IRB Chair Letter

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Food and Drug Administration
Research Involving Human Subjects Committee

DATE: May 17, 2016
FROM: Chair, Research Involving Human Subjects Committee
SUBJECT: RIHSC Protocol #16-034T
Study Title: "Online Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use among General Market Youth (Wave 3)"
Principal Investigator: David Cortes, MA; FCB
FDA Sponsor: Tesfa Alexander, PhD; CTP
TO: Tesfa Alexander, PhD, CTP
Cathy Backinger, PhD, MPH; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your proposal, entitled, "Online Quantitative Study of Youth Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use among General Market Youth (Wave 3)." This study proposes to conduct research with the target audience (youth aged 13-17 years) to gain insight into their tobacco-related knowledge, attitudes, beliefs, and behaviors. The purpose is to further inform FDA's ongoing efforts to prevent and reduce tobacco use among youth 12-17 years old who have experimented with cigarettes or who are at risk of initiating cigarette use.

Because your study is no greater than minimal risk, it could be reviewed using the expedited procedure outlined in 45 CFR 46.110.
The RIHSC determined your study satisfies the criteria outlined in 45 CFR 46.404 for research not involving greater than minimal risk to children. Assent and parental permission will be obtained prior to the start of the study.
Dr. Alexander's human subject protection training will expire September 5, 2016. Please update the training and submit update to RIHSC by August 1, 2016.
Your protocol is APPROVED.
EFFECTIVE PERIOD OF APPROVAL:
This protocol has been approved May 17, 2016 to May 16, 2017.
FDA IRB:
Research Involving Human Subjects Committee, FWA #00006196
Chair: Jeffrey DeGrasse, PhD
Office of the Commissioner
Food and Drug Administration

RESPONSIBILITIES:
The Principal Investigator is responsible for ensuring that the investigation is conducted according to the investigational plan 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 the Study Protocol or Informed Consent. 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 the approval date of May 16, 2017, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than March 15, 2017.
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.