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

*This protocol template is designed for observational research and research involving non-therapeutic interventions.*

*Use a different protocol template for research on therapeutic interventions. See the COMIRB website for* [*Protocol Templates*](https://research.cuanschutz.edu/comirb/home/forms/comirb-forms)*. Contact* [*COMIRB@ucdenver.edu*](mailto: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 research.*

<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 research. List citations at the end under References.*

<Insert text>

**3. Objectives**

*Describe the study objectives. 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).*

<Insert text>

**4. Study Design**

*State the hypothesis (es), if any. Describe the type/design of the study. Indicate if single site or multi-site.*

<Insert text>

**5. Study Population**

*Describe the population 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 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. Describe any restrictions during any parts of the study (e.g., fasting or other dietary restrictions). Identify procedures required for screening.*

*Insert a table if helpful to illustrate the schedule of activities. Capture the procedures that will be accomplished at each study visit, and all contact with study participants (e.g., telephone contacts).*

*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>

**7. 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 and/or known risks from medical products or procedures used in the research. 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>

**8. Unanticipated Problems**

*Describe the process for monitoring participants for unanticipated problems. The language below is provided as an example. Edit as appropriate.*

The study team will monitor participants for unanticipated problems (UPs). A UP is any untoward medical event associated with the study procedures, 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.

**9. Data Analysis**

*Clearly define the outcomes this study will use to achieve its aims, and distinguish primary from secondary outcomes, if appropriate. 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. Include a power calculation or other justification of sample size here.*

<Insert text>

**10. Future Research of Stored Specimens**

*If biological specimens will be retained for future research not encompassed by this protocol, explain how specimens and associated data will be managed and distributed for future research. Include where specimens will be stored and estimate how long specimens will be stored. Indicate whether specimens might be released to other research teams on campus or released to collaborators at other institutions. Explain how samples would be identified prior to release (e.g., specimens will be coded and participant identifiers will not be released). Indicate the conditions under which evidence of IRB approval of the future study will be required. Address future research in the consent form. Delete this section if not storing specimens for future research.*

<Insert text>

**11. 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>

**12. 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 the study team 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>

**13. References**

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

<Insert text>