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CONSENT FORM

Project Title:	Sensory Perception of Sweet Flavors in E-Cigarette
Principal Investigator:	Juyun Lim
Student Researcher:	Alexa Pullicin
Sponsor:	National Institute of Health & Food and Drug Administration
Version Date:	March 26, 2018

1. WHAT IS THE PURPOSE OF THIS FORM?

This form contains information you will need to help you decide whether to be in this research study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

2. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to understand how sweet flavors added to e-cigarettes affect 1) how you perceive nicotine, and 2) your liking/disliking of the e-cigarette vapor. The e-cigarette market has grown significantly in recent years, with thousands of flavors currently available. Despite the common use of flavors in e-cigarette liquids, the interactions between these flavors and inhaled nicotine have never been measured in a controlled manner. This study will aim to understand these interactions. The data collected from this study will guide FDA decision making with respect to the potential banning or setting up the limits of flavor components for use in e-liquids. The results of this study will be used for publication in scientific journals and conference presentations.

3. WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this study because:

1) You are healthy;
2) You are between 21 and 35 years of age;
3) You have been vaping for at least 1 month;
4) You currently use an e-cigarette with nicotine;
5) You have used at some point an e-cigarette with medium (9-12 mg/mL, or levels 0.9 to 1.2) or high (18-36 mg/mL, or levels 1.8 to 3.6) nicotine strength
6) You do not have mouth or throat problems that would keep you from vaping comfortably;
7) You do not have health problems that would keep you from tasting or smelling normally;
8) You do not have any food ingredient allergies and allergies to food additives, propylene glycol (PG), or vegetable glycerin (VG)
9) You do not have allergies to natural or artificial cherry flavors or fragrances;
10) You do not have any respiratory allergies (frequent sneezing, nasal congestion, nasal discharge);
11) You do not have a history of pulmonary disease or asthma;
12) You are not in the process of trying to quit vaping;

13) You are not pregnant, breast feeding, or trying to become pregnant.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this research study, you will first be asked to participate in a brief practice session. This practice session will allow you to become familiar with the procedures and stimuli (the e-cigarettes and e-liquids) used during the experiment. This practice session will involve using different printed or computer-displayed scales to make ratings about a list of sensory experiences. Once you have successfully completed the practice session, we will start the experiment. During the experiment, you will be asked to puff 9 different e-cigarettes (3 puffs each) containing e-liquids with flavor and nicotine levels up to 12mg/mL (nicotine level 1.2). The maximum amount of nicotine that you will be exposed to during this test is about 1 mg. As a comparison, research studies have cited that a regular domestic tobacco cigarette contains an average of 10-14 mg of nicotine. After puffing each e-cigarette, you will be asked to make ratings about liking or disliking of the vapor, and about the intensity of sweetness, bitterness, and irritation. You will have at least a one minute break between each trial. If needed, you can request that your break is longer than one minute. You will be asked to rinse your mouth with water at the start of testing and between each trial. It is expected that the duration of the entire session will take about an hour. *If you are female, you will be asked to take a pregnancy test before beginning the testing session.

5. WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

There may be risks related to the study procedures that are not yet known to the researchers. There may be a risk of harm to an unborn child. Thus, if you are a woman of childbearing potential, we will provide a pregnancy test before beginning the study. The products you will test contain nicotine. Nicotine is an addictive chemical. Participating in this study may result in physical discomfort due to the inhalation of nicotine. Some adverse effects have been reported to the FDA due to e-cigarettes by e-cigarette users. The signs/symptoms most commonly reported include: headache, pain, numbness, itching or unusual sensation, tiredness, weakness, dizziness, confusion, aggravated breathing, coughing, wheezing, auditory problems, eye redness. You must immediately let the experimenter know if you feel that you are experiencing any adverse reactions.

6. WHAT HAPPENS IF I AM INJURED?

Oregon State University has no program to pay for research-related injuries. If you think that you have been injured as a result of being in this study, we will contact an emergency medical service to take you to a medical center or hospital. Oregon State University will not provide you with any medical treatment or financial compensation for injury. That is, if you are injured, you (or your insurer) will have to pay for any care. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your legal rights. If you believe that you have been harmed as a direct result of taking part in our study, please contact the Principal Investigator, Juyun Lim, at (541) 737-6507 or Juyun.lim@oregonstate.edu.

7. WHAT ARE THE BENEFITS OF THIS STUDY?

This study is not designed to benefit you directly. The results are intended to increase our understanding of effects of sweet flavors on the perception and appeal of e-cigarettes.

8. WILL I BE PAID FOR BEING IN THIS STUDY?

You will be paid for being in this research study. After completing the full session, you will receive a $40 gift card to Fred Meyer. If you or the study team decides to terminate your participation before you complete the study, you will be paid at minimum wage per hour. This means if your session is terminated before 30 minutes, you will receive a $5 Fred Meyer gift card. If your session is terminated after 30 minutes, but before completing the study, you will receive a $10 Fred Meyer gift card. Remember that you are free to decline to participate at any time. You will always be paid for the time that you have served.

9. WHO IS PAYING FOR THIS STUDY?

The NIH/FDA is paying for this research to be done.

10. WHO WILL SEE THE INFORMATION I GIVE?

The information you provide during this research study will be kept confidential to the extent permitted by law. Research records will be stored securely and only researchers will have access to the records. The NIH, FDA, other federal regulatory agencies, and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. If the results of this project are published, your identity will not be made public. The data collected from this study will be shared with an external collaborator for the purpose of assistance with data analysis; however, personal identifiers including your name and email address will not be included.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug

Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

11. WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your participation in this study is completely voluntary. If you decide to participate, you may change your mind and withdraw from the experiment at any time. A decision to withdraw from the study will in no way affect future interactions with the primary investigator or research staffs or Department of Food Science and Technology. The research staffs may remove you from the study if they believe that is in your best interests. If you choose to withdraw from this project before it ends, the researchers may keep information collected about you and this information may be included in study reports.

12. WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this research project, please contact: Juyun Lim at (541) 737-6507 or juyun.lim@oregonstate.edu. If you have questions about your rights as a participant, please contact the Oregon State University Institutional Review Board (IRB) Office, at (541) 737-8008 or by e-mail at IRB@oregonstate.edu.

13. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Do not sign after the expiration date: 01/03/2019

Participant's Name (printed): _____

_____ _____

(Signature of Participant) (Date)

_____ _____

(Signature of Person Obtaining Consent) (Date)