Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: Menthol and non-menthol cigarette smoking in young adults

Sponsor: National Institute on Drug Abuse/Food and Drug Administration Center for Tobacco Products (CTP)

Principal Investigator: Amy M. Cohn, PhD

Phone Number: 405-271-1903

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to participate in this research study because you are a current smoker and meet study eligibility criteria. This study is being conducted by the University of Oklahoma Health Sciences Center and is funded by the National Institutes of Health (NIH). Joining the study is voluntary. You do not have to answer any questions that make you feel uncomfortable. You can stop participating or answering questions at any time.

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to understand why people smoke menthol and non-menthol cigarettes. We are interested in how smoking these cigarettes affects your smoking, how you feel, and attitudes about different types or brands of cigarettes. We think that you will be in the study for 6 months.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?

Before any study-related tests and procedures are performed, we will ask you to read and sign this consent document. Then, we will ask you to take part in the following study activities:

- Complete a baseline survey where you will answer questions about your personal history, tobacco use behavior, attitudes, and tobacco-related behaviors
- Take part in three in-person laboratory visits which may last up to 2 hours each. You will be asked to refrain from cigarette smoking or using other nicotine products for at least 12 hours before each visit. At each lab visit, we will ask you to have a smoking session. You will provide breath samples to measure when you last smoked. You will also complete questionnaires about your behavior and mood, both before and after smoking. We will also measure your heart rate and blood pressure before and after smoking. Note: You may complete these visits remotely, via password protected video in the event social isolation is necessary, or at your choosing.
- You will complete daily surveys about your mood and behavior through a phone application for 14 days. At the end of the 14 days (2-weeks) you will complete a survey asking about your experience with the phone surveys.
- Finally, at 2, 4, and 6 months after your initial enrollment, we will do a short survey in-person, online, or via the phone (your preference) about your tobacco use and behavior.

For a complete description of the study procedures, refer to the Detailed Information section of the consent form.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?

If you agree to take part in this study, you may benefit directly through increased understanding of factors underlying your use of cigarettes. We also hope that the information learned from this study will benefit other people in the future.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?

This study has minimal risk however there are known complications that arise from smoking cigarettes that may affect the individual or an embryo, fetus, or infant. The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate in this study. If at any point during the three in-person study visits you decide to stop smoking, you will be reimbursed for your time up to that point and be released from the study. We will not ask you to smoke cigarettes if you decide you want to stop smoking. We will also provide you with a list of places where you may choose to seek treatment. If you decide to stop smoking after the in-person study visits, you will still be able to continue in the study and unless you tell us you want to drop-out of the study.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?

You will be paid for your time and effort. Below describes the compensation for completing each phase of the study:

- Completing the baseline survey: $35
- Completing the daily surveys: up to $98 (if you complete all surveys)
- Visit/Session 1 $45 (if eligible and decide to participate); $25 if you are not eligible at this first visit.
- Visit/Session 2 - $45
- Visit/Session 3 - $45

Below describes the compensation for completing the daily telephone surveys for 14 days:

- $1 for each completed telephone survey x 28 (14 days x twice a day) surveys = $28
- $10 bonus for each week if you complete all surveys for that week x 2 weeks = $20
- $50 bonus if you complete 85% of the telephone surveys (23 of 28) during the 2 weeks

Follow-up Surveys

- $15 for completing the 2-week follow-up survey (at the end of the daily surveys), the 2-month follow-up survey, and the 4-month follow-up survey (total of $45)
- $55 for completing the final follow-up survey (at 6-months)
- $100 bonus for completing all phases of the study

Travel

- $10 for each of three in-person lab visits or $10 for curbside pickup/delivery of study materials if you take the study remotely (up to $30 total)

If you refer someone who is eligible and agrees to participate, you will receive a $25 referral bonus. You will receive a maximum of one referral bonus.

The total possible compensation (including referral) is $523.

You will be asked to provide your social security number, your residency status (a copy of your green card must be provided if applicable), and whether you are a University of Oklahoma employee for tax reporting purposes. If you are unwilling or unable to provide your social security number, residency status (and green card if applicable), or University of Oklahoma employment status you will not be eligible to participate in the research study.

For additional information about possible costs, please refer to the Detailed Information section of the consent form and ask the study team about any expected additional costs or insurance problems.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 250 people will take part in this study in Oklahoma. All of these individuals will participate at this location.

