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

DATE: July 27, 2012

FROM: Chair, Research Involving Human Subjects Committee

Subject: **RIHSC Protocol #12-076C(TP)**
Study Title: "Experimental Study on the Presentation of Harmful and Potentially Harmful Tobacco Constituents"
FDA Sponsor & PI: Laura Shay, PhD, CTP

To: **Laura Shay, PhD**, CTP
Lester Lacorte, MD, CTP Liaison to the RIHSC

Your protocol entitled "Experimental Study on the Presentation of Harmful and Potentially Harmful Tobacco Constituents" has been reviewed by the Research Involving Human Subjects Committee (RIHSC). The purpose of your study is to understand adolescent perceptions and knowledge about health and tobacco marketing and advertising. You propose to conduct focus groups with adolescents and adults to determine opinions and assist in developing educational materials to raise awareness about disease and disability caused by tobacco products.

Because the study can be classified as "minimal risk", i.e. research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group program evaluation, human factors evaluation, or quality assurance methodologies, it can 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 survey.

Your protocol is APPROVED.

EFFECTIVE PERIOD OF APPROVAL:
This protocol has been approved from July 27, 2012 - July 26, 2013.

IRB OF RECORD:
Research Involving Human Subjects Committee, FWA #00006196
Chair: Luciana Borio, MD
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 July 26, 2013, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than May 1, 2013.

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 Martha Monser at 301-796-4627 or by email at martha.monser@fda.hhs.gov and Rhondalyn Cox at RIHSC@fda.hhs.gov .

Luciana Borio, MD
Chair, RIHSC