JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

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APPROVAL/DETERMINATION MEMO

Amendment Approval

Date: July 19, 2021

To: Meghan Moran, PhD
Department of Health Behavior and Society

From: Katherine C. Smith, PhD
Chair, IRB- X

Study Title: How Consumers use Flavors to Make Inferences about Electronic Nicotine Delivery System (ENDS) Product Qualities and Intentions to Use (Phase 2)

IRB No.: 11186/MOD1313

☐ Approved ☐ Approved, minor change (single reviewer) ☐ Approved Expedited Cat: ☒ Determined to be Exempt Cat: (2)(i)	Approval/Determination Date: July 10, 2021 Approval Lapse Date: March 30, 2022

As Principal Investigator for this IRB approved study, you are responsible for conducting the study in accordance with the ethical principles of the Belmont Report, in compliance with all relevant laws and regulations, and in accordance with JHU institutional policy.

This approval includes the following:

1). To add a new recruitment method to recruit youth participants 13-17 years old by contacting parents who are a survey panelists and inviting them to have one of their children join the study.

This approval is inclusive of the following documentation:

Research Plan/Sponsor's Protocol:

- Research Plan (PI version #4, June 28, 2021)

Recruitment Material:

- Parental Recruitment Email (PI version #2, June 21, 2021)
  (IRB version #1, July 10, 2021)

***DHHS** ☒ 45 CFR 46 ☐ CR ☒ Revised CR **FDA** ☐ 21 CFR 50, 56 ☐ IND, 21 CFR 312 ☐ IDE, 21 CFR 812 ☐ IND/IDE held by JHSPH PI ☐ Dept. of Defense Funding ☐ Min. Risk ☐ Greater than min. risk ☐ GWAS ☐ Reliance Agreement ☐ Clinical Trial/GCP ***Study Site(s):** ☒ U.S. ☐ International ***List Country(ies):**	***Consent/Parental Permission Required From:** ☒ Adult Participant ☐ LAR ☒ One Parent ☐ Two Parents 46.406, 50.53 ☐ Legal Guardian of Children in Foster Care ☐ Minor Consent as Adult ***Vulnerable Populations:** ☒ Children ☐ Foster Care Children **DHHS** **FDA** ☒ 46.404 ☐ 50.51 ☐ 46.405 ☐ 50.52 ☐ 46.406 ☐ 50.53 ☐ Preg. Women/Fetuses 46.204 ☐ Neonates ☐ Prisoners	***Adult Consent:** ☐ Written Consent ☐ Waiver of Signature ☐ Exempt (Electronic) ☒ Alteration of Consent; meets 46.116 (f)(3) criteria ☐ Waiver of Informed Consent; meets 46.116 (f)(3) criteria ***Assent:** ☐ Written (signed) ☒ Oral ☐ Statement in Parent Permission Form ☐ Electronic ☐ Waived for all children ☐ Waived for children ***HIPAA**: ☐ JHM ☐ Non-JHM ☐ Authorization ☐ Prep. To Research ☐ HIPAA Alteration/Waiver ☐ JHM Data Tracking ☐ Limited Data Set ☐ DUA	***Parental Permission:** ☐ Written Permission ☐ Waiver of Signature ☐ Exempt (Electronic) ☐ Alteration of Permission; meets 46.116 (f)(3) criteria ☒ Waiver of Permission; ☐ Meets 46.116 (f)(3) ☒ 46.408, with Substitute Mechanism provided ***Sample Size:** (screened plus enrolled) 5,000 ***Final Enrollment:** ***Secondary Data Analysis**: (specimens/participants)

***Complete for Exempt Studies for operational purposes to help track documents; HSR code provisions do not apply.**

As principal investigator of IRB approved research, you are responsible for meeting the following requirements of approval:

1) Informing the co-investigators listed on the application of the status of the research.

2) Submitting an Amendment Application or Administrative Amendment for any changes in research. These changes in research are required to be reviewed and approved prior to the activation of the changes, unless you are correcting or clarifying language in approved instruments.

3) Reporting Unanticipated problems involving risk of harm to participants or others that are related to the study procedures to the JHSPH IRB within 10 days of the time that the PI learns of such problems. Submit a Problem Event Report Form must be submitted to the IRB immediately.

4) Using only the most recently approved JHSPH IRB approved consent forms, with the JHSPH stamp or logo, unless otherwise approved by the IRB. All consent forms signed by subjects enrolled in the study should be stored securely, in paper or electronic form, until 3 years following study completion unless otherwise approved by the IRB.

5) Submitting in a timely fashion Continuing Review Applications or Progress Reports. The Approval Lapse Date above marks the end of this approval; no study activity may take place after that date without new IRB approval. Submit your report to the IRB Office no later than six weeks prior to the approval lapse date to allow time for IRB review to be completed prior to that date.

6) If your study is an NIH funded clinical trial, e.g., “A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”, it must be registered on clinicaltrials.gov, and one IRB approved consent form used in the study must be posted on a publicly available Federal website.

7) If your research involves international travel, please don’t forget to register with the International Travel Registry https://travelregistry.johnshopkins.edu/Travel so that the school may locate you in the event of an emergency.

KS/sro