

Title: "Natural" and "Organic" Cigarette Descriptors: Association With Expectancies, Subjective Effects, Topography, and Biomarkers of Exposure Among Daily Smokers

NCT number: NCT05468333

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University of Nevada, Reno

Institutional Review Board

Approved on: September 12, 2023

**University of Nevada, Reno
Consent Form for Social Behavioral Research**

Title of Study: **Evaluation of Capital Cigarettes**
Principal Investigator: **Jennifer Pearson, MPH, PhD**
775-682-5005
Co-Investigators **Yeongkwon Son, PhD**
Melissa Mercincavage, PhD
Study Contact: **775-682-5005**
Study ID Number: **TBD**
Sponsor: **Capital Cigarette Company**

Introduction

You are being invited to participate in a research study. Before you agree to be in the study, read this form carefully. It explains why we are doing the study, and the procedures, risks, discomforts, benefits, and precautions involved.

At any time, you may ask one of the researchers to explain anything about the study that you do not understand.

You do not have to be in this study. Your participation is voluntary.

Take as much time as you need to decide. If you agree now but change your mind, you may quit the study at any time. Just let one of the researchers know you do not want to continue.

Why are we doing this study?

We are doing this study to find out what people think about organic, natural, and conventional versions of a new brand of cigarettes, and to see if smoking these different types of cigarettes changes their exposure to chemicals in cigarette smoke.

Benefits of research cannot be guaranteed but we hope to learn whether people like organic and natural cigarettes as much as conventional cigarettes.

Why are we asking you to be in this study?

We are asking you to be in this study because you are an adult smoker and have indicated willingness to be in the study.

How many people will be in this study?

We expect to enroll up to 300 participants.

What will you be asked to do if you agree to be in the study?

If you agree to be in this study, we will ask you to come to the lab four more times to smoke your usual brand of cigarettes and to try three new kinds of cigarettes. We will ask you to look



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at the advertising, smoke the cigarette, and answer some questions about your smoking experience. You must come to the next four sessions abstinent from nicotine and smoking for 12 hours. This usually means that you will smoke your last cigarette around 8 or 9pm the night before your lab session, then wake up and come directly to the lab without smoking in the morning.

We will also ask you to provide a saliva sample before and after you smoke cigarettes in the lab. The purpose of the saliva sample is to measure your exposure to some of the harmful chemicals in cigarette smoke. We are interested in seeing if your exposure to harmful chemicals from smoking is different depending on whether you smoke the conventional cigarette, the natural cigarette, or the organic cigarette. We will not analyze your saliva for any other substances other than those associated with cigarette smoking. The saliva sample collection process involves you drooling into a small plastic test tube before and after smoking your own cigarette in Session 2 and the Capital Cigarettes in Sessions 3-5.

We may terminate your participation if you fail to show up to lab sessions, or if you do not follow instructions and smoke within 12 hours of your study session.

How long will you be in the study?

The study will take about 6 total hours of your time; you'll participate for about 3-4 weeks.

What are your choices if you do not volunteer to be in this research study?

If you decide not to be in the study, you can withdraw at any time.

What if you agree to be in the study now, but change your mind later?

You do not have to stay in the study. You may withdraw from the study at any time by telling the researchers during the session or calling/emailing the Principal Investigator and telling her you would like to withdraw. If you leave the study early, whether by your choice or because a researcher suggests it, you will not receive payment for the study activities that you did not complete.

What if the study changes while you are in it?

If anything about the study changes or if we want to use your information in a different way, we will tell you and ask if you if you want to stay in the study. We will also tell you about any important new information that may affect your willingness to stay in the study.

Is there any way being in this study could be bad for you?

If you participate in this study, you may be in mild nicotine withdrawal before Sessions 2-5. Symptoms of mild nicotine withdrawal include headache, irritability, constipation, and nausea. These symptoms will go away after you smoke a cigarette during the session.

Another potential risk is loss of confidentiality if we were to lose possession of your data. However, we do not associate your name or other identifying information with your study data (only the data we use to schedule visits), so we think this risk is minimal.



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We do not anticipate any other potential risks to you from this study.

What happens if you become injured because of your participation in the study?

In the unlikely event that this research activity results in an injury, treatment will be available. This includes 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.

Will being in this study help you in any way?

We cannot promise you will benefit from being in this study.

Who will pay for the costs of your participation in this research study?

No costs are associated with participation in this study.

Will you be paid for being in the study?

If you participate in this study, you will receive up to \$200. You will receive \$20 for attending each session. You will receive an additional bonus of \$10 for the second session (total \$30), \$20 for the third session (total \$40), \$30 for the fourth session (total \$50), and \$40 for the fifth session (total \$60) if you have not smoked (tobacco or cannabis) or consumed nicotine for 12 hours before the session, as measured in the lab using a device that measures the carbon monoxide in your exhaled breath. This measurement may lead to a determination that you are not eligible to continue in the study, so it is very important that you do not smoke (tobacco or cannabis) or consume nicotine for 12 hours before coming to the lab. We will provide payment as Visa gift cards, cash, or ClinCard. For accounting purposes, we will have to provide your name to the UNR Controller's Office when you receive the Visa gift cards, cash, or ClinCard.

Who will know that you are in this study and who will have access to the information we collect about you?

The researchers, University of Nevada, Reno Institutional Review Board, and Capital Cigarettes will have access to your study records.

How will we protect your private information and the information we collect about you?

We will treat your identity with professional standards of confidentiality and protect your private information to the extent allowed by law. Personal information will be replaced with codes. The list linking participant names and the codes will be stored securely and separately from the research data. We will destroy the list linking participant names and codes when we are done collecting data. The research data will be stored on a secure network server and any paper files and our study laptop will be kept in a locked suite.

We will not use your name or other information that could identify you in any reports or publications that result from this study.

Do the researchers have monetary interests tied to this study?

The researchers and/or members of their families do not have any monetary interests tied to this study.



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Who can you contact if you have questions about the study or want to report an injury?

At any time, if you have questions about this study or wish to report an injury or complication that may be related to your participation in this study, contact Dr. Jennifer Pearson (775) 682-5005 or jennipearson@unr.edu.

Who can you contact if you want to discuss a problem or complaint about the research or ask about your rights as a research participant?

You may discuss a problem or complaint or ask about your rights as a research participant by calling the University of Nevada, Reno Research Integrity Office at (775) 327-2368. You may also use the online *Contact the Research Integrity Office* form available from the [Contact Us](#) page of the University's Research Integrity Office website.

Agreement to be in study

If you agree to participate in this study, you must sign this consent form. We will give you a copy of the form to keep.

Participant's Name Printed

Signature of Participant

Date

Signature of Person Obtaining Consent

Date