**IRB Chair Letter**

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

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*DATE: December 12, 2017*

*FROM: Chair, Research Involving Human Subjects Committee*

*SUBJECT: RIHSC Study #17-078CTP Amendment*
*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 an amendment to your study, entitled, "Qualitative Study on Consumer perceptions of Cigarettes Health Warning Images," for RIHSC review. 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.*

*Your amendment proposes to make text changes to the study documents required by OMB. The required phrasing changes relate to the concept of "confidentiality," and include:*
*• Adolescent Screener – change two occurrences of "confidential" to "private," in the "Introduction" section*
*• Adult Screener – change one occurrence of "confidential" to "private to the extent allowable by law," in the introductory section*
*• Parental Permission Form, Adolescent Assent form, and Adult Consent Form – remove "confidentiality of," in the "Risks/Discomforts" section*
*None of these documents have been re-dated or re-versioned; all have an OMB number and the expiration date of 6-30-18.*

*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.*

*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 amendment is APPROVED.*

*Approval of this amendment does not alter your effective date of RIHSC approval. Your study is approved until November 29, 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.*