TYPE OF REVIEW – NON HUMAN SUBJECTS RESEARCH DETERMINATION/ETHICAL EVALUATION

Determination Date: November 09, 2022

IRB ID: 10502-NKulper

Protocol: HEADS UP! Outreach to At-Risk Groups Formative Research

Sponsor: Centers for Disease Control and Prevention (CDC), Division of Injury Prevention (DIP)

Principal Investigator: Nora Kuiper, MPH

Sterling IRB is in receipt of submission materials for the above-referenced study.

- Exemption or Non-Human Subjects Research Determination Request
- FG Guide Parents_English
- FG Guide Parents_ES-US
- FG Guide Youth
- Consent Form_Parent Participat_English
- Consent Form_Parent Participat_ES-US
- Parental Consent Form for Youth Participant

Based on the information available to the IRB, the Sterling IRB Chairman (or designee) has determined that this submission does not constitute human subjects research, and is therefore ineligible for IRB approval. Although it is not within the IRB's jurisdiction to approve non human subjects research, the IRB Chairman (or designee) has conducted an ethical evaluation of the above-referenced study to assess whether any aspect of the study, as submitted, appears to violate any human subject protections. Following review, the IRB Chairman's (or designee's) assessment of the study is as follows:

The above-referenced study, as submitted to Sterling IRB, does not appear to be in violation of any human subject protections.

This evaluation *does not* constitute IRB approval of the proposed study.

Sterling IRB's determination that the materials submitted are non human subjects research and its ethical evaluation assessment are based on the study-related information available to Sterling IRB as of the determination date listed above. Should any changes be made to the study subsequent to Sterling IRB's determination, the determination noted herein as well as the findings of this evaluation and are no longer applicable.

As the project applicant you are responsible for following all policies of Sterling IRB as described in the Exemption or Non-Human Subjects Research Determination Request Submission Agreement which you accepted with project submission. It is your responsibility to ensure this project is conducted in accordance with applicable regulations (local, state and federal) as well as any requirements established by the IRB at the time of the review determination. Refer to the Investigator Handbook at www.sterlingirb.com for details of these responsibilities.

The Board will be apprised of this evaluation.