IRB Chair Letter

IRB Chair Letter

Check here to enter IRB Chair LetterComment: *MEMORANDUM*
Department of Health and Human Services
Food and Drug Administration
Research Involving Human Subjects Committee

DATE: *December 12, 2017*

FROM: *Chair, Research Involving Human Subjects Committee*

SUBJECT: *RIHSC Protocol #17-032CTP Amendment*
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 make minor edits to the "Study Screener, Assent, and Consent" document, in "Section B: Post-Test Outcomes," requested and already approved by the RTI IRB (No new version or date has been added to the file):
• Change instruction to, "Please tell us how much you agree…," from question, "How much do you agree…."
• Add to instruction to study team, "Display as scrolling list."
• Add an answer option, "9. Prefer not to answer," to all the questions in this section.

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