WHAT IS THE STATUS OF THE DRUGS/DEVICES/PROCEDURES USED IN THIS STUDY?
At the in-person laboratory visits, you will smoke your own or usual cigarette brand and commercially available Camel Crush cigarettes in this study. The Food and Drug Administration Center for Tobacco Products regulates cigarettes.

WHAT IS INVOLVED IN THE STUDY?
If you are eligible and agree to participate, this study will require you to complete

- 3 in-person visits to our laboratory or 3 virtual study sessions,
- Daily cell phone surveys for 14 days (on your phone or a study provided phone),
- Interim surveys at 2-weeks, 2 months, and 4 months after you are enrolled, and
- A final follow-up survey 6 months after you are enrolled.

The first visit /session will last about 2.5 hours.

The three in-person visits or virtual sessions will be scheduled at least 2 days apart and will last between 1 and 2 hours, depending on the session. We will ask that you refrain from cigarette smoking and using other nicotine products for at least 12 hours before each in-person visit.

If you are female, to be eligible you cannot be pregnant, breastfeeding, or plan to become pregnant. If you do become pregnant, please notify the study staff as soon as possible. We will ask you to take a pregnancy test at every in-person study visit or virtual session. We expect that if you are a female of child bearing age who is able to conceive, you will use reliable contraception and not be planning pregnancy or breastfeeding during the study. Participants with a positive pregnancy test at any in-person visit will be notified and will

not be able to continue participation in the laboratory portion of the study. If you become pregnant, please let staff know as soon as possible.

Special Note about Response to the Coronavirus Outbreak (COVID-19)

In order to protect your health and the health of the staff members, the order in which you complete the activities of this study (daily phone surveys and in-person laboratory sessions) may vary due to COVID-19 restrictions that could be imposed at the national, local, or university-level. When the university is operating "as normal", you will complete the 3 in-person laboratory sessions first, and then begin the daily phone assessments after the final in-person session. You will complete the baseline survey during the first in-person visit.

If you are being recruited when in-person data collection activities are limited or restricted due to COVID-19, you will be asked to provide consent online (by electronically signing this document), complete the baseline survey online, and then begin the daily phone surveys after that, before the lab visits. One of our research staff will schedule a brief phone call with you to explain how to complete the daily surveys, before you start them. Once we are able to begin in-person data collection in the laboratory, you will be contacted by a member of our team to determine if you are still interested in attending in-person visits and eligible to participate. If you are interested and meet eligibility criteria, we will schedule the 3 in-person laboratory sessions. We will make every effort to contact you and schedule those sessions as soon as we can after you are enrolled. Given the uncertainty of the COVID-19 outbreak, we are unable to say how long you may need to wait. In both instances, you will be compensated for the portion of the study you have completed up to that point. If in-person visits are deemed unsafe and social isolation persists, remote/virtual smoking sessions may also be provided as an option in place of in-person laboratory visits. If you select remote/virtual visits, you will be provided a smartphone compatible portable carbon monoxide (iCO) monitor and so that we can test your breath for carbon monoxide at the beginning of each remote (video) smoking session and after you smoke each cigarette.

Study Procedures

In-Person Laboratory Visits. At each in-person visit, you will participate in a smoking session. During the first visit, you will smoke your own cigarettes as you wish, during a 60-minute smoking session. At all lab visits, we will ask you to have a smoking session similar to the first in-person visit. You will provide breath samples to quantify when you last smoked. You will also complete questionnaires about your behavior and mood, both before and after smoking. We will also measure your heart rate and blood pressure before and after smoking.

Visit 1: We will review eligibility criteria similar to what you answered over the phone. We will also take your heart rate and blood pressure. If you are still eligible at this point and you agree to participate, we will ask you to provide some additional information about yourself and your use of cigarettes, other tobacco products, and behaviors related to tobacco use. We will then ask you to participate in your first smoking session. During this session, you will smoke your own cigarette that you brought with you today. Before you smoke, we will test your breath for carbon monoxide, and check your heart rate and blood pressure. You will smoke your cigarette through a mouthpiece that allows us to measure the puffs you take. After you finish smoking, we will conduct another breath test, and check your heart rate and blood pressure. Both before and after smoking we will have you answer some questionnaires about how you are feeling.

