



KDH RESEARCH &  
COMMUNICATION

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

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

**Disposition**

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|-----------------------|---|
| Date:                 | March 18, 2024  |
| To:                   | Kristen D. Holtz, Ph.D.<br>Principal Investigator   |
| From:                 | Carol J. De Vita, Ph.D.<br>Acting KDHRC Institutional Review Board (IRB) Chairperson                        |
| Project:              | The Real Cost Campaign  |
| Research study:       | Creative Concept Testing Designed to Prevent Youth and Young Adult Cigarette Smoking (CIGS W7 Focus Groups) |
| KDHRC Job Code:       | 14-0144-00-00   |
| KDHRC IRB Protocol #: | 2023-07-06  |

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|                  |   |
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| Disposition:     | Amended full approval                         |
| Approval date:   | March 18, 2024 (amended by this action)       |
| Expiration date: | September 25, 2024 (unchanged by this action) |

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**Discussion**

**Section 1. Previous IRB approval**

On December 17, 2023, the IRB granted you full approval with a final disposition for your research packet and all related items pertaining to the study entitled The Real Cost Campaign: Creative Concept Testing Designed to Prevent Youth and Young Adult Cigarette Smoking (CIGS W7 Focus Groups), KDHRC IRB Protocol # 2023-07-06. At that time, pursuant to the resulting disposition, the IRB informed you that if the packet and or any related items that were fully approved by the IRB 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.

## **Section 2: Amendment request**

On March 13, 2024, you submitted to me an 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 an IRB member appointed to this review by the IRB Chairperson, examine the amendment and rule on its approval for use in the study.

## **Section 3. Fully approved disposition**

Today, March 18, 2024, I reviewed your amendment request and offer the following outcomes:

### Outcome 1:

I determine that the research study described in KDHRC IRB Protocol # 2023-07-06 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:

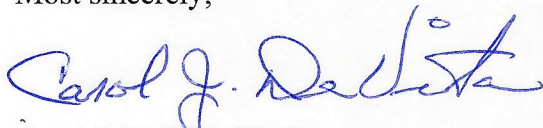
I accept the amendment and therefore the entirety of the revised packet for this study, rendering it applicable for exclusive use in the research study described in KDHRC IRB Protocol # 2023-07-06, but only in its fully approved form as determined by the IRB. The expiration date of this packet remains unchanged as September 25, 2024.

### 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 [cdevita@att.net](mailto:cdevita@att.net).

Most sincerely,



Carol J. De Vita, Ph.D.

KDHRC Institutional Review Board Member