



KDH RESEARCH &
COMMUNICATION

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

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

Date:	December 17, 2023
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:	Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B FGS)
KDHRC Job Code:	19-0174-00-00
KDHRC IRB Protocol #:	2023-11-12

Disposition:	Amended full approval
Approval date:	December 17, 2023 (amended by this action)
Expiration date:	December 6, 2024 (unchanged by this action)

Discussion

Section 1. Previous IRB approval

On December 8, 2023, 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: Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B FGS), KDHRC IRB Protocol # 2023-11-12. A 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 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: Amendment request

On December 14, 2023, you submitted to me, via memo, a subsequent amendment request with one minor alteration to the study's approach, which represents 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, December 17, 2023, I reviewed your amendment request and offer the following outcomes:

Outcome 1:

I determined that the research study described in KDHRC IRB Protocol # 2023-11-12 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:

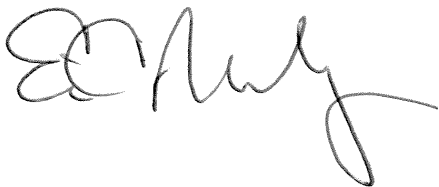
I accepted the amendment and therefore the entirety of the revised packet for this study, rendering it applicable for exclusive use in the research study described in KDHRC IRB Protocol # 2023-11-12, but only in its fully approved form as determined by the IRB. The expiration date of this packet remains unchanged as December 6, 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 404.668.3728 or etwombly@7research.org.

Most sincerely,

A handwritten signature in black ink, appearing to read "Eric Twombly", with a stylized flourish at the end.

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



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INSTITUTIONAL REVIEW BOARD
Disposition**

Date:	December 8, 2023
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:	Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B FGS)
KDHRC Job Code:	19-0174-00-00
KDHRC IRB Protocol #:	2023-11-12
Disposition:	Amended full approval
Approval date:	December 8, 2023 (amended by this action)
Expiration date:	December 6, 2024 (unchanged by this action)

Discussion

Section 1. Previous IRB approval

On December 6, 2023, 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: Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B FGS), KDHRC IRB Protocol # 2023-11-12. A 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 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: Amendment request

On December 7, 2023, you submitted to me, via memo, a subsequent amendment request with one minor alteration to the study's approach, which represents 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, I reviewed your amendment request and offer the following outcomes:

Outcome 1:

I determined that the research study described in KDHRC IRB Protocol # 2023-11-12 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:

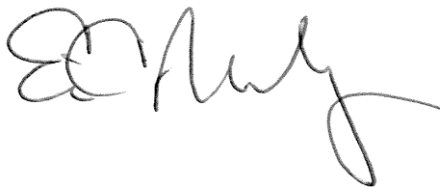
I accepted the amendment and therefore the entirety of the revised packet for this study, rendering it applicable for exclusive use in the research study described in KDHRC IRB Protocol # 2023-11-12, but only in its fully approved form as determined by the IRB. Furthermore, pursuant to your request, the expiration date of this packet remains unchanged as December 6, 2024.

Outcome 3:

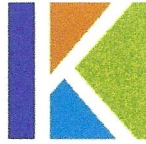
If the packet and or any related items that are fully approved by the IRB in this disposition are changed in any manner, method, or form, then the packet, in its entirety, may no longer be used by you or any other party without additional review and approval by the IRB.

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

Most sincerely,

A handwritten signature in black ink, appearing to read "Eric Twombly", with a long, sweeping horizontal stroke extending to the right.

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



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Institutional Review Board Disposition

Date:	December 6, 2023
To:	Kristen D. Holtz, Ph.D. Principal Investigator
From:	Carol J. De Vita, Ph.D. KDHRC Institutional Review Board (IRB) Acting Chairperson
Project:	The Real Cost Campaign
Research Study:	Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B Focus Groups)
KDHRC Job Code:	19-0174-00-00
KDHRC IRB Protocol #:	2023-11-12

DISPOSITION:	Full approval
Approval date:	December 6, 2023
Expiration date:	December 6, 2024

Discussion

Section 1. IRB submission

On November 30, 2023, you submitted a packet of items on The Real Cost Campaign's **Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B Focus Groups)**, KDHRC IRB Protocol # 2023-11-12, and asked the IRB to review and issue a disposition on that packet. The packet included the following reviewable items:

- Research Protocol
- Screener (Appendix A1)
- Screener Contact Sheet (Appendix A2)
- Parental Consent Form (Appendix B)
- Participant Assent Form (Appendix C)
- Participant Consent Form (Appendix D)

- Discussion Guide (Appendix E)

Section 2. IRB review

Today, December 6, 2023, you presented the research study and its packet of items list in Section 1 at a meeting of the IRB. I presided over the meeting as the IRB Acting Chairperson. Other IRB members in attendance and who reviewed and voted on the packet of items included Angela Snyder, Ph.D.; David Brandt, and Dexter Cooper.

Immediately following your presentation, the IRB fully reviewed the research study and its packet of items in accordance with the 45 CFR Part 46, Subpart D Federal Regulations, which provides for necessary protections for subjects in research studies. During the review, the IRB determined that the research study and its packet of items meet the criteria found in the risk category described in 45 CFR 46.404 (“Research not involving greater than minimal risk”) and they contain sufficient safeguards to manage the study’s minimal human subjects risk. Therefore, the packet of items listed in Section 1 is fully approved with a final disposition for the exclusive use in the study entitled “**Creative Concept Testing Designed to Prevent Youth and Young Adult ENDS use (ENDS W4B Focus Groups)**,” KDHRC IRB Protocol # 2023-11-12, pursuant to the stipulations in Section 3 below.

Section 3. Stipulations

With respect to the disposition of today’s IRB review, the fully approved items are subject to the following stipulations:

Stipulation 1:

The IRB grants the appropriate use of the packet of items listed in Section 1, under KDHRC IRB Protocol # 2023-11-12, but only in their fully approved form as determined by the IRB, to December 6, 2024.

Stipulation 2:

If the research extends past December 6, 2024, one year from today, then the packet of items listed in Section 1, under KDHRC IRB Protocol # 2023-11-12, is subject to an annual review by the IRB. An annual review request must be submitted 30 days prior to the expiration date.

Stipulation 3:

If any item listed in Section 1, under KDHRC IRB Protocol # 2023-11-12, is changed in any manner, method, or form from what is fully approved by the IRB in this final disposition, then the packet of items, in its entirety, may no longer be used by you or any other party without additional review by the IRB. Furthermore, no modifications can be made to any item without an IRB amendment. Please contact the IRB for an amendment request form as needed.

Stipulation 4:

You are required to report immediately to IRB any (a) infractions, (b) unanticipated problems involving risks to subjects or others, and (c) adverse events in the use of the packet of items listed in Section 1, under KDHRC IRB Protocol # 2023-11-12, by completing and submitting to

the IRB the KDHRC Institutional Review Board *Unanticipated Problems and Adverse Events Form*. Should the need arise to report to the IRB, then please contact the IRB immediately for the form.

Stipulation 5:

Upon completion of this research, under KDHRC IRB Protocol # 2023-11-12, you are required to certify to the IRB the closure of the research. Please contact the IRB at any time for a copy of the KDHRC Institutional Review Board *Closure Form*.

I wish you the best of luck with this research. If you have any questions about this disposition, then please contact me immediately at cdevita@att.net.

Most sincerely,

A handwritten signature in cursive script that reads "Carol J. De Vita, Ph.D." The signature is written in dark ink and is positioned above the printed name.

Carol J. De Vita, Ph.D.
KDHRC Institutional Review Board (IRB) Acting Chairperson