Informed Consent: NCT05705375

The University of Texas at Arlington (UTA)

Informed Consent for Studies with Adults

TITLE OF RESEARCH PROJECT
Understanding the effect of hookah (waterpipe) size on smoking behavior, toxicant exposures and subjective experiences

PRINCIPAL INVESTIGATOR
Ziyad Ben Taleb MD, MPH, PhD Principal Investigator
Department of Kinesiology
ziyad.bentaleb@uta.edu
817-272-8297

IMPORTANT INFORMATION ABOUT THIS RESEARCH PROJECT
This study is investigating the effect of using different sizes of hookah sizes and the expected impact on smoking behavioral, toxicant exposures and subjective experiences among adult hookah smokers. You can choose to participate in this research study if you are healthy and a hookah smoker between the ages of 21 and 39 years old.

You might want to participate in this study if you want to contribute to the research aiming at understanding the impact of smoking tobacco using different sizes of hookah and the expected effect on smoking behavioral, toxicant exposures and subjective experiences among adult hookah smokers. This type of research is needed to inform the public health community and the regulatory bodies on the potential impact of regulating hookah size and its expected effect on limiting toxicant exposures and preventing hookah size-related misperceptions. Most importantly, this project will help the FDA in developing size-specific regulatory standards to control the marketing and sales of hookah devices and to protect public health. However, you might not want to participate in this study if you do not have the time to attend up to three study visits (each lasting around 3 hours) on the UT Arlington campus.

NOTE: DO NOT participate in this study: if you are pregnant, breast feeding or intending to be pregnant; if you have any chronic medical condition; if you have history of heart disease, low or high blood pressure; if you have a psychiatric disorder or history of seizures; if you regularly use prescription medications (other than vitamins).

Check the box to confirm the following statement *(For women only)*:
☐I affirm that I am NOT pregnant, and I am NOT breastfeeding.

This study has been reviewed and approved by an Institutional Review Board (IRB). An IRB is an ethics committee that reviews research with the goal of protecting the rights and welfare of human research subjects. Your most important right as a participant is informed consent. You should take your time to consider the information provided by this form and the research team a ask questions about anything you do not fully understand before making your decision about participating.

TIME COMMITMENT
To participate in this study, you are expected to attend up to three separate lab sessions on the UTA Campus in Arlington, Texas. Each session last around 3 hours. The 3 lab sessions can be completed within 3-4 weeks period depending on your schedule and the lab schedule. The investigators may

choose not to perform one or more of the 3 visits or procedures depending on the research requirement, your availability, and lab availability. Your participation is voluntary. If you do not want to participate or you want to stop participating at any time, you can. You will not be punished in anyway if this happens. Please ask questions if there is anything you do not understand.

RESEARCH PROCEDURES

A detailed list of the study's procedures is described below. If at any time you wish to discuss the information above or any other risks you may experience, you may ask questions now or contact the Principal Investigators listed on the front page of this form.

- Smoke hookah for up to 45 minutes.
- Receive an anthropometrics measurements (screening) including measurement of blood pressure, weight, height, and pulse
- Your expired breath will be examined for carbon monoxide (colorless, odorless gas that is usually detected in low quantities in human bodies), using an exhaled breath monitors (device that you breathe in and it will measure the levels of carbon monoxide in your body). Your lung function will be assessed using a spirometer (device that you breathe in and it will measure the capacity and function of your lungs). These measurements will be assessed before and after the break session.
- Your puffing behavior (e.g. total number of puffs, duration of puffs, volume…etc.) will be recorded using a computerized device that is attached to the wastepipe hose.
- You will complete questionnaires, with responses made on a computer/tablet assessing your background information, smoking history and subjective feelings/perceptions before and after each smoking session.
- You will be provided with a saliva collection kit and will receive clear instruction from the staff on how to collect a small sample of your own saliva (~2 ml) that will be analyzed for nicotine content. These samples will be collected before and after each smoking session.
- Urine pregnancy test will be performed once at the first lab visit using over the counter available kits where you will be asked to pee in a cup and then research staff will dip the test strip in it to test for pregnancy (*for women only*).

POSSIBLE BENEFITS

Participant benefit: Participants will benefit by being involved in a study that can increase their awareness about the health consequences of hookah smoking. They will be given educational material at the end of the study that explains the health impact of hookah smoking and includes resources that are available to help with quitting, such as national, state and local cessation services.

