



KDH RESEARCH &
COMMUNICATION

KDH Research & Communication Institutional Review Board
FWA00011177, IRB 00005850, IORG0004908

**KDH RESEARCH & COMMUNICATION (KDHRC)
INSTITUTIONAL REVIEW BOARD
Disposition**

Date: April 5, 2022
To: Kristen D. Holtz, Ph.D.
Principal Investigator
From: Eric C. Twombly, Ph.D.
KDHRC Institutional Review Board (IRB) Chairperson
Project: The Real Cost Campaign
Research Study: Online Quantitative Study of Reactions to Rough-Cut Advertising
Designed to Prevent Youth Tobacco Use (Copytesting)
KDHRC Job Code: 19-0174-00-00
KDHRC IRB Protocol #: 2022-02-08
Disposition: Amended full approval
Approval date: April 5, 2022 (amended by this action)
Expiration date: March 23, 2023 (unchanged by this action)

Discussion

Section 1. Previous IRB approval

On March 17, 2022, the IRB granted you full approved with a final disposition for your research packet and all related items pertaining to the study entitled The Real Cost Campaign: Online Quantitative Study of Reactions to Rough-Cut Advertising Designed to Prevent Youth Tobacco Use (Copytesting), KDHRC IRB Protocol # 2022-02-08. You then sought and received from the IRB an amendment approval on March 23, 2022. In both cases, pursuant to the resulting dispositions, the IRB informed you that if the packet and or any related items that were fully approved by the IRB were changed in any manner, method, or form, then the packet, in its entirety, may no longer be used by you or any other party without additional review and approval by the IRB.

Section 2: Subsequent amendment request

On April 1, 2022, you submitted to me, via memo, a subsequent amendment request with minor alterations to the study's approach, which do indeed represent material changes to the IRB approved packet from previous IRB determination, and you requested that I, as the IRB Chairperson, review the amendment and rule on its approval for use in the study.

Section 3. Revised determination and fully approved disposition

Today, April 5, 2022, I reviewed your amendment request and offer the following outcomes:

Outcome 1:

I determined that the research study described in KDHRC IRB Protocol # 2022-02-08 and the amendment continues to meet the criteria found in the risk category described in 45 CFR 46.404: "Research not involving greater than minimal risk."

Outcome 2:

I accepted the amendment and therefore the entirety of the revised packet for this study, rendering it applicable for exclusive use in the research study described in KDHRC IRB Protocol # 2022-02-08, but only in its fully approved form as determined by the IRB. Furthermore, pursuant to your request, the expiration date of this packet remains unchanged as March 23, 2023.

Outcome 3:

If the packet and or any related items that are fully approved by the IRB in this disposition are changed in any manner, method, or form, then the packet, in its entirety, may no longer be used by you or any other party without additional review and approval by the IRB.

If you have any questions on this disposition, then please contact me immediately. I may be reached at 404.668.3728 or etwombly@7research.org.

Most sincerely,



Eric C. Twombly, Ph.D.
KDHRC Institutional Review Board Chairperson