

## **JHSPH Institutional Review Board Office**

615 N. Wolfe Street / Room E1100 Baltimore, Maryland 21205-2179

Phone: 410-955-3193 Toll Free: 1-888-262-3242 Fax: 410-502-0584

Email: <a href="mailto:jhsph.irboffice@jhu.edu">jhsph.irboffice@jhu.edu</a>
Website: <a href="mailto:www.jhsph.edu/irb">www.jhsph.edu/irb</a>

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

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)

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

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.

<sup>\*</sup>Complete for Exempt Studies for operational purposes to help track documents; HSR code provisions do not apply.

- 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