Visit 2: For your following visits, you will be asked to smoke a few puffs of two different types of study cigarettes. One will be flavored to taste like mint/menthol and the other will be flavored to taste like traditional tobacco flavoring. These are commercially available cigarettes. The order in which you smoke

the two types of study cigarettes will be randomly chosen. Before you smoke, we will test your breath for carbon monoxide, and check your heart rate and blood pressure. You will smoke the cigarette through a mouthpiece that allows us to measure the puffs you take. After you finish smoking, we will conduct another breath test, and check your heart rate and blood pressure. Both before and after smoking we will have you answer some questionnaires about how you are feeling.

Visit 3: For your final visit, you will be asked to complete a computer task in which you hit targets on a computer screen of cigarettes. You can "earn" cigarette puffs for each target you correctly hit on the computer screen, for up to 10 puffs after completing the computer task. After the task is complete, you can smoke the puffs that you earned. You will wait in the laboratory to fill out some survey questions about how you are feeling and we will talk to you about how to complete the daily surveys for the next phase of the study (if you have not already completed them). As with the previous visit, we will test your breath for carbon monoxide when you first arrive. We will check your heart rate and blood pressure immediately before and after you smoke. You will smoke the cigarette through a mouthpiece again. Both before and after smoking we will have you answer some questionnaires about how you are feeling.

At all lab visits, we will ask you to have a smoking session similar to the first study session. You will provide breath samples to quantify when you last smoked. You will also complete questionnaires about your behavior and mood, both before and after smoking. We will also measure your heart rate and blood pressure before and after smoking.

Daily Surveys. For every morning and evening, you will receive an automated notification on a cell phone to answer some questions about how you feel, your smoking behavior, and other behaviors through an app that we will install on your phone or a study-provided phone (if your phone does not have the Android operating system). The notifications will be scheduled to happen during times of the day or evening when you are typically awake. During this phase, which will last for 14 days, you should engage in your normal life routines and smoke as you normally would. At the end of the 14 days, we will ask you to take a brief survey (either online or via the telephone) to ask how you are doing and find out your experience with the daily surveys. If you are enrolled in the study under normal operating conditions, you will begin the daily surveys after your third lab visit. If you are enrolled during a time of COVID-19 restrictions, you will begin the daily surveys after you complete the baseline survey online and have a brief training with one of our program staff about how to do them.

Finally, 2, 4, and 6 months after you enroll in the study, we will do a short survey with you, preferably in our lab, but if you cannot make it, we can do it over the phone or online. This survey will ask about your smoking and tobacco use and tobacco-related behaviors. We will contact you about once per month to keep in contact so we may schedule these follow-up surveys.

Update about the impact of Tobacco 21 regulation on study recruitment

Because of the new Tobacco 21 regulations at the state and federal level, individuals under the age of 21 are not allowed to purchase tobacco products, and the research team is no longer allowed to "furnish" tobacco products to individuals under the age of 21. As a result, individuals ages 18 to 20 enrolled in the study will complete a modified study protocol, where they will smoke their usual brand cigarette (e.g., as outlined in Lab Visit 1), they will complete the daily diary assessments, and they will complete all follow-up assessments. These individuals will not smoke the experimental cigarettes (lab Visits 2 and 3), until or unless a waiver of approval to provide these experimental cigarettes has been given by the state.

CAN I WITHDRAW FROM THE STUDY?

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher. Refusal to participate or withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you withdraw, you will be compensated for your time up to that point. Your data up to that point may be used for study purposes unless you request otherwise

There may be circumstances under which your participation may be terminated by the investigator without your consent. We may discontinue you from the study if we believe being in the study may put you at significant risk; if you are unable or unwilling to follow study procedures, such as keeping your visit appointments, or unwilling or unable to abstain from nicotine or tobacco products; or if you are female and are pregnant or breastfeeding, or become pregnant.

WHAT ARE THE RISKS OF THE STUDY?

The cigarettes you smoke during this study will be your own brand and the study cigarettes that we provide to you will be commercially available.

The study cigarettes contain tobacco and nicotine. Although smoking is associated with disease, we do not expect the disease risk to be significantly greater when smoking the study cigarettes versus the cigarettes you typically smoke. At the end of the study, you will be offered resources to help you stop smoking. Quitting smoking can greatly reduce risks to your health.

