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 22, 2016*
FROM: *Chair, Research Involving Human Subjects Committee*
SUBJECT: *RIHSC Protocol #16-076CTP*
Study Title: "LGBT Young Adult Tobacco Use Prevention Campaign: Copy Testing Wave 1B"
Principal Investigator: Mayo Djakaria, MPH; Rescuse Social Change Group
FDA Sponsor: Leah Hoffman, MPH; CTP
TO: *Leah Hoffman, MPH; CTP*
Cathy Backinger, PhD, MPH; CTP Liaison to the RIHSC

You have submitted a request for RIHSC review for your proposal entitled, "LGBT Young Adult Tobacco Use Prevention Campaign: Copy Testing Wave 1B." Your study proposes to assess the development of messaging related to reducing tobacco initiation and use among self-identified LGBT young adults (aged 18-24) who are non-daily smokers. This study will inform on whether creative concept video advertisements provide an understandable and engaging message about tobacco harms. Participants will be recruited through targeted social media advertisements and will be randomly assigned to two groups; those who view video ads and those who do not. Both groups will answer screeners related to their gender identity, sexual identification and smoking. Questionnaires will assess the perceived effectiveness and themes of the ads presented. Information from this study may assist FDA in developing ads focused on tobacco-related health issues for the target audience.
Because your protocol is no greater than minimal risk, it could be reviewed using the expedited procedure outlined in 45 CFR 46.110.

Your protocol is APPROVED.
EFFECTIVE PERIOD OF APPROVAL:
This protocol has been approved November 22, 2016 – November 21, 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, November 21, 2017, you will need to submit a continuing review application and all supporting documentation to the RIHSC no later than September15, 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