Informed consent form

Official Title of the study: Assessing the effect of nicotine reduction on ENDS users' addiction and exposures

NCT number: Not applicable

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FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY
"Assessing the effect of nicotine reduction on ENDS user's addiction and exposures"

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to evaluate the effect of nicotine reduction (NR) on ENDS users' satisfaction, dependence, harm perception, and toxicants exposure.
- **Procedures**: If you choose to participate, you will be asked to come to the research lab two times for a study clinic session. During each study lab visit, there will be one vaping session, a blood draw before and after the vaping session and a short survey will be administered before and after each vaping 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.
- **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.
  - E-cigarette use can lead to nicotine dependence and other known smoking-related diseases.
  - Since 2019, there has been a number of e-cigarette/vaping associated lung injury (EVALI; or severe acute respiratory illness) being reported to public health agencies. Most tested cases have involved marijuana e-cigarette products. However, there has been a considerable decline in EVALI cases and CDC data do not suggest a resurgence of EVALI at this time.
- **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 e-cigarette use. You will also be given educational material at the end of the study that explains the health impact of e-cigarette use 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 nicotine reduction (NR) on ENDS users' satisfaction, dependence, harm perception, and toxicants exposure.

NUMBER OF STUDY PARTICIPANTS
If you decide to be in this study, you will be one of 120 people in this research study.

DURATION OF THE STUDY
Your participation will involve attending the lab for two sessions (2 hours each) unless you have already participated in previous studies. The sessions will be separated by a 48- hour 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
Note: You will be provided a rapid antigen COVID-19 testing prior to each lab session. Only when the result is negative, you could proceed to the next step.

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. Urine pregnancy test will be performed once at the first lab visit using commercially. Available tests (*for women only*).
3. Attending the lab for two e-cigarette use sessions (a maximum 60 minute vaping session) in which differ by nicotine concentration (0%, 3%, 5%).
4. 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.
5. Lung function will be tested and repeated before and after each of the two e-cigarette use sessions.
6. Complete a short survey before and after each of the two e-cigarette use sessions.
7. Heart rate and blood pressure will be monitored continuously during e-cigarette use sessions using a digital monitor.
8. Answering a brief questionnaire on the phone 3 months after your two e-cigarette use 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. E-cigarette use: E-cigarette use 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 e-cigarette use sessions of this study will not exceed the risk you would have otherwise encountered during two recreational e-cigarette use sessions. In addition, the amount of e-cigarette liquid that will be consumed during the two e-cigarette use sessions of this study will not exceed the regular amount used recreationally. DO NOT participate in this study if you do not use e-cigarettes 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; or 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 e-cigarette use. In addition, participants will be given educational material at the end of the study that explains the health impact of e-cigarette use and includes resources that are available to help with quitting, such as national, state and local cessation services.
- Society benefit: Understanding the effect of nicotine reduction on e-cigarette users will help researchers and public health agencies expand their knowledge about e-cigarette 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.

To help us protect your privacy, we have 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 proceedings.
There are circumstances where the Certificate doesn't 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 (only required for FDA-regulated studies)
- when a positive COVID-19 result is tested because we are required by law to report the result to the health department
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse or vulnerable adult reported by the researcher
- if the investigator reports cases of contagious disease to the state

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 and blood. After such removal, the information as well as the blood 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 total payment of $200 for your participation upon completion of the 2 clinic study sessions and a 3-month follow-up session. 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

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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 305-348-0056 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