



KDH RESEARCH &
COMMUNICATION

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

PROTOCOL APPROVAL

DATE: January 16, 2020
TO: Kristen Holtz, Ph.D.
Principal Investigator
KDH Research & Communication
FROM: Edward Morgan, IRB Chair
PROTOCOL: FDA ETC Focus Groups
MEETING DATE: January 14, 2020
APPROVAL DATE: January 15, 2020
EXPIRATION DATE: December 31, 2020

IRB APPROVED DOCUMENTATION:

Materials submitted to the IRB

- Attachment A: Research Protocol
- Attachment B: Consent Form – Study 1
- Attachment C: Screener – Study 1
- Attachment D: Screener Contact Sheet – Study 1
- Attachment E: Discussion Guide
- Attachment F: Ranking Worksheet – Study 1
- Attachment G: Rating Worksheet – Study 1
- Attachment H: Stimuli [for reference only]
- Attachment I: Screener – Study 2
- Attachment J: Recruitment Flyer – Study 2 [for reference only]
- Attachment K: Consent Form – Study 2

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 the consent form – study 1 (Attachment B)
- Review and vote on the screener – study 1 (Attachment C)
- Review and vote on the screener contact sheet – study 1 (Attachment D)
- Review and vote on the discussion guide (Attachment E)
- Review and vote on the ranking worksheet – study 1 (Attachment F)
- Review and vote on the rating worksheet – study 1 (Attachment G)
- Review and vote on the screener – study 2 (Attachment I)
- Review and vote on the consent form – study 2 (Attachment K)

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 full approval

- Attachment D: Screener Contact Sheet – Study 1
- Attachment E: Discussion Guide
- Attachment F: Ranking Worksheet – Study 1
- Attachment G: Rating Worksheet – Study 1

Outcome 3: The following documents received conditional approval pending chair-only re-review of requested changes:

Protocol - Attachment A

1. Request for change: make change to ordering of inclusion criteria for study 2. LGBTQ+ should come first.
 - Revisions made: re-ordered inclusion criteria. See highlighted text on page 8 of protocol.
2. Request for change: add “will” under General Methods on page 5
 - Revisions made: added “will” to sentence. See highlighted text on page 5.

Consent Form – Study 1: Attachment B

1. Request for change: delete repeated “Certificate of Confidentiality” sentence on page 3.
 - Revisions made: deleted repeated sentence. See highlighted text on page 3.
2. Request for change: delete “youth” in last paragraph.
 - Revisions made: deleted “youth” and replaced with “consent”. See highlighted text on page 4.

Screener – Study 1: Attachment C

1. Request for change: add name of vendor.
 - Revisions made: vendor is yet to be selected. Once the vendor is selected, we will ask IRB approval via amendment.

Screener – Study 1: Attachment I

1. Request for change: include language that indicates that potential participants should only mention letter and not option.
 - Revisions made: include language that indicates selection of letter. See highlighted text on pages 2 and 3.

Consent Form – Study 1: Attachment K

1. Request for change: delete repeated “Certificate of Confidentiality” sentence on page 3.
 - Revisions made: deleted repeated sentence. See highlighted text on page 3.
2. Request for change: delete “youth” in last paragraph.
 - Revisions made: deleted “youth” and replaced with “consent”. See highlighted text on page 4.
3. Request for change: add “up to nine participants” on page 1.
 - Revisions made: added “up to nine participants”. See highlighted text on page 1.
4. Request for change: fix the following typos:
 - i. Page 2 – add “s” on “other”.
 - ii. Page 3 – add “article” before incentive.
 - Revisions made:
 - i. Added “s” in sentence. See highlighted text on page 2.
 - ii. Added “the” in sentence. See highlighted text on page

Outcome 4: Revised materials were submitted to the chair, who reviewed and approved the changes on January 15, 2020. The following documents received full approval after chair re-review. The IRB issued final disposition forms showing approval of the documents for use in an external research project.

- Attachment A: Research Protocol
- Attachment B: Consent Form – Study 1
- Attachment C: Screener – Study 1
- Attachment D: Screener Contact Sheet – Study 1
- Attachment E: Discussion Guide
- Attachment F: Ranking Worksheet – Study 1
- Attachment G: Rating Worksheet – Study 1
- Attachment I: Screener – Study 2
- Attachment K: Consent Form – Study 2

Conclusion:

If there are any changes to the IRB approved materials and reference only materials, IRB approval will be needed prior to use.

Edward Morgan

1-16-20

IRB Chairperson

Date