RESEARCH INFORMED CONSENT

Carbon monoxide levels and changes in acute pulmonary function following e-cigarette use

Protocol Number 627260

Sponsor: LB595 Cancer and Smoking Grant Program

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Rev 1.23.15
INTRODUCTORY STATEMENT
You are being invited to participate in a research study that will evaluate the ways that smoking cigarettes and using electronic cigarettes (e-cigarettes) may affect the function of the lungs. In addition, this study will examine the impact that smoking and e-cigarette use has on the ability of hemoglobin (the part of red blood cells responsible for carrying oxygen throughout the body) to carry oxygen. Dr. Arouni and the research team are working to find out what health effects are associated with e-cigarette use. The information that we learn from the participants in this study will be used to plan future studies that will determine what health effects may be associated with e-cigarette use. There will be approximately 180 adult participants in this study. Creighton University is the only site for this study.

This form is a Research Study Informed Consent Agreement, also referred to as “Consent.” The information in this Consent should help you make an informed decision about whether you should take part in this Research Study. This Consent, along with information you receive from Dr. Arouni and her staff, will help explain to you the risks and benefits of participating in this Research Study.

This Consent may contain words you do not understand. If there are any words or information in this Consent you do not clearly understand, please ask someone from the study team to explain them to you before you agree or disagree to participate.

After considering all of the written information provided to you, as well as your discussions with the study team, you may decide that you want to participate in the Research Study. If so, you will be asked to sign this Consent.

Study Purpose and Procedures
Previous research has shown that smoking cigarettes increases airway resistance, making it difficult for the lungs to deliver oxygen into the cardiovascular system (which includes the heart, lungs, and brain). Prolonged conditions of increased airway resistance are associated with increased respiratory system damage in smokers compared to non-smokers. The effects of e-cigarette use on lung function have not yet been studied, so there is currently not enough information about whether e-cigarette use results in lung damage.

Carbon monoxide (a chemical that is present in the breath and blood of smokers) is created upon combustion of cigarettes. When carbon monoxide is breathed in it will bind to hemoglobin found on red blood cells in blood in place of oxygen. As a result, the heart has to work harder to get enough oxygen to the tissues of the body. Whether e-cigarette use is associated with the production of carbon monoxide the same way that cigarettes are is not known at this time.

This study will include healthy people who are current regular e-cigarette users to test whether there is any change in pulmonary function, carbon monoxide levels, and blood pressure, and heart rate. If you agree to participate in this study, we will ask you to complete one study visit. To be eligible for the study, you must be a daily user of a nicotine containing e-cigarette who has not smoked cigarettes for a minimum of one month.
At the beginning of the study, we will collect information about your smoking and e-cigarette history. We will also test the amount of carbon monoxide in your breath at the beginning of the study visit. Carbon monoxide is tested by blowing into a small device that measures how much of this chemical is in your body.

You will need to refrain from nicotine (from smoking or vaping) and caffeine for at least 2 hours prior to the visit.

**Procedures**

- Obtain informed consent with a listed investigator
  - Complete the Smoking Assessment (which includes smoking history)
- Take a carbon monoxide breath test
- Blood pressure and heart rate measurement
- Lung function evaluated by use of spirometry. (A spirometer is a small machine that you will be asked to breathe into to evaluate lung function)
- You will be randomly assigned (like the flip of a coin) to use either a STAM eGo electronic cigarette or a Blu e-cigarette. You will also be randomly assigned a different flavor and nicotine content. The flavors that you could be assigned to are: Pina Colada, Tobacco, and Menthol. You will also be assigned to either high nicotine (13-16 mg/ml) or zero nicotine. You will take 8 “puffs” from the e-cigarette. This will take place in a room in the Cardiac Center that has been temporarily exempted from the Creighton University Tobacco Free Campus policy for this study, or at our community partner Plumes. If you are assigned to the eGo e-cigarette, the cartridge and mouthpiece for the e-cigarette will be new and only used by you for this study (it will be discarded when you are done). The rest of the e-cigarette (battery and atomizer) will be used by other people during the study and will remain with the study team when you are done. If you are assigned to the Blu e-cigarette, it will be discarded when you are done.
- After vaping, blood pressure, heart rate, and carbon monoxide, and lung function (spirometry) will be re-measured.

