CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Electronic Cigarette Use in Young Adult Men and Women **: Study 2**
Principal Investigator: *Deepa Camenga, MD*
Funding Source: National Institute on Drug Abuse, National Institutes of Health.

Invitation to Participate and Description of Project:

You are invited to participate in a research study designed to look at the behaviors of young adult men and women who use combustible tobacco products and electronic cigarettes. We are asking approximately 16 males and 16 females to participate in this study. You have been asked to participate because you are a young adult who uses both combustible tobacco products and electronic cigarettes (e-cigarettes).

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures:

This study lasts 8-10 days. If you agree to participate in this study, you will be asked to 1) Participate in two in-person study visits at the APT Foundation in New Haven/a public location; 2) complete surveys; 3) keep a daily record of your e-cigarette and combustible tobacco product use for 7 days; 4) respond to random prompts (delivered via your cell phone) asking about your recent tobacco/e-cigarette use; and 5) email/text videos of yourself using a breath CO monitor to the study cell phone (2x per day).

Baseline visit: This visit will occur at the APT Foundation.

- You will be asked to complete surveys that ask about your combustible tobacco product and e-cigarette use.
- You will also be asked to provide a saliva sample that will be used to measure levels of cotinine (a biomarker of tobacco exposure). Women will be asked to provide a urine sample to confirm the absence of pregnancy.
- You will be asked to download the MetricWire application to your personal cell phone. You will also receive training on how to use the MetricWire data collection application. MetricWire provides Android and iOS mobile applications that allow participants to view study details, submit responses to survey questions and upload multimedia. (www.metricwire.com**). During the ecological momentary assessment (EMA) portion**

APPROVED BY THE YALE UNIVERSITY IRB 9/7/2018 VALID THROUGH 1/17/2019

of the study, the app will prompt you to answer questions about your combustible tobacco product and e-cigarette use two times/day and will ask you to complete a daily night time diary describing your e-cigarette and combustible tobacco product use

- You will receive a breath carbon monoxide monitor (to be returned at the follow-up visit) and will be trained on how to use it daily to record a video of yourself blowing into the monitor. You will be asked to send the videos to the study cell phone via text/email, two times per day.
- This visit will take approximately 60-90 minutes and can occur at the APT Foundation in New Haven.

Follow-Up visit: This will occur between Days 8-10

- You will be asked to complete short surveys that ask about your combustible tobacco product and e-cigarette use.
- You will be asked to provide a breath carbon monoxide sample to confirm tobacco use. You will return the breath carbon monoxide monitor to the research assistant.
- You will also be asked to provide a saliva sample that will be used to measure levels of cotinine (a biomarker of tobacco exposure).
- This visit will take approximately 30-45 minutes and can occur at the APT Foundation in New Haven/a public location.

The research team will use several methods of contact to keep in touch with you. We will ask you to provide us with the following information about yourself:

- Phone numbers to reach you to speak by phone
- Phone number which we can text you to remind you of appointments
- E-mail addresses
- Current home and work addresses (If you are unable to complete an in-person or phone interview, we may send you a follow-up questionnaire with a self-addressed, stamped envelope).
- Contact information of family and friends who may know how best to reach you, or to pass you a message to contact us. If we need to contact those individuals, the research team will not reveal any information about the study or your treatment (we will not ask about drug use or other problems).

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

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Future Re-contact:

Although your participation in this study is scheduled to last for approximately 8-10 days, we would like to contact you, if you are willing, future studies. If you agree to be re-contacted, you are under no obligation to participate in future research. Please initial your choice below:

___ Yes, I would like to be contacted for future research opportunities.

___ No, I do not want to be contacted for future research opportunities.

Risks and Inconveniences:

