KDH RESEARCH & COMMUNICATION

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

KDH RESEARCH & COMMUNICATION (KDHRC)
INSTITUTIONAL REVIEW BOARD
Disposition

DATE:	February 16, 2021
TO:	Kristen D. Holtz, Ph.D. Principal Investigator KDHRC
FROM:	Eric C. Twombly, Ph.D. KDHRC Institutional Review Board (IRB) Chairperson
PROJECT:	The Real Cost Campaign: Media Tracking Study to Prevent Tobacco Use
KDHRC PROTOCOL #:	2021-01-02
KDHRC JOB CODE:	19-0174-00-00
DISPOSITION:	Full approval
APPROVAL DATE:	February 16, 2021
EXPIRATION DATE:	February 16, 2022

Discussion

Section 1. Original KDHRC IRB approval

On January 25, 2021, you received approval from the KDHRC IRB for a packet of items to use exclusively in The Real Cost Campaign: Media Tracking Study to Prevent Tobacco Use research study, KDHRC Protocol # 2021-01-02, pending further review by the Institutional Review Board of the U.S. Food and Drug Administration (FDA IRB). The packet contained these items:

- Research protocol
- Email Invitation (Appendix A)
- Parental Notification and Opt-out Form (Appendix B)
- Youth Assent Form (Appendix C)

- Young Adult Consent Form (Appendix D)
- Screener (Appendix E)
- Questionnaire (Appendix F)

Section 2. FDA IRB review

On February 8, 2021, you received the FDA IRB's review results, which are listed below.

Research protocol

- Add the name and FWA # of the reviewing IRB.
- Remove the FDA FWA # from under "FDA Project Leads".
- Modify the protocol to state assent/consent will be obtained before potential participants are screened.
- Explicitly state that FDA will have no access to the consent forms.
- Clarify the disposition plan for the screener data and the survey data and the merged dataset that will be used to create the deidentified dataset.

Youth Assent Form

- Update the assent and consent forms with language on the Certificate of Confidentiality, consistent with what is presented in the Parental Notification and Opt-out Form.

Young Adult Consent Form

- Update the assent and consent forms with language on the Certificate of Confidentiality, consistent with what is presented in the Parental Notification and Opt-out Form.

Section 3. Disposition request

On February 16, 2021, you submitted a memo to me that described the FDA IRB's required changes and requested further consideration of the packet and a fully approved disposition from the KDHRC IRB to begin and execute the research study. With the memo, you submitted a revised packet that highlighted the required changes.

Section 4. Determination and full approval disposition

Today, February 16, 2021, I determined that the changes required by the FDA IRB are minor and editorial, which allowed me, under the authority of KDHRC's IRB governing policies, to perform a chair-only review of your submission and request and produce these outcomes:

<u>Outcome 1:</u>
I determined that the research study described in KDHRC Protocol # 2021-01-02 and its revised packet as described in Section 1 continues to meet the criteria found in the risk category described in 45 CFR 46.404: "Research not involving greater than minimal risk."

<u>Outcome 2:</u>
I reviewed the revised packet, and because you executed the required revisions satisfactorily, I accepted the revised packet. Therefore, the packet and all related items listed in Section 1 above

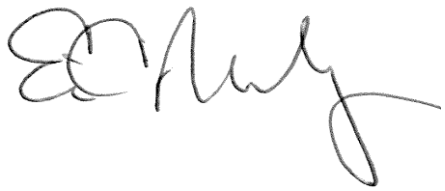
are fully approved with a final disposition for exclusive use in The Real Cost Campaign: Media Tracking Study to Prevent Tobacco Use research study, KDHRC Protocol # 2021-01-02, effective today, February 16, 2021.

Outcome 3:
Pursuant to its final disposition, the IRB grants the appropriate use of the packet and all related items listed in Section 1, but only in their fully approved form as determined by the IRB, until February 16, 2022.

Outcome 4:
If the packet and or any related items listed in Section 1 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