevant basic, clinical, social or behavioral research. Discuss important literature and data that provide background for the trial and that address the rationale underlying the intervention. List citations at the end under References.*

<Insert text>

**3. Objectives and Endpoints**

*Describe the study objectives and endpoints. An objective is the reason for performing the study related to the scientific question(s) being explored. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate, to explore) and incorporate the overall intent (e.g., feasibility, acceptability, effectiveness, dissemination, implementation, observation, exploration).*

*A study endpoint is a specific measurement or observation to assess the effect of the study intervention. Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested. Give succinct and precise definitions of the study endpoints used to address the study’s primary objective and secondary objectives (e.g., specific diagnostic tests that define effectiveness, assessments of psychosocial characteristics, participant or group acceptance, participant or group reported outcomes).*

<Insert text>

**4. Study Design**

*State the hypothesis (es) associated with the objectives and endpoints. Describe the type/design of the study. Define the number of study groups/arms and the duration of the study intervention. Indicate if single site or multi-site. Describe how participants are assigned to study groups, randomization and blinding, as applicable. Insert a schematic to illustrate the study design if helpful.*

<Insert text>

**5. Study Population**

*Describe the population(s) to be studied. Inclusion criteria are characteristics that every potential participant must satisfy to qualify for study entry. Exclusion criteria are characteristics that make an individual ineligible for study participation. If the study involves more than one study population, describe criteria for each population. The description of the study population should match the level of analysis. For example, if the evaluation will be at the group level, instead of a participant level, the target groups should be described.*

**Population:** <Insert text>

**Inclusion Criteria:**

* <Insert text>

**Exclusion Criteria:**

* <Insert text>

**Strategies for Recruitment and Retention:**

*Identify general strategies for participant recruitment and retention. When applicable, consider and include strategies adapted to the cultural context of the study or population. For multi-site research, identify the sites where participants will be recruited and the anticipated number of participants to be recruited from each site. Submit all recruitment materials (e.g., advertisements, invitations, and/or other solicitations).*

*If incentives will be offered to participants describe the type of incentive (e.g., vouchers, gift cards, gift items), amount, and the timing and/or conditions for compensation in relation to study activities. If participants are minors, state whether the minor or the parent/guardian will receive the incentive.*

<Insert text>

**6. Study Intervention**

*Describe the study intervention and/or product, including any control or comparison interventions, conditions or products (e.g., placebo). Describe how the study intervention will be administered, including frequency or schedule; whether there will be interventionists (i.e., a specified individual who administers the intervention); the setting in which the intervention will be delivered; and the treatment course, number of sessions constituting a complete or “full-dose” intervention. If the study will have different intervention groups, discuss why there is equipoise between the different study arms.*

*For studies of drugs or dietary supplements, describe the drug/supplement and control product, if any. Describe the procedures for selecting each participant's dose, including the timing of dosing, the duration, the planned route of administration, and the relation of dosing to meals.*

*For studies of devices, provide a description of each important component, property and the principle of operation of the device.*

*For behavioral interventions, include the parameters that are relevant to delivery of the intervention and control/comparison condition, as relevant (e.g., intensity, duration, and/or frequency/number of sessions; number, difficulty level and/or intervals between trials in computer-administered intervention applications). Specify whether participants will interact with other participants or with a shared interventionist after assignment to study arms, and whether face-to-face or virtually.*

<Insert text>

**7. Discontinuation and Participant Withdrawal**

*Describe the criteria for discontinuing the study intervention (e.g., halting rules), including any monitoring tests and associated clinical decision points. Include reasons for temporary discontinuation of the study intervention (e.g., type and quantity of adverse events), clearly stating the length of time, if applicable, and describe the data to be collected at the time of study intervention discontinuation and approaches for restarting administration of or rechallenging with study intervention.*

*Provide a list of reasons participation may be discontinued. Include a discussion of replacement of participants who withdraw or discontinue early, if replacement is allowed. Describe efforts that will be made to continue follow-up of participants who discontinue the study intervention, but remain in the study for follow-up. Reasonable efforts must be made to undertake protocol-specified safety follow-up procedures to capture adverse events (AE), serious adverse events (SAE), and unanticipated problems (UPs). Define when participants are lost to follow-up and describe plans to minimize loss to follow-up and missing data.*

<Insert text>

**8. Study Assessments and Procedures**

*Describe study procedures, measures, and assessments. Note if a specifically qualified person (e.g., physician, psychologist) should be performing any of the assessments. Distinguish between procedures and evaluations required for screening, performed to support determinations of efficacy, and performed to monitor safety.*

*Capture the procedures that will be accomplished at each study visit, and all contact with study participants (e.g., telephone contacts). Describe any restrictions during any parts of the study (e.g., fasting or other dietary restrictions). Describe the nature and duration of study follow-up. Insert a table if helpful to illustrate the schedule of activities.*

*If study procedures include obtaining information through a review of existing data (e.g., review of health records), identify the source records and describe the data to be obtained.*

*If biological specimens are collected, identify the types of specimens and timing of collection. Distinguish between specimens requiring a research procedure (e.g., research blood draw) versus specimens obtained from remnant or discarded clinical specimens.*

