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

*This protocol template is designed for Exempt Research, Categories 1, 2 or 3. These categories are explained on the* [*COMIRB website - Review Levels*](https://research.cuanschutz.edu/comirb/home/info/review-levels#exempt)*.*

*Use a different protocol template for expedited or full board research, or for secondary research. 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 and the reason for conducting the research. If there is an educational intervention (Exempt Category 1 only), state the name and the nature of the intervention, and explain the underlying rationale.*

<Insert text>

**2. Background**

*Should be approximately half a page. Provide applicable background and/or context (e.g., educational, epidemiological, public health, or social) for the topic. Summarize any previous relevant 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) associated with the objectives. Describe the study design; be specific and cite relevant literature for design and/or methods. Indicate if single site or multi-site.*

<Insert text>

**5. Study Population**

*Describe the population to be studied. List inclusion and exclusion criteria. 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. 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, if any (Exempt categories 1 and 3 only)**

*Describe the study intervention and any control or comparison conditions being used in the study. Delete this section for observational research. Note that most behavioral interventions are ineligible for review under exempt category #3 and should be submitted for Expedited review.*

<Insert text>

**7. Study Assessments and Procedures**

*Describe study procedures, measures, and assessments. If study procedures include obtaining information through a review of existing data (e.g., review of school records), identify the source records and describe the data to be obtained. 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. When applicable, discuss any cultural adaptations that will be implemented.*

<Insert text>

**8. Risk/Benefit Assessment**

*Describe potential risks and benefits (e.g., physical, psychological, social, legal, or other) that individual participants could experience as a result of the study. Consider whether the research has potential for group or social risks and, if so, describe those potential risks.*

<Insert text>

**9. Data Analysis**

*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).*

<Insert text>

**10. Informed Consent**

*Describe how participants are informed about the research and asked for their voluntary participation. Outline plans for inclusion of non-English speakers. For research on children, address obtaining permission from parents or guardians, and obtaining assent from the child.*

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

<Insert text>

**11. References**

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

<Insert text>