



KDH RESEARCH &  
COMMUNICATION

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

PROTOCOL APPROVAL

DATE: November 19, 2019

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

FROM: Edward Morgan, IRB Chair

PROTOCOL: FDA Youth Tobacco Prevention Broad Quantitative Research Package

MEETING DATE: November 14, 2019

APPROVAL DATE: November 19, 2019

EXPIRATION DATE: January 31, 2022

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**IRB APPROVED DOCUMENTATION:**

**Materials submitted to the IRB**

- Attachment A: Research Protocol
- Attachment B: Email Invitation
- Attachment C: Youth Screener
- Attachment D: Adult Screener
- Attachment E: Parental Notification and Opt-Out Form
- Attachment F: Youth Assent Form
- Attachment G: Adult Consent Form
- Attachment H: Youth Questionnaire [for reference only]
- Attachment I: Adult Questionnaire [for reference only]
- Attachment J: 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 the email invitation (Attachment B)
- Review and vote on the youth screener (Attachment C)
- Review and vote on the adult screener (Attachment D)
- Review and vote on the parental notification and opt-out form (Attachment E)
- Review and vote on the youth assent form (Attachment F)
- Review and vote on the adult consent form (Attachment G)

## **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:

### Protocol - Attachment A

1. Request for change: make change to sentence structure under parental opt-out.
  - Revisions made: changed sentence structure. See highlighted text on page 6 of protocol.
2. Request for change: update title of Table 2.
  - Revisions made: updated title of table 2. See highlighted text on page 8 of protocol.
3. Request for change: add age breakdown for adult participants.
  - Revisions made: added age breakdown. See highlighted text on page 8 of protocol.
4. Request for change: make change to sentence structure under parental opt-out.
  - Revisions made: changed sentence structure. See highlighted text on page 9 of protocol.
5. Request for change: define “PII” on page 9 and delete definition on page 13.
  - Revisions made: defined “PII” on page 9 and deleted definition on page 13. See highlighted text on page 9.

### Email Invitation: Attachment B

1. Request for change: delete “approximately” in first paragraph.
  - Revisions made: deleted “approximately”. See highlighted text on page 1.
2. Request for change: change sentence structure in paragraph.
  - Revisions made: changed sentence structure. See highlighted text on page 1.
3. Request for change: include placeholder for OMB clearance number.
  - Revisions made: included placeholder for OMB clearance number. See header on page 1.

4. Request for change: fix the following typos:
  - i. Page 1 – delete “d” on “and”.
  - Revisions made:
    - i. Deleted “d” in sentence. See highlighted text on page 1.

#### Youth Screener: Attachment C

1. Request for change: update table heading.
  - Revisions made: update table heading. See highlighted text on page 1.
2. Request for change: under question D12, change option G from “50-99 times” to “51-99 times”.
  - Revisions made: updated option G. See highlighted text on page 5.
3. Request for change: under question D12a, change option E from “9-15 days” to “10-15 days”.
  - Revisions made: updated option E. See highlighted text on page 8.
4. Request for change: under question D18, change option G from “50-99 times” to “51-99 times”.
  - Revisions made: updated option G. See highlighted text on page 7.
5. Request for change: include placeholder for OMB clearance number.
  - Revisions made: included placeholder for OMB clearance number. See header on page 1.

#### Adult Screener: Attachment D

1. Request for change: under question B5, include skip pattern under option C.
  - Revisions made: included skip pattern. See highlighted text on page 4.
2. Request for change: include placeholder for OMB clearance number.
  - Revisions made: included placeholder for OMB clearance number. See header on page 1.
3. Request for change: fix the following typos:
  - i. Page 1 – change “youth” to “adults”.
  - ii. Table 2 – change “youth” to “adults”.
  - iii. Table 2 – change “ho” to “who”.
  - iv. Page 5 – box under D8, delete “ever tried”.
  - Revisions made:
    - i. Changed “youth” to “adults”. See highlighted text on page 1.
    - ii. Changed “youth” to “adults”. See highlighted text in table 1.
    - iii. Changed “ho” to “who”. See highlighted text in table 1.
    - iv. Deleted “ever tried”. See highlighted text on page 5.

#### Parental Notification and Opt-Out Form – Attachment E

1. Request for change: under reimbursement, restructure sentence to ensure that youth participant and parent understand incentive system.
  - Revisions made: restructured sentence. See highlighted text on page 2.
2. Request for change: include placeholder for OMB clearance number.

- Revisions made: included placeholder for OMB clearance number. See header on page 1.

Youth Assent Form – Attachment F

1. Request for change: include placeholder for OMB clearance number.
  - i. Revisions made: included placeholder for OMB clearance number. See header on page 1.
2. Request for change: fix the following typos
  - i. Page 2 – under “will I be paid for being in this study”, change “your” to “you”
    - Revisions made:
      - i. Changed “your” to “you”. See highlighted text on page 2.

Adult Participant Consent Form

1. Request for change: include placeholder for OMB clearance number.
  - i. Revisions made: included placeholder for OMB clearance number. See header on page 1.
2. Request for change: fix the following typo
  - i. Page 1: under “what will I do”, delete “his or her”
    - Revisions made:
      - i. Deleted “his or her”. See highlighted text on page 1.

Outcome 3: Revised materials were submitted to the chair, who reviewed and approved the changes on November 19, 2019. 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.

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- Attachment B: Email Invitation
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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*

**11-19-2019**

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IRB Chairperson

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Date