



KDH RESEARCH &
COMMUNICATION

KDHRC Institutional Review Board
FWA00011177, IRB 00005850, IORG0004908
Edward Morgan, Chair

PROTOCOL APPROVAL

DATE: November 1, 2017

TO: Kristen Holtz, Ph.D.
Principal Investigator
KDH Research & Communication

FROM: Edward Morgan, IRB Chair

PROTOCOL: The Real Cost General Market: Wave 4 Creative Concept Testing Designed to Prevent Youth Use

MEETING DATE: October 25, 2017

APPROVAL DATE: November 1, 2017

EXPIRATION DATE: November 1, 2018

IRB APPROVED DOCUMENTATION:

Materials submitted to the IRB

Attachment A. Protocol
Attachment B. Parental Permission Form
Attachment C. Youth Assent Form
Attachment D. Screener
Attachment E: Discussion Guide
Attachment F: Stimuli (for reference only)

Actions taken

The IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects. The Principal Investigator asked the IRB to take the following actions:

- Review and vote on the research protocol (Attachment A)
- Review and vote on parental permission form (Attachment B)
- Review and vote on youth assent form (Attachment C)

- Review and vote on the screener (Attachment D)
- Review and vote on the discussion guide (Attachment E)

Outcomes

Outcome 1: The IRB determined that the research study meets the criteria found in the risk category described as follows:

- 45 CFR 46.404: *“Research not involving greater than minimal risk.”*

Outcome 2: The following documents received conditional approval pending chair-only re-review of requested changes:

Attachment A. Protocol

1. Request for change: Assent form should be read out loud with participants before the focus group begins in order to ensure the participants fully understands the research and what participating requires.
 - o Revisions made: Added language to the protocol to reflect this.
2. Request for change: Simplify and clarify the sentence, “The following processes are in place to protect personally-identifiable and sensitive data: 1) raw data that include sensitive information (e.g., screening questionnaires and audio recordings) will be destroyed by deletion or secure shredding once the data have been extracted and aggregated, and 2) information from the screener will never become part of a system of records containing permanent identifiers that can be used for retrieval.”
 - o Revisions made: Simplified last part of sentence.
3. Request for change: The Recruitment Plan and Screening procedures section mentions that responses to questions will consist of non-revealing, yes/no answers. However, the questions in the screener are not yes/no responses.
 - o Revisions made: Deleted text about yes/no answers on p. 5.
4. Adjust section in protocol detailing the discussion guide to more accurately reflect the sections of the discussion guide.
 - o Revisions made: Adjusted the appropriate headings in the protocol on page 5, and also adjusted the discussion guide.

Attachment B. Parental permission form

1. Request for change: Add risk language about the possibility that a focus group participant could share information about things discussed in the focus group, thus breaking confidentiality.
 - Revisions made: Added text to address this risk in the “Anticipated Risks” section.
2. Request for change: The “Participation and Withdrawal” section states, “What if my child changes her mind?” Please add “his” to this section.
 - Revisions made: added, “his or” to this section.

Attachment C. Youth assent form

1. Request for change: Shorten sentences and simplify language to make the assent form easier to understand.
 - Revisions made: Simplified language and shortened sentences where possible. Overall these changes adjusted the overall reading age to 13 (was 14-15). Because the reading level of the assent form remains high, we also will offer to go through the assent form

verbally the day of the focus group, before it begins (see p. 1 first paragraph for this addition).

2. Request for change: Add risk language about the possibility that a focus group participant could disclose information discussed in the focus group, thus breaking confidentiality.
 - Revisions made: Added text to address this risk in the “Could anything bad happen to me during this study?”.

Attachment D. Screener

1. Request for change: Add a question about English being the primary language of the youth.
 - Revisions made: Added question 5 on page 3. Renumbered accordingly.
2. Request for change: To prevent the youth from revealing tobacco-use status to a parent overhearing the screening call: On tobacco use behavior questions, please ask youth to respond to the question by stating the number that corresponds with his or her answer.
 - Revisions made: to 12b, 12c (formerly 11b, 11c); 13a, 13b, 13c (formerly 12a, 12b, 12c); 14a, 14b (formerly 13a, 13b); and 15a, 15b, 15c (formerly 14a, 14b, 14c)

Attachment E. Discussion Guide

1. Request for change: Reallocate time to total 90 minutes, currently totals 95 minutes
 - Revisions made: Changed p. 3 “Vaping: Experience and Associations” from 15 minutes to 10 minutes.
2. Request for change: Ensure sections of Discussion Guide match sections mentioned in Attachment A. Protocol
 - Revisions made: Underlined relevant sections to make consistent.

Outcome 3: Revised materials were submitted to the chair, who reviewed and approved the changes on October 27, 2017. The following documents received full approval after chair re-review.

Attachment A. Protocol

Attachment B. Parental Permission Form

Attachment C. Youth Assent Form

Attachment D. Screener

Attachment E: Discussion Guide

Outcome 4: Upon receipt of new information from the FDA sponsor, the PI requested an amendment to the IRB materials as follows:

There will still be a \$50 incentive for participation. Now, youth participants will receive \$25 for participating and parents/guardians of participants will receive \$25.

This change does not affect our permission/assent procedures, assessment of risk, approach toward protecting confidentiality, or any other key component of the IRB packet and procedures described therein. The documents that required edits to reflect this change are listed below.

- Attachment A. Protocol: Pages 4, 8, 9
- Attachment B. Parental Permission Form: Page 3
- Attachment C. Youth Assent Form: Pages 2 & 3
- Attachment D. Screener: Pages 2, 3, 4, 7

Outcome 6: The IRB met remotely (by email discussion) to discuss the amendment and revised materials. They voted to fully approve the materials. The IRB issued final disposition forms showing approval of the documents for use in an external research project. The final disposition forms with amendment are attached to this letter.

Conclusion:

If there are any changes to the IRB approved material, IRB approval will be needed prior to use.



11-2-17

IRB Chairperson

Date