1. Risks Associated with Loss of Confidentiality Every effort will be made to keep your information confidential; however, this cannot be guaranteed. The main risk associated with the study is the possibility that confidential information obtained during the study will be disclosed. All efforts will be made to protect subjects' confidentiality. The alternative to participation is for a potential subject to decide NOT to participate. Confidentiality of the results are specifically protected by Federal laws, and all records will be identified by code number only, with the master file kept under lock by the Project Director.
2. Risks with use of electronic cigarette: The e-cigarette delivers nicotine in much the same way that a regular cigarette does, through inhalation. **The long-term risks of e-cigarettes are currently unknown.** The most frequently reported side effects of e-cigarette are cough, dry mouth, shortness of breath, throat irritation, and headache.[1] Other adverse events may include nausea and stomach cramps. Several studies have noted that the reported adverse events were classified as mild. You should call the study's Principal Investigator if you have concerns with any of these symptoms.

Breath and saliva Collection - There are no known risks associated with providing breath carbon monoxide or saliva samples. These tests are non-invasive and the main inconvenience is associated with the time needed to give the samples.

Benefits:

This study does not provide direct benefits to participants. However, the results from this study may help scientists understand how young men and women switch from cigarettes to e-cigarettes.

Economic Considerations:

To remunerate you for the time you spend participating in this study, you will be compensated with a monetary payment via cash. You can earn up to $150 for participating in this study. This includes:

- $15 for each in person study visit ($30 total for two visits)
- $50 for completion of the EMA procedures
- Up to $14 for completion of 85% of more of the EMA prompts

- Up to $56 for on-time and valid video recordings of breath carbon monoxide measurement
- **TOTAL Possible payment is $150.**

According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.

As a participant in this study, you will be responsible for the costs associated with:

1. Purchasing your e-cigarette, e-liquid, or any other e-cigarette product components.
2. Transportation to and from study visits
3. Operating your cell phone

Alternatives:

The alternative to study participation is to not participate in the study.

Confidentiality and Privacy:

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

If you decide to take part in this research study, you will be asked to give us information about your cigarette and e-cigarette use. We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, and social security number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All personal information will be coded and stored in a locked cabinet and any data stored on a computer will be password protected to further protect your confidentiality. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for a minimum of 3 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

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 National Institutes of Health 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.**Confidentiality of data collected via MetricWire:**

Through the Metric Wire's Notice of Privacy Practices ("Privacy Notice") individuals you will be informed of the Company's legal duties and these Policies and Procedures, as well as your individual rights with respect to Protected Health Information.[2] The data obtained from the MetricWire app is stored on Health Insurance Portability and Accountability Act (HIPAA) and 21 CFR Part 11 compliant servers and it is encrypted during transit. All employees of MetricWire must adhere to HIPAA.

The data from MetricWire will be property of the Yale University investigators. This data and any kind of logs, will be kept in a secure HIPAA compliant database stored at Yale School of Medicine. This server is firewall and password protected, with limited access only to investigators.

The information about your health that will be collected in this study includes:

- Research records
- Records about phone calls made as part of this research
- Records about your study visit
- Laboratory test results including urine cotinine and pregnancy test results

Representatives from the Yale Human Research Protection Program, the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Information about you and your health which might identify you may be used by or given to:

- Yale University School of Medicine
- Members of the Human Investigations Committee or Ethics Committee(s)
- The Principal Investigator Deepa Camenga, MD
- Co-Investigators and other investigators
- Study Coordinator and members of the research team
- The Department of Health and Human Services (the National Institute of Health funds this study)

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in this study and signing this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury:

- If you are injured while participating in the study, seek treatment and contact the study doctor as soon as you are able.
- Yale School of Medicine does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.
- You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal:

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing from the Study:

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. The researchers may withdraw you from participating in the research if necessary. You may be withdrawn if you develop severe side effects from using the e-cigarette. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

Withdrawing Your Authorization to Use and Disclose Your Health Information:

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Deepa Camenga, MD, 464 Congress Street, Suite 260, New Haven, CT, 06519.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions:

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization:

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject: _____

Signature: _____

Date: _____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator *Deepa Camenga at 203-737-8310 or deepa.camenga@yale.edu.* If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.