Synthetic Cooling Agents in Combustible Cigarettes: A Pilot Study

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The Ohio State University Consent to Participate in Research

Study Title:	"Synthetic Cooling Agents in Combustible Cigarettes: A Pilot Study"
Principal Investigator:	**Alayna P. Tackett, PhD**
Sponsor:	The Department of Internal Medicine (DOIM), The Ohio State University Wexner Medical Center

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to take part in this study because you are a current young adult smoker. The purpose of this study is to understand how synthetic cooling additives impact on smoking perceptions, use behavior, and discover the contents of cooling agents. Your participation in this study will consist of completing 3 clinic visits in which you smoke *ad-lib* one of three randomly assigned cigarettes that differ either by menthol or synthetic cooling agent content. Procedures will include coming to the Center for Tobacco Research to answer questionnaires, providing nasal fluid samples, lung function testing, and smoking 3 different types of cigarettes.

3. There are risks from participating in this study. The most common risks are feeling uncomfortable while answering survey questionnaires. More detailed information about the risks of this study can be found under the "Risk and Discomfort" section.

4. You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn more about the effects of adding synthetic cooling additives to cigarettes.

5. If you decide not to participate in this research, your other choices may include not participating in this study.

1. Why is this study being done?

The purpose of this study is to understand how synthetic cooling additives impact smoking perceptions, use behavior, and discover the contents of cooling agents.

2. How many people will take part in this study?

Approximately 50 participants will take part in the study.

3. What will happen if I take part in this study?

Participation involves taking part in a study at The Center for Tobacco Research. All equipment and materials needed to conduct the study visits will be provided to you, however you will be asked to bring your own preferred cigarette to your study visit. You will be asked to participate in 3 study visits over the course of 1 month (3 weeks; 1 session/week).

If you decide to take part, this is what will happen:

Eligibility:

- To ensure eligibility pregnancy exclusion will be confirmed with a urine test (pregnancy tests will be completed at each visit throughout the study).
- You will provide basic demographic information.

Study Sessions 1 – 3 (2 – 2.5 hours each visit):

- If you are eligible, you will complete the first smoking session and will be randomized to smoke the first cigarette condition.
- A trained phlebotomist will take blood pressure and heart rate.
- You will be instructed to smoke the first cigarette.
- Collect nasal swabs (5 minutes; 10 minutes total; pre/post smoking). The nasal swabs tell us how much nicotine or other substances are in your body and how well you can breathe. A study team member will provide you with instructions on how to collect.
    - Samples will be collected pre and post smoking at each visit. Briefly, saline will be spritzed into each nostril. You will insert each strip into a nostril, then place a cushioned nose clamp on your nose for 2 minutes. Following the 2 minutes you will remove each strip and place them into pre-labeled microtubes

- Use the spirometry machine (5 – 10 minutes each assessment; pre/post smoking). A study team member will instruct you on how to use this machine. You will take a few blows in this device to make sure you are comfortable with the process. You will be asked to complete this pre and post smoking.
- You will also be asked several questionnaires throughout the study session to capture what you think about the cigarettes you smoke and how you feel (~30-45 minutes throughout the study).

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

4. How long will I be in the study?

This study requires 1 visit per week for 3 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. If you decide to stop participating in the study, we just ask that you let study staff know that you are no longer interested.

6. What risks, side effects or discomforts can I expect from being in the study?

- **Spirometry Machine:** Spirometry is a common test used to see how well a person's lungs work. While spirometry is generally safe, you may feel short of breath or dizzy for a moment after the test. If you have a history of heart conditions or have had a recent heart attack, you should not participate in this study.
- **Nasal Swab Collection:** Nasal swab collection is a common, safe procedure used often in clinical settings. Nasal swab use can be associated with nasal discomfort, headache, earache, runny nose, sneezing, and bloody nose. Symptoms may last anywhere from a few hours to a full day.
- **Surveys/Questionnaires:** Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to.
- **Breach of Confidentiality:** There is a small risk that people who are not connected with this study will learn your identity or your personal information.
- **Reproductive Risks:** Nicotine can harm an unborn child or infant. If you are pregnant or start breastfeeding in the next 30 days, you may not participate in this study.
- **Unforeseen Risks:** There may be other risks that are not known at this time.

7. What benefits can I expect from being in the study?

There are no direct benefits.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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 the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. Will my de-identified information be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

11. What are the costs of taking part in this study?

There is no cost to you for participating in this study.

12. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income.

You will receive $80 for each visit that you attend ($240 total), and an additional bonus of $50 for protocol compliance (attending all 3 visits) for a possible total of $290.

If you are ineligible for this study at the Baseline Session, you will receive $10 compensation for your time.

Payment for the study will be issued via ClinCard. A ClinCard works like a credit or debit card, and can be mailed to your home address. You will be given instructions on how to use the card and it will be given to you after completion of the orientation session. If the card is lost or stolen, please call ClinCard services (1-215-690-5363 or 1-215-609-4378) to report the lost or stolen card and to obtain a new card. Upon reception of the ClinCard, our research team assumes no responsibility to recover lost or stolen funds.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact **Dr. Alayna Tackett at 1-844-744-2447**.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact 1-844-744-2447*.*

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)** **AM/PM**
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time