MEMORANDUM

Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: April 25, 2018

FROM: Chair, Research Involving Human Subjects Committee

SUBJECT: RIHSC Study #18-028CTP
Study Title: "The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use"
Principal Investigator & FDA Sponsor: Maria Roditis, PhD; CTP

TO: Maria Roditis, PhD; CTP
Carolyn Dresler, MD; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your study submission, entitled, "The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use." Your study proposes to determine if television ads designed to prevent youth from using tobacco are understandable and engaging. Approximately 4000 youth aged 13 to 17 who are tobacco experimenters or susceptible non-users and 1000 adults will view ads and complete a questionnaire. Because your study is no more than "minimal risk," it can be reviewed using the expedited procedure outlined in 45 CFR 46.110.

Below are comments for your consideration. If you make changes to your protocol and/or informed consent documents (assent, consents, and parental permissions) in response to these comments, please submit the altered documents in an amendment.

Comments
1. In both screening forms you refer to questions that are not on the document. For instance, see question B_1 on the adult screener and D1 on the youth screener. Each one refers to a question that is not included on the screener.

2. Consider whether you should have a Certificate of Confidentiality for this study. Please consult with your Center's point of contact for Certificates of Confidentiality. The protections and limits to protections provided by the Certificate should be described in the informed consent document.

The Chair has determined your study satisfies the criteria outlined in 45 CFR 46.404 for research not involving greater than minimal risk to children. The requirement for documentation of informed consent is waived for subject and parent/guardian consent to screening, and the requirement for documentation of assent, consent, and parental permission is waived under 45 CFR 46.116(d). Consent for screening, assent, consent, and parental permission will be obtained before eligible subjects start the study.

Your study is **APPROVED.**

EFFECTIVE PERIOD OF APPROVAL:
This study has been approved from April 25, 2018 to April 24, 2019.

FDA IRB:
Research Involving Human Subjects Committee
US Food and Drug Administration
FWA #00006196
Chair: Jeffrey DeGrasse, PhD

RESPONSIBILITIES:
The Principal Investigator is responsible for ensuring that the investigation is conducted according to the approved protocol and applicable regulations and for protecting the rights, safety, and welfare of subjects. The Principal Investigator is also responsible for complying with the following requirements:
1. Promptly reporting to the RIHSC all changes in the research activity including any modifications to protocol or parental permission or assent forms. [45 CFR 46.103(b)(4)(iii)] Changes in approved research may not be initiated without RIHSC review and approval except when necessary to eliminate apparent immediate hazards to the subjects. [45 CFR 46.103(b)(4)(iii)]
2. Promptly reporting to the RIHSC all unanticipated problems involving risk to human subjects or others. [45 CFR 46.103(b)(5)(I)]
3. Providing periodic reports to the RIHSC, as required. [45 CFR 46.109(e)]

PROGRESS OR FINAL REPORT:
If you wish to continue your study beyond April 24, 2019, you will need to submit a CONTINUING REVIEW APPLICATION FORM and applicable materials to the RIHSC no later than February 15, 2019.

If your study is completed or terminated within the next year, please submit a FINAL REPORT to the RIHSC Executive Director. This report should contain the following information, if applicable:

1. RIHSC FILE Number/Study Title/Study Investigator(s)/Institution where study is being/was conducted.
2. Brief summary of the project status, including a description of all changes, amendments, or supplements to the previously approved protocol and consent form.
3. Number of subjects initially approved by the RIHSC for inclusion in the study and the number actually entered into the study.
4. Number of subjects whose participation was completed as planned.
5. Number of subjects that dropped out of the study.
6. Summary of Adverse Events that can reasonably be attributed to the study.
7. List of abstracts or publications, and/or a brief description of any available study results.

If you have questions, or would like further information, please do not hesitate to contact the RIHSC Program Management Staff by email at RIHSC@fda.hhs.gov, or by phone at (301) 796-9605.