IRB Chair Letter

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Food and Drug Administration
Research Involving Human Subjects Committee

DATE: *August 15, 2016*
FROM: *Chair, Research Involving Human Subjects Committee*
SUBJECT: *RIHSC Protocol # 16-048CTP*
Study Title: "Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products"
Principal Investigator: Jonathan Blitstein, PhD; RTI
FDA Sponsor: Katherine Margolis, PhD; CTP
TO: *Katherine Margolis, PhD; CTP*
Cathy Backinger, PhD; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review of your protocol titled, "Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products." This study proposes to gather information on different ways of presenting harmful and potentially harmful constituent information to adults and youth. You plan to conduct nationwide in-depth interviews to collect information from the subject population. This will assist in informing you on how the details of HPHC should be presented, communicated, and improve understanding by the public.

Because your protocol 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 protocol is APPROVED.

EFFECTIVE PERIOD OF APPROVAL:

This protocol has been approved August 15, 2016 – August 14, 2017.

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 the approval date of August 14, 2017, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than June 1, 2017.

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

Note to file:

8-18-16 Amendment was filed in order for RPMS to make correction of date error made on the approval letter.