Some questions may make you feel uncomfortable. You may refuse to answer any questions. However, if you refuse to answer questions that are required to determine your eligibility for the study, you will not be able to continue in the study. There is a potential risk for an unanticipated breach of confidentiality. Below we describe the methods we will follow to ensure your confidentiality is maintained.

In addition to the risks described in the Key Information section, you may also be at risk for acute side effects of nicotine including headache, nausea/vomiting, increased heart rate, increased blood pressure, runny/stuffy nose, change in taste, heartburn, hiccups, sweating, or diarrhea. You should discuss these with the researcher and/or your regular doctor. Other drugs may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the cigarettes are stopped, but in some cases side effects can be serious or long lasting and permanent.

For more information about risks and side effects, contact Amy Cohn, PhD or the study coordinator at 405-271-7759 24 hours a day. We are available Monday through Friday during regular business hours (9am-5pm) to return phone calls.

REPRODUCTIVE RISKS FOR WOMEN:

If you are a female, you must not be and should not become pregnant nor breast-feed an infant while participating in this study. Smoking cigarettes while you are pregnant or breastfeeding may involve risks to an embryo, fetus, or infant, including birth defects which are currently unforeseeable. In order to reduce your risk of pregnancy, you or your partner should use one or more of the acceptable methods of birth control listed below, regularly and consistently, while you are in this study.

Acceptable methods of birth control (continuing throughout the study) include:

- An approved oral contraceptive (birth control pill)
- Intra-uterine device (IUD)

- Hormone implants
- Contraceptive injection (Depo-Provera)
- Barrier methods (diaphragm with spermicidal gel or condoms)
- Transdermal contraceptives (birth control patch)
- Vaginal contraception ring (birth control ring)
- Sterilization (tubal ligation, hysterectomy or vasectomy)

Certain drugs may interact with contraceptive agents and reduce their effectiveness; therefore, you should inform the study staff of all medications (prescription and over-the-counter) that you are currently taking or begin taking during the study.

IN CASE OF PREGNANCY:

If you become pregnant or suspect that you are pregnant, you should immediately inform the study personnel. We will perform a pregnancy test at each in-person visit. If pregnancy is confirmed, you will be withdrawn from the study. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies, and the National Institutes of Health. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

We work with a university vendor who supplied the mobile application for the automated daily phone surveys. The company will take appropriate steps to protect your privacy. Your information is stored securely and separately from your survey responses. Your personal information will not be sold or given to any other people or companies for any purpose.

Posting Study on ClinicalTrials.gov:

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

Certificate of Confidentiality:

To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. 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 U.S. government that is used for checking or evaluating federally-funded projects or for information that must be disclosed in order to meet the requirements of the US Food and Drug Administration.

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, 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. This means that you and your family should actively protect your own privacy.

Identifiable Private Information:

- Your information may be used for future studies without your additional consent. We will remove direct identifiers from your information/specimen and assign a code. The key to this code will be kept separately and only the researcher and approved study personnel for this study will have access to the code. If your information is shared with another investigator for research purposes, they will not be able to re-identify you.

WHAT ARE THE COSTS?

You may have some travel costs for your study visits and you will be using your own cigarettes for part of the study. You will be reimbursed $10 for each in-person visit, or $10 for three curbside pick-up/drop-offs of study materials if you take the study remotely. You can earn up to $30 total for travel. If you use your personal phone to complete the daily automated phone calls, we will reimburse you $40 for the 2 weeks that you have it, or you may have a study phone provided to you if your phone does not have the Android operating system. There are no other costs to you.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?

You will be watched throughout the study for Adverse Events. All Adverse Events will be recorded and will be followed until they are resolved or stabilized. Formal policies are in place for emergency procedures. If you are injured as a direct result of taking part in this study an Emergency Medical Service will take you to a medical center.

Complications arising as a result of the natural progression of an underlying or pre-existing condition may be billed to you or your insurance. Please check with the investigator or with your insurance company if you have questions.

No other funds have been set aside by the University of Oklahoma Health Sciences Center or the National Institutes of Health to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. Please be sure to discuss leaving the study with the principal investigator or a staff member. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact Amy M. Cohn, PhD at 405-271-1903 or the study coordinator at 405-271-7759 or at PrismStudy@ouhsc.edu.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and for questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

SIGNATURE:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18)	**Printed Name**	**Date**
SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**