CONSENT FORM

Changes in Biomarkers Associated with Use of Electronic Cigarettes among African American Menthol and Nonmenthol Smokers

You are invited to participate in a research study of **Changes in Biomarkers Associated with Use of Electronic Cigarettes among African American Menthol and Nonmenthol Smokers**. You were selected as a possible participant because you identified yourself as being African American or Black and you smoke either mentholated or nonmentholated cigarettes. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Dr. Anne Joseph from the Department of Medicine at the University of Minnesota. It is funded by ClearWay Minnesota.

Study Purpose

The purpose of the study is to determine the pattern of use of electronic cigarettes and changes in biomarkers (or chemicals in the body) associated with the use of electronic cigarettes among African American menthol and nonmenthol smokers. This is not a treatment study. Participating in the study does not mean you must stop smoking cigarettes, although you may quit if you wish

Study Procedures

If you agree to participate in this study, we would ask you to do the following:

Baseline/Randomization visit: At this visit the study's goal and procedures as well as your responsibilities will be reviewed with you. You will be asked to sign this consent form. If you sign the consent form, smoking status will be confirmed with either a carbon monoxide test or a urine nicotine test. If you remain eligible, you will complete baseline assessments that include questions about demographics (for example age, gender, education, and employment), tobacco use, and nicotine dependence. You will then receive either e-cigarettes that contain nicotine or one that has no nicotine depending on the study group to which you are assigned (determined by flipping a coin). You will not know the nicotine content of the e-cigarettes you will be assigned to receive. Within each study group, you will be allowed to select your preferred flavor (menthol or non-menthol) of electronic cigarettes. Before making your selection, you will be allowed to sample both menthol and non-menthol flavored brands of e-cigarettes by taking a few puffs from both brands during the visit. You will receive enough supply of study products to last until your next appointment plus 7 days extra in case you change your appointment day. You will be given verbal and written instructions about how to use e-cigarettes. You will be asked to bring all, used and unused, e-cigarettes to every visit. You will also be asked to give about a cup of your urine to be tested for body chemicals associated with use of tobacco.

Weeks 2 and 6: Approximately three days before each of these visits, you will be contacted by study staff either by phone, email, or text to remind you of your next appointment. At these visits you will update your contact information and answer a few questions related to cigarette smoking, do a CO test, and receive more e-cigarettes to last until your next visit (week 2 only). E-cigarettes will be provided through week 6. Study staff will count the number of e-cigarettes you have left. You will also be asked to give about a cup of your urine to be tested for body chemicals associated with use of tobacco at week 6.

Week 12 (End of study): You will complete a survey over the phone.

Risks of Study Participation

There are some risks related to changes in smoking behavior that you may experience while in the study. These might include headaches, being uncomfortable, changes in mood, weight gain, and the possibility of changing smoking habits. You will be asked by staff at every individual session about side effects from the electronic cigarettes you are using as well as any new health problems you experience. You can call the study phone number, which is ***(612) 626-8798***, to report serious side effects and be advised whether or not to keep using the products.

Side effects of the electronic cigarette are not known since little research has been done on this product. Electronic cigarettes are not regulated by the FDA. There is a notice from the FDA regarding the safety of this product that states they do not know whether electronic cigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using electronic cigarettes. Some of the samples tested have detectable levels of toxic chemicals. Side effects may be similar to the use of the nicotine inhaler, such as sore throat or burning in the throat, stomach ache, nausea, sore throat, or pain, belching, coughing, or stuffy nose. They may also include vomiting or diarrhea.

Some people in the study may receive an e-cigarette that does not contain any nicotine. Taking a placebo may be similar to not taking any medication. If you receive such e-cigarettes, you smoking habit may stay the same or get worse, or you may stop smoking.

Pregnancy Risks: If a woman is pregnant or breastfeeding, she will not be allowed to take part in this study because the effects of e-cigarette on an unborn baby is not known. If you are a woman and you are able to get pregnant, you must have a urine test to see if you are pregnant. You must agree to this test if needed in your case. If you are not pregnant and agree to use an effective method of preventing pregnancy while using the e-cigarette, you will be allowed to take part in the study. If you are woman and you becomes pregnant while in the study and using the e-cigarette, you will be asked to tell the staff and immediately and stop using the e-cigarette.

Benefits of Study Participation

There is no direct benefit to you from participating in this study.

Alternatives to Study Participation

This is not a study to help you quit smoking. If you would like to quit smoking, you should talk to your healthcare provider or buy over the counter medications approved for quitting smoking.

Study Costs/Compensation

You will be compensated for your time and inconvenience in the study according to the following schedule: you will receive $40 for completing the baseline visit, $40 for completing the week 2 visit, $50 for completing the

week 6 visit, and $20 for completing the week 12 phone call. If you complete all study visits, your total compensation will be $150 over the entire study (12 weeks). You will only receive compensation for the visits you completed.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however be reviewed by government agencies and by departments at the University with appropriate regulatory oversight. Information from this study will not be added to your clinic or hospital record. If study data are sent through the internet to these agencies, adequate provisions will be made to protect your privacy. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

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

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to self or others.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Anne Joseph and Dorothy Hatsukami. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at 612-625-8983.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____

Printed name of Subject _____

Date_____

Signature of Person Obtaining Consent_____

Date_____