IRB Chair Letter

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

DATE: *November 30, 2017*

FROM: *Chair, Research Involving Human Subjects Committee*

SUBJECT: *RIHSC Study #17-078CTP*
Study Title: "Qualitative Study on Consumer perceptions of Cigarettes Health Warning Images"
Principal Investigator: Denise Dickinson, MPH; RTI International
FDA Sponsor: David Portnoy, PhD, MPH; CTP

TO: *David Portnoy, PhD, MPH; CTP*
Cathy Backinger, PhD, MPH; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your study, entitled, "Qualitative Study on Consumer perceptions of Cigarettes Health Warning Images." Your study proposes to conduct a series of 20 focus groups with adults and youth (16 to 17 years old) to evaluate consumer comprehension, perceptions, and reactions to cigarette graphic health warning images.

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.

The RIHSC waives the requirement for documentation of informed consent for subject assent and parental permission, under 45 CFR 46.116(d), before the subjects are screened for eligibility.

Your study is APPROVED.

EFFECTIVE PERIOD OF APPROVAL:
This study has been approved November 30, 2017 to November 29, 2018.

Below is a comment for your consideration. If you make changes to your protocol and informed consents in response to this comment, please submit those altered documents in an amendment.

Comment:
1. Certificate of Confidentiality (CoC)
A. Original Statement: Certification of Confidentiality (CoC), is not addressed in the protocol, and there is no statement about it in the protocol and the consent documents.
B. Issue/Justification: The 21st Century Cures Act requires certificates of confidentiality for certain human subject research.
C. Consideration: The statements need to be included in the protocol and informed consent documents if you determine (after working through your Center) that a CoC is needed.

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 November 30, 2018, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than September 15, 2018.

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.

Signed By: 

IRB Chair