IRB Chair Letter

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

DATE: May 17, 2017
FROM: Chair, Research Involving Human Subjects Committee
SUBJECT: RIHSC Protocol #17-032CTP
Study Title: "Experimental Study on Warning Statements for Cigarette Graphic Health Warnings"
Principal Investigator: James M. Nonnemaker, PhD, MSPH, BS; RTI International
FDA Sponsor: David B. Portnoy, PhD, MPH; CTP
TO: David B. Portnoy, PhD, MPH; CTP
Cathy Backinger, PhD, MPH; CTP Liaison to the RIHSC

You have submitted an amendment to your proposal, entitled, "Experimental Study on Warning Statements for Cigarette Graphic Health Warnings," for RIHSC review. Your study proposes to examine consumer reactions to two different versions of textual warning statements that focus on negative health consequences of cigarette use. The study aims to compare the effect of exposure to the 9 original statements in the Tobacco Control Act to revised versions of those statements.

Your amendment proposes to:
• Add a Paperwork Reduction Act Statement to the following study documents: Adult Study Invitation Email, Parent or Guardian Permission for Youth Study Participation, Youth Assent for Study Participation, Adult Consent for Study Participation, Screening Questionnaire, Questionnaire (aka Instrument)
• Change wording from "After completing" to "If you complete," the survey, on the Youth Assent for Study Participation and the Adult Consent for Study Participation documents
• Change wording from "for your child's participation" to "if your child completes the survey," regarding voluntary participation, on the Parent or Guardian Permission for Youth Participation document

Because your proposed changes are minor and do not increase risk, your request 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.
Your amendment is APPROVED.
Approval of this amendment does not alter your effective date of RIHSC approval. Your protocol is approved until May 3, 2018.
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