Society benefit: This project will help the FDA in developing size-specific regulatory standards to control the marketing and sales of hookah devices and to protect public health.

POSSIBLE RISKS/DISCOMFORTS

If you do experience any discomfort, please inform the research team. Below is the list of the study procedures applied in this study along with their risk profile:

1. Hookah use: Hookah smoking can lead to dependence, other tobacco and substance use, and many of the known smoking-related diseases. However, any involved risk in participating in the three hookah smoking sessions of this study will not exceeds the risk you would have otherwise encountered during three recreational sessions of hookah smoking at home or at a hookah cafe. Also, the amount of tobacco that will be smoked during the three hookah smoking sessions of this study will not exceed the regular amount smoked recreationally at home or at a hookah café. Moreover, to eliminate any potential risk of infection due to repeated use of lab hookahs, we will use disposable hose and mouth pieces for each session. Moreover, all solid non-disposal parts (base, stem) will be washed with soap, dried and sterilized with UV light after each use.

2. Anthropometrics. There is no risk or discomfort associated with this procedure.

3. Monitoring of puffing behavior: There is no risk or discomfort associated with this procedure.

4. Pregnancy urine test (women). There is no risk or discomfort associated with this procedure.

5. Exhaled Breath monitor. There is no risk or discomfort associated with this procedure.

6. Lung Function test: There is no risk with this measurement, although subjects may feel slightly tired from the required breathing effort

7. Saliva collection: We will used disposable and sterile collection kit. There is no risk or discomfort associated with this procedure.

Also, please remember that you have the right to quit any study procedures at any time without penalty and may do so by informing the research team.

While you are in the study, it is important that you report any illness or injury that occurs to the research team immediately. The University of Texas at Arlington does NOT offer compensation for any injuries resulting from your participation in this research. If you suffer a research-related injury, any resulting medical costs will be your responsibility or that of your insurance / third-party payer. However, as a research subject, you will not lose any of your legal rights.

COMPENSATION

You will receive a payment of $150 for the completion of the three study sessions. This payment compensates for your time, and transportation. Therefore, you will not be responsible for any costs to participate in this study. The Internal Revenue Service (IRS) considers all payments

made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UTA's accounting office for the purpose of payment. If your total payments for the year exceed $600.00, UTA will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total in a year, you are responsible for reporting the payments to the IRS.

ALTERNATIVE OPTIONS

There are no known alternatives available to you other than not taking part in this study. However, any significant new findings developed during the course of the research, which may relate to your willingness to continue participation will be provided to you.

CONFIDENTIALITY

The research team is committed to protecting your rights and privacy as a research subject. All paper and electronic data collected from this study will be stored in a secure location on the UTA campus and/or a secure UTA server for at least three (3) years after the end of this research. The results of this study may be published and/or presented without naming you as a participant. The data collected about you for this study may be used for future research studies that are not described in this consent form. If that occurs, an IRB would first evaluate the use of any information that is identifiable to you, and confidentiality protection would be maintained.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding. However, there are circumstances where the Certificate does not protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies;
- when information must be disclosed to meet FDA requirements;
- if you give someone written permission to receive research information, or if you voluntarily disclose your study information;
- if the researcher reports that you threatened to harm yourself or others;
- in cases of child abuse or elder abuse reported by the researcher;
- if the investigator reports cases of contagious disease (such as HIV) to the state

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

CONTACT FOR QUESTIONS

Questions about this research study or reports regarding an injury or other problem may be directed to Dr.Ziyad Ben Taleb at 817-272-8297 or ziyad.bentaleb@uta.edu . Any questions you may have about your rights as a research subject or complaints about the research may be directed to the Office of Research Administration; Regulatory Services at 817-272-3723 or regulatoryservices@uta.edu.

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

Signature & Name of Research Team Member Conducting the Consent **DATE**

CONSENT

By signing this form, you are confirming that you understand the study's purpose, procedures, potential risks, and your rights as a research subject. By agreeing to participate, you are not waiving any of your legal rights. You can refuse to participate or discontinue participation at any time, with no penalty or loss of benefits that you would ordinarily have. Please sign below if you are at least 18 years of age and voluntarily agree to participate in this study.

SIGNATURE OF VOLUNTEER **DATE**

**If you agree to participate, please provide the signed copy of this consent form to the research team. They will provide you with a copy to keep for your records.*