



KDH RESEARCH &
COMMUNICATION

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

Institutional Review Board Disposition

Date: November 22, 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 (as needed): Gathering Consumer Feedback on The Real Cost Campaign
(ENDS Ad Focus)
KDHRC job code: 19-0174-00-00
KDHRC IRB protocol #: 2023-05-03

DISPOSITION: Full approval
Approval date: November 22, 2023
Expiration date: November 22, 2024

Discussion

Section 1. IRB submission

At an IRB meeting on November 16, 2023, you presented a packet of items from **Gathering Consumer Feedback on the Real Cost Campaign (ENDS Ad Focus)**, KDHRC IRB Protocol # 2023-05-03, and asked the IRB to review and issue a disposition on that packet. The packet included the following reviewable items:

- Research protocol
- Email Invitation for Parents (Appendix A)
- Parental Opt-out Form (Appendix B)
- Youth Full Assent Form (Appendix C)
- Brief and Assent Screener (Appendix D)
- Survey (Appendix E)

Section 2. IRB review

Immediately following your presentation to the IRB at the November 16, 2023, the IRB performed a full review of 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. I presided over the review as the Acting Chairperson.

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." Furthermore, the IRB granted conditional human subjects approval to the research study and its packet of items pending chairperson-only re-review of the required revisions detailed in the comments and edits that I saved on the KDHRC secure data and information server.

Section 3. Submission of revised packet

Yesterday, November 21, 2023, you submitted to me a revised packet of items pursuant to Section 2 above.

Section 4. Disposition

Today, November 22, 2023, I reviewed the revised packet of items, and because you executed the required revisions satisfactorily, I accept it. Therefore, effective today, the packet and the items listed in Section 1 above are fully approved with a final disposition for the exclusive use in The Real Cost Campaign's **Gathering Consumer Feedback on the Real Cost Campaign (ENDS Ad Focus)**, KDHRC IRB Protocol # 2023-05-03, pursuant to these stipulations:

Stipulation 1:

The IRB grants the appropriate use of the packet of items listed in Section 1, under KDHRC IRB Protocol # 2023-05-03, but only in their fully approved form as determined by the IRB, to November 22, 2024.

Stipulation 2:

If the research extends past November 22, 2024, one year from today, then the packet of items listed in Section 1, under KDHRC IRB Protocol # 2023-05-03, 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 # 2023-05-03, 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 # 2023-05-03, 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 # 2023-05-03, you are required to certify to the IRB the closure of the research. Please contact me at any time for a copy of the KDHRC Institutional Review Board *Closure Form*.

If you have questions about this disposition, then please contact me immediately at cdevita@att.net.

Most sincerely,

A handwritten signature in black ink that reads "Carol J. De Vita, Ph.D." The signature is written in a cursive, flowing style.

Carol J. De Vita, Ph.D.

KDHRC Institutional Review Board (IRB) Acting Chairperson