Informed consent form

Official Title of the study: Understanding health warning effects on waterpipe (hookah) smokers' experiences and exposures

NCT number: Not applicable

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FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY
"Understanding health warning effects on waterpipe (hookah) smokers' experiences and exposures"

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to evaluate the effect of hookah health warning labels (HWLs) on smokers' satisfaction, dependence, harm perception, and toxicants exposure.

- **Procedures**: If you choose to participate, you will be asked to come to the research lab twice for a study clinic session. During each study lab visit, there will be one hookah smoking session, a blood draw before and after the smoking session, an exhaled breath sample will be collected before and after the smoking session, and a short survey will be administered before and after each smoking session. We will also call after 3 months to ask you a few questions.

- **Duration:** This will take 2 study clinic sessions. Each session will last about 2 hours each.

- **Risks:** The main risks or discomforts from this research are:
  - Risks of drawing blood include temporary discomfort from the needle stick, bruising, and it can rarely lead to infection.
  - Hookah smoking can lead to nicotine dependence and other known smoking-related diseases.

- **Benefits:** The main benefit to you from this research is being involved in a study that can increase your awareness about the health and addictive consequences of hookah smoking. You will also be given educational material at the end of the study that explains the health impact of hookah and includes resources that are available to help with quitting, such as national, state and local cessation services.

- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.

- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY
The purpose of this study is to evaluate the effect of hookah health warning labels (HWLs) on smokers' satisfaction, dependence, harm perception, and toxicants exposure.

NUMBER OF STUDY PARTICIPANTS
If you decide to be in this study, you will be one of 248 people in this research study.

DURATION OF THE STUDY
Your participation will involve attending the lab for two sessions (2 hours each), separated by a 48 hours period. You will also receive a phone call from a research team member 3 months after completing your second session to ask you some study follow-up questions.

PROCEDURES
If you agree to be in the study, we will ask you to do the following things:

1. Receive a physical screening from a qualified research health professional including measurement of blood pressure, weight, body temperature, and pulse.
2. Exhaled breath will be examined for carbon monoxide using a portable breath monitor.
3. Urine pregnancy test will be performed once at the first lab visit using commercially. available tests (*for women only*).
4. Attending the lab for two hookah smoking sessions (a maximum 45 minutes hookah smoking session) in which the hookah may or may not have a HWL.
5. A qualified research nurse will draw a small amount of blood (10 ml) before and after each of the two smoking sessions. A certain amount of your blood sample will be analyzed for nicotine content and the rest will be stored for future studies.
6. A 1-2 ml of exhaled breath condensate will be collected before and after each of the two smoking sessions.
7. Complete a short survey before and after each of the two smoking sessions.
8. Heart rate and blood pressure will be monitored continuously during hookah smoking sessions using a digital Monitor.
9. Answering a brief questionnaire on the phone 3 months after your second lab smoking session.

RISKS AND/OR DISCOMFORTS
The study has the following possible risks to you:

1. Blood draw: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and it can rarely lead to infection.
2. Hookah smoking: 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 two hookah smoking sessions of this study will not exceeds the risk you would have otherwise encountered during two recreational sessions of hookah smoking at home or at a hookah cafe. In addition, the amount of tobacco that will be smoked during the two hookah smoking sessions of this study will not exceed the regular amount smoked recreationally at home or at a hookah cafe. DO NOT participate in this study if you do not smoke hookah regularly or are trying to quit smoking. Also, 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 or birth control).

   Check the box to confirm the following statement *(For women only)*:

   ☐ I affirm that I am NOT pregnant, and I am NOT breastfeeding.

3. COVID-19 Safety Information: Please read our COVID-19 Safety Information sheet for details on the guidelines and measures we will be following and asking you to complete in order to prevent COVID-19 infection and/or spread. DO NOT participate in this study if you are currently experiencing fever, chills, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, or diarrhea. If you are experiencing these symptoms, *please let us know, and contact your preferred health care provider for a checkup and further evaluation of these symptoms, as these may be a sign of possibly being sick with COVID19.*

   Please check the box below to confirm the following statement:

   ☐ I have read and understand the addendum entitled *"Important Information about participating in a Research Study during COVID-19".* I agree to follow this study's and FIU's guidelines for COVID-19 prevention. I understand that I will be given a copy of this form for my records.

BENEFITS

The study has the following possible benefits to you:

- Participant benefit: Participants will benefit by being involved in a study that can increase their awareness about the health and addictive consequences of hookah smoking. In addition, participants will be given educational material at the end of the study that explains the health impact of hookah and includes

resources that are available to help with quitting, such as national, state and local cessation services.

- Society benefit: Understanding the effect of flavor on hookah users will help researchers and public health agencies expand their knowledge about hookah products as well as spread and protect public health in the US.

ALTERNATIVES

There are no known alternatives available to you other than not taking part in this study. 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 records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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 website at anytime.

USE OF YOUR INFORMATION

Identifiers about you will be removed from the identifiable private information, blood, and exhaled breath condensate samples. After such removal, the information as well as the blood and exhaled breath condensate samples could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. Your biospecimens will not be used for commercial profit. The researchers will not include or generate whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

COMPENSATION & COSTS

You will receive a payment of $72 for your participation upon completion of the 2 clinic study sessions. This payment compensates for your time, transportation and parking. There are no costs to you for participating in this study.

MEDICAL TREATMENT

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance

company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Wasim Maziak at FIU Robert Stempel College of Public Health and Social Work , Department of Epidemiology, Phone: 305-348-4501, e-mail: wmaziak@fiu.edu

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date