*Identify all instruments used in the study (e.g., surveys, interview and/or focus group guides, etc.). Validated and published instruments should be clearly identified with citations and need not be submitted with the protocol and application. Submit any other instruments used for this study.*

*Address whether the results of any research procedures will be provided to participants (e.g., imaging, laboratory tests, or behavioral assessments).*

*When applicable, discuss any cultural adaptations that will be implemented.*

<Insert text>

**9. Risk/Benefit Assessment**

*Describe potential risks (e.g., physical, psychological, social, legal, economic, or other) that individual participants could experience as a result of the study, in the short or long term. Include a discussion of known potential risks from previous studies. If studying a licensed medical product, the package insert or device labeling should be used as the primary source of risk information. Consider whether the research has potential for group or social risks and, if so, describe those potential risks.*

Risks: <Insert text>

*Describe potential benefits (e.g., physical, psychological, social, legal, or other) to individual participants, participating groups, or society in general, as a result of participating in the study. Do not include financial or other compensation to participants in this section (see Recruitment and Retention below).*

Benefits: <Insert text>

**10. Safety Monitoring Plan**

*Describe the overall plan for ongoing monitoring of subject safety and safety of the study interventions during the trial. Include a description of roles that will be responsible for monitoring safety and any real-time or acute assessments/triage that might be needed based on the study procedures. 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. Provide the definitions of an adverse event (AE) and serious adverse event (SAE), describe how AEs will be recorded, assessed and reported. The language below is provided as an example. Edit as appropriate.*

**Adverse Events and Serious Adverse Events**

Adverse event (AE) means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. An AE or suspected adverse reaction is considered a "serious" adverse event (SAE) if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

All AEs will be captured on a study case report form (CRF). Information to be collected includes event description, time of onset, clinician’s assessment of severity, relationship to study procedures and/or intervention (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

A clinician with appropriate expertise in <insert condition> will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected, and an unanticipated problem (UP), if the nature, severity, or frequency of the event is not consistent with the risk information previously described or provided for the study procedures. UPs will be reported to the IRB as soon as possible, but in no event later than 5 working days after the PI first learns of the event.

AEs will be compiled and reported to the <describe as appropriate: Data and Safety Monitoring Board (DSMB) as outlined in the DSMB charter, Safety Monitor, etc.>. *(For research subject to oversight by the Cancer Center Data Monitoring Committee, reference Cancer Center policy.)*

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the <sponsor, Data and Safety Monitoring Board (DSMB), safety monitoring committee, independent safety monitor> as soon as possible, but in no event later than 5 working days after the PI first learns of the event.

**11. Data Analysis**

*Describe the statistical tests and analysis plans for the protocol. They should indicate how the study will answer the most important questions with precision and a minimum of bias, while remaining feasible. State the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specifying the type of comparison (e.g., superiority, equivalence or non-inferiority, dose response) and time period for which each endpoint will be analyzed.*

*Include number of participants to recruit, screen, and enroll to have adequate power to test the key hypotheses for the study. Provide information to validate your calculations and judge the feasibility of enrolling and following the necessary number of participants.*

*For qualitative research, describe the analytical methodology. For descriptive statistics, describe how categorical and continuous data will be presented (e.g., percentages, means with standard deviations, median, range). For inferential statistics, indicate the p-value and confidence intervals for statistical significance (Type I error) and whether one or two-tailed.*

<Insert text>

**12. Informed Consent Process**

*Describe how informed consent will be administered. Describe any proposed waivers or alterations to informed consent. Outline plans for obtaining consent from non-English speakers.*

*For research on children, address obtaining consent from parents or guardians, and obtaining assent from the child. If applicable, address re-consent processes for children who become adults during the study.*

*If screening or enrolling adults unable to consent on their own behalf, describe procedures for determining competency and assessing participants' understanding of the research. If applicable, describe procedures for obtaining consent from a proxy or LAR for adults unable to consent on their own behalf.*

*Submit all consent documents (e.g., consent forms, assent forms, information sheets, "postcard consents," consent scripts, web-based consent materials, audio/visual content, and any other related consent material).*

<Insert text>

**13. Confidentiality and Privacy**

*Describe protections for maintaining confidentiality of participant data, including, but not limited to forms, records and samples. Describe any special data security measures (password-protected database, encryption, locked drawer, other). Describe whether identifiers will be attached to data or specimens, or whether data will be coded or permanently unlinked from identifiers. If research data/samples will be coded, describe how access to the “key” for the code will be limited.*

*Include a discussion of the circumstances in which data or samples will be shared with other researchers. Describe any situations in which personally identifiable information will be released to third parties. Indicate who has access to records, data, and samples. Consider if monitors or auditors outside of study investigators will need access.*

*Certificate of Confidentiality: If the research is covered by a certificate of confidentiality, explain that anyone with access to research records will not disclose identifying information except when the participant consents or in instances prescribed by the certificate of confidentiality (i.e., when federal, state, or local law or regulation requires disclosure.) Note that all NIH-funded research projects are covered by a certificate of confidentiality.*

<Insert text>

**14. References**

*List relevant literature and cite all publications referenced in the text of the protocol.*

<Insert text>