



KDH RESEARCH &
COMMUNICATION

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

DATE: October 24, 2019

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

FROM: Edward Morgan, IRB Chair

PROTOCOL: FDA Youth Tobacco Prevention Broad Qualitative Research Package

MEETING DATE: October 24, 2019

APPROVAL DATE: October 24, 2019

EXPIRATION DATE: January 31, 2022

IRB APPROVED DOCUMENTATION

Materials submitted to the IRB:

- Attachment A: Research Protocol
- Attachment B: Parental Permission Form
- Attachment C: Youth Assent Form
- Attachment D: Screener
- Attachment E: Screener Contact Sheet
- Attachment F: Discussion Guide (for reference only)
- Attachment G: Concept Rating Sheet (for reference only)
- Attachment H: Concept Ranking Sheet (for reference only)
- Attachment I: 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 Screener Contact Sheet (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 full approval after IRB review

- Research Protocol (Attachment A)
- Parental Permission Form (Attachment B)
- Youth Assent Form (Attachment C)
- Screener (Attachment D)
- Screener Contact Sheet (Attachment E)

Outcome 3: The IRB issued final disposition forms showing approval of the documents for use in an external research project.

- Research Protocol (Attachment A)
- Parental Permission Form (Attachment B)
- Youth Assent Form (Attachment C)
- Screener (Attachment D)
- Screener Contact Sheet (Attachment E)

Conclusion

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



10-25-2019

IRB Chairperson

Date