RTI INTERNATIONAL

Office of Research Protection

3040 Cornwallis Road ▪ PO Box 12194 ▪ Research Triangle Park, NC 27709-2194 ▪ USA
Telephone 919-316-3358 ▪ Toll Free 1-866-214-2043 ▪ Fax 919-316-3897 ▪ www.rti.org

APPROVAL

November 20, 2018

James Nonnemaker

919-541-7064, x27064

jnonnemaker@rti.org

Dear James Nonnemaker:

On 11/20/2018, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title:	Experimental Study of Cigarette Warning Labels
Investigator:	James Nonnemaker
IRB ID:	STUDY00020375
Funding Source:	FDA Ctr Tobacco Products
Customer/Client Name:	DHHS FDA OAGS
Project/Proposal Number:	0212926.032
IND, IDE, or HDE:	None

The IRB approved the protocol from 11/20/2018 to 11/19/2019. Before 11/19/2019 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 11/19/2019, approval of this study expires on that date.

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,
The RTI Office of Research Protection

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APPROVAL

December 11, 2018

James Nonnemaker

919-541-7064, x27064

jnonnemaker@rti.org

Dear James Nonnemaker:

On 12/11/2018, the IRB reviewed the following submission:

Type of Review:	Modification
Title:	Experimental Study of Cigarette Warning Labels
Investigator:	James Nonnemaker
IRB ID:	MOD00000470
Funding Source:	FDA Ctr Tobacco Products
Customer/Client Name:	DHHS FDA OAGS
Project/Proposal Number:	0212926.032
IND, IDE, or HDE:	None

The IRB approved the modification from 12/11/2018 to 11/19/2019. Before 11/19/2019 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted before the expiration date of 11/19/2019, approval of this study expires on that date.

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,
The RTI Office of Research Protection

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: November 15, 2018

FROM: Chair, Research Involving Human Subjects Committee

SUBJECT: RIHSC Study #18-061CTP
Study Title: "Experimental Study of Cigarette Warning Labels"
Principal Investigator: James Nonnemaker, PhD; RTI International
FDA Sponsor: David Portnoy, PhD, MPH; CTP

TO: David Portnoy, PhD, MPH; CTP
Carolyn Dresler, MD, MPA; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your study, entitled, "Experimental Study of Cigarette Warning Labels." Your study proposes to compare effects of new graphic health warnings (GHW) to the existing, text-only Surgeon General's (SG) warnings. The goal is to garner a better understanding on consumers' knowledge, beliefs, and perceptions about the harms of cigarette smoking. Adolescent, young adult, and adult smokers and non-smokers as well as adolescents who are susceptible to initiation of cigarette smoking will be randomly assigned. You propose to compare survey responses to determine whether GHW or SG warnings result in a change in understanding about the negative health consequences of cigarette smoking.

Below is a comment for your consideration. If you make changes to any to your study documents in response to this comment, please submit the tracked-changed documents in an amendment.

1. Consider if it is appropriate for RTI to answer questions about rights as a participant or if a disinterested party, such as the RIHSC, should be the point of contact.

Because your study is no greater than minimal risk, it 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 study is **APPROVED**.*

EFFECTIVE PERIOD OF APPROVAL:
This study has been approved November 15, 2018 – November 14, 2019.

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 14, 2019, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than September 15, 2019.

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

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 19, 2018*
FROM: *Chair, Research Involving Human Subjects Committee*
SUBJECT: ***RIHSC Study #18-061CTP***
Study Title: *"Experimental Study of Cigarette Warning Labels"*
Principal Investigator: *James Nonnemaker, PhD; RTI International*
FDA Sponsor: *David Portnoy, PhD, MPH; CTP*

TO: *David Portnoy, PhD, MPH; CTP*
Carolyn Dresler, MD, MPA; CTP Liaison to the RIHSC

You have submitted an amendment to your study, entitled, "Experimental Study of Cigarette Warning Labels," for RIHSC review. This study proposes to garner a better understand on consumers' knowledge, beliefs, and perceptions about the harms of cigarette smoking.
Your amendment proposes to make updates to your study documents to include:
Protocol
Clarifying the consent process for each session; sections 10 and 11
Indicating that the study must be completed on a laptop or desktop; section 14
Consent/Assents/Parental Permission
Asking subjects to agree not to distribute copies of the study stimuli
Including separate assent documents for each session
Clarifying that Lifepoints are distributed to the parent's account
Changes to programming notes
Emails to adults and parents of youth
Updating the number of subjects from 9,760 to 10,000
Updating programming notes
Indicating that the study must be completed on a laptop or desktop
Surveys
Indicating that the study must be completed on a laptop or desktop
Making editorial changes and including directions to subjects
Updating programming notes
Clarifying that Lifepoints are distributed to the parent's account
Screener
Clarifying the consent process for each session; sections 10 and 11
Indicating that the study must be completed on a laptop or desktop; section 14
Updating programming notes
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 study is approved until November 14, 2019.
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