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: *October 23, 2018*

FROM: *Chair, Research Involving Human Subjects Committee*

SUBJECT: *RIHSC Study #18-038CTP*
Study Title: "Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products: Pilot Cognitive Testing and Experimental/Quantitative Study"
Principal Investigator: Jessica Pepper, PhD; RTI
FDA Sponsor: Katherine Margolis, PhD and Jennifer Bernat, PhD; CTP

TO: *Katherine Margolis, PhD; CTP*
Carolyn Dresler, MD, MPA; CTP Liaison to the RIHSC

Your study submission, entitled, "Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products: Pilot Cognitive Testing and Experimental/Quantitative Study," was reviewed by the Research Involving Human Subjects Committee (RIHSC) Chair. This study proposes to test the effectiveness of sample formats to communicate harmful and potentially harmful constituents in tobacco products information. Results will be used to inform strategies to effectively communicate understandable and not misleading information about HPHCs to the layperson.

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 Chair determined that your study was APPROVABLE with certain stipulations. These were sent to you in a letter dated October 9, 2018. Your response, received October 19, 2018, adequately addresses the RIHSC's concerns.

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 from October 23, 2018 to October 22, 2019.

FDA IRB:
Research Involving Human Subjects Committee
US Food and Drug Administration
FWA #00006196
Chair: Jeffrey DeGrasse, PhD

RESPONSIBILITIES:
The Principal Investigator is responsible for ensuring that the investigation is conducted according to the approved protocol 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 protocol or parental permission or assent forms. [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 October 22, 2019, you will need to submit a CONTINUING REVIEW APPLICATION FORM and applicable materials to the RIHSC no later than August 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

MEMORANDUM

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

DATE: October 23, 2018

FROM: Chair, Research Involving Human Subjects Committee

SUBJECT: **RIHSC Study #18-038CTP**
Study Title: "Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products: Pilot Cognitive Testing and Experimental/Quantitative Study"
Principal Investigator: Jessica Pepper, PhD; RTI
FDA Sponsor: Katherine Margolis, PhD and Jennifer Bernat, PhD; CTP

TO: Katherine Margolis, PhD; CTP
Carolyn Dresler, MD, MPA; CTP Liaison to the RIHSC

Your study submission, entitled, "Measuring Consumer Comprehension of Displays of Harmful and Potentially Harmful Constituents (HPHCs) in Tobacco Products: Pilot Cognitive Testing and Experimental/Quantitative Study," was reviewed by the Research Involving Human Subjects Committee (RIHSC) Chair. This study proposes to test the effectiveness of sample formats to communicate harmful and potentially harmful constituents in tobacco products information. Results will be used to inform strategies to effectively communicate understandable and not misleading information about HPHCs to the layperson.

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 Chair determined that your study was **APPROVABLE** with certain stipulations. These were sent to you in a letter dated October 9, 2018. Your response, received October 19, 2018, adequately addresses the RIHSC's concerns.

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 from October 23, 2018 to October 22, 2019.

FDA IRB:
Research Involving Human Subjects Committee

US Food and Drug Administration
FWA #00006196
Chair: Jeffrey DeGrasse, PhD

RESPONSIBILITIES:

The Principal Investigator is responsible for ensuring that the investigation is conducted according to the approved protocol 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 protocol or parental permission or assent forms. [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 October 22, 2019, you will need to submit a **CONTINUING REVIEW APPLICATION FORM** and applicable materials to the RIHSC no later than August 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.