Consent Form
University of Oklahoma Health Sciences Center (OUHSC)

The Impact of Waterpipe Tobacco Flavors on Waterpipe Smoking Intentions, Perceptions, Patterns, and Toxicant Exposure

Principal Investigator: Theodore L. Wagener, Ph.D.
Sponsor: National Institutes of Health

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

The University of Oklahoma Health Sciences Center does not endorse nicotine or tobacco use. For assistance with quitting tobacco use, please call 1-800-784-8669.

Why Have I Been Asked To Participate In This Study?

You are being asked to take part in this study because you are a current Hookah user who is interested in using hookah in the next 6 months.

Why Is This Study Being Done?

The purpose of this study is to see what people think about different types of hookah preparations.

How Many People Will Take Part In The Study?

About 94 people will take part in this study. All participants will participate at this location.

What Is Involved In The Study?

You will come to the lab on four different days, with each day separated by at least 48 hours, and asked to smoke a different type of hookah tobacco on each day. You will smoke each hookah tobacco for up to 1 hour, and each visit will last approximately 2 hours to provide you time before and after smoking to complete self-report measures and for the research assistant to collect blood samples.
If you take part in this study, here is what will happen at the study visits:

- At every visit, you will fill out questionnaires about smoking and take a breathing test.
- At each visit, you will provide blood samples before smoking hookah, during a 10-minute puffing period (one sample after 5 minutes and another after 10 minutes), and after smoking hookah. We will test the blood samples for nicotine. The blood draw will be conducted by a trained research staff or nurse.

How Long Will I Be In The Study?
You will be in the study for between 1 week and 6 months, depending on the duration of the periods between study visits. There may be anticipated circumstances under which your participation may be terminated by the investigator without regard to your consent. If we feel that your health or best interest would be at risk by you continuing to participate in the study, we will terminate your participation. 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 first.

What Are The Risks of The Study?
Some people feel uncomfortable answering questions about smoking or their health. You may choose to leave any question blank. There is a slight risk of discomfort, bruising, or infection with an IV blood draw.

The products you will be using (hookah tobacco) have the same FDA warnings as cigarettes. Short term risks are relatively low. In the long-term, hookah use has been associated with increased risk for lung disease, heart disease, and lung and oral cancer.

Reproductive Risks for Women and Men:

Risks for females:
If you are a female, you must not be and should not become pregnant nor breast-feed an infant while on this study. Taking the study drug(s), nicotine and tobacco products may cause birth defects and other harm to the fetus. There may be additional risks, which are currently unforeseeable. Due to these risks, women will complete a urine pregnancy test at the first visit.
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.

Risks for males:
In order to reduce the risk of getting someone pregnant, 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.

Risks for both females and males:
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) o Sterilization (tubal ligation, hysterectomy or vasectomy)

If you become pregnant or suspect that you are pregnant, or (for males) if you make someone pregnant during this study, you should immediately inform the study personnel. If you become pregnant or suspect that you are pregnant while on this study, tell a trained research staff immediately; the trained research staff will perform a pregnancy test. If pregnancy is confirmed, you may be withdrawn from the study. A trained research staff will assist you in getting obstetrical care at your cost. The trained research staff and the Sponsor will follow the progress of your pregnancy and will request access to yours and/or your infant's medical records for least eight weeks after delivery. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

Are There Benefits to Taking Part in The Study?
If you agree to take part in this study, there is no direct benefit to you. Through this study, we will learn about different smoking patterns when using different types of hookah products. This information may be used to inform future research and legislation associated with hookah tobacco.

What Other Options Are There?
Your participation in this study is voluntary. You can choose not to participate or withdraw from the study at any time.

What about Confidentiality?
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 include the US Food & Drug Administration and other regulatory agencies, the Oklahoma Tobacco Research Center, and the National Institutes of Health.

The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

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.

To help protect your privacy, a Certificate of Confidentiality will be obtained from the federal government. 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 federal Food and Drug Administration (FDA).

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.

If you are enrolled in the study after the expiration or termination of the Certificate, the protection afforded by the Certificate as described above will not apply.

What Are the Costs?
There is no cost to being in this study. All hookah products will be provided free of charge.

Will I Be Paid For Participating in This Study?
You will be paid $50 for completing each study visit. You will also receive an additional $50 as a completion bonus on the final visit. The total you may receive for this study is $250.

What if I am Injured or Become Ill While Participating in this Study?
In the case of injury or illness resulting from this study, emergency medical treatment is available. The sponsor will not pay any costs associated with your treatment.

No funds have been set aside by The University of Oklahoma Health Sciences Center, The Children's Hospital at OU, or The Oklahoma Tobacco Research Center to compensate you in the event of illness or injury.

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. However, please discuss leaving the study with the principal investigator or your regular physician. You may discontinue your participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

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

Whom Do I Call If I have Questions or Problems?
If you have questions about your study visits, scheduling, or other general questions, please contact the study office at (405)271-4749.

If you have questions, concerns, or complaints about the study or have a research-related injury, contact the study coordinator at 405-271-6872, 24 hours a day.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

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) *(Or Legally Authorized Representative)*	Printed Name	Date
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date

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