**Risks of Participating in the Study**
E-cigarettes are relatively new and there is little research available about their safety. The study team has selected two types of e-cigarettes that are very commonly purchased and widely available.

The carbon monoxide breath tests and spirometry that will be done are non-invasive and do not pose any more risk than that encountered in everyday life.

**Confidentiality Risk**
A possible risk involved in this study involves the potential social and psychological risks associated with accidental disclosure of confidential medical information from the data collected throughout the study. Several procedures will be in place to prevent such an occurrence.
Benefits of Participating in the Study
You may not directly benefit from participation in this study. By your participation in this study, the investigators may gain knowledge that may help you and others who want to use e-cigarettes in the future.

Disclosure of Appropriate Alternatives
You do not have to participate in this study. If you do not want to participate in the study, you may still receive smoking cessation treatment from Creighton University at the usual charge. You may stop participating in the study at any time.

Confidentiality
We will do everything we can to keep your records confidential. However, it cannot be guaranteed. We may need to report certain information to agencies as required by law.

Both records that identify you and this consent form signed by you may be looked at by others. The list of people who may look at your research records are:

- The investigator and their research staff and students
- The Creighton University Institutional Review Board (IRB) and other internal departments that provide support and oversight at Creighton University.

We may present the research findings at professional meetings or publish the results of this research study in relevant journals. However, we will always keep your name, address or other identifying information private.

We will also ask you to sign a separate form called the HIPAA Authorization which will give you more specific information concerning the use of your health information.

Compensation for Participation
You will receive a stipend of $20 to compensate for your time and travel.

Research-Related Injury
The investigators will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care at the usual charge. The costs of this care will be charged to you or to your health insurer. No funds are available from Creighton University to repay you or compensate you for a study-related injury or illness. There is also no compensation available for payment of your lost wages or other losses.

By signing this consent form, you will not be waiving any of your legal rights that you otherwise would have as a subject in a research study.
Contact Information
If you would like to speak to someone about this study, you may call the Study Coordinator, Shavonne Washington-Krauth, at (402) 280-5287.

CONSEQUENCES OF SUBJECT’S DECISION TO WITHDRAW
Your participation is voluntary. You are free to leave this study at any time. Your decision not to participate, or to leave this study at some point after it has begun, will not result in penalties or loss of benefits to which you are otherwise entitled to that are unrelated to the research study, and will not affect your future medical care at this facility.

Your participation may also be ended without your consent if the study team feels that it is in your best interest. The investigators or the IRB may discontinue the study at any time. If you decide to withdraw your consent to participate after your visit is complete, you may contact the Principal Investigator, Amy Arouni, MD, at (402) 717-0717 or the Study Coordinator, Shavonne Washington-Krauth, at (402) 280-5287 and request that your data is removed from the data set.
SIGNATURE CLAUSE

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled, or any effect on your medical care.

My signature below indicates that all my questions have been answered. I agree to participate in the project as described above.

_______________________________   _______________________
Printed Name of Subject

_______________________________   _______________________
Signature of Subject Date Signed

The Creighton University Institutional Review Board (IRB) offers you an opportunity (anonymously if you so choose) to discuss problems, concerns, and questions; obtain information; or offer input about this project with an IRB administrator who is not associated with this particular research project. You may call or write to the Institutional Review Board at (402) 280-2126; address the letter to the Institutional Review Board, Creighton University, 2500 California Plaza, Omaha, NE 68178 or by email at irb@creighton.edu.

A copy of this form has been given to me.       _________Subject’s Initials

For the Research Investigator—I have discussed with this subject (and, if required, the subject’s guardian) the procedure(s) described above and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

_______________________________   _______________________
Signature of Responsible Investigator Date Signed

We would appreciate your feedback on your experience as a research participant at Creighton University; please fill out our survey at http://www.creighton.edu/participantsurvey
Bill of Rights for Research Participants

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.

2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.

3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.

4. To be told about the reasonably foreseeable risks of being in the study.

5. To be told about the possible benefits of being in the study.

6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.

7. To be told who will have access to information collected about you and how your confidentiality will be protected.

8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject.

9. If the study involves treatment or therapy:
   a. To be told about the other non-research treatment choices you have.
   b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.