THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Gender Differences in Standardized Research E-Cigarette (SREC) Product Use, Acceptability, Reinforcement, and Nicotine Dependence Symptoms 2018-0794

Study Chair: Jason D. Robinson

_____ _____
Participant's Name Medical Record Number or Study ID

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study is to learn more about the effects of switching from smoking regular cigarettes to electronic cigarettes (e-cigarettes). E-cigarettes use water vapor to deliver nicotine. Researchers also will study the effect gender has on e-cigarette use.

This is an investigational study.

This research may help inform the FDA how best to regulate e-cigarettes with the goal of improving public health.

Taking part in this study may help you find it easier to quit smoking completely. After you complete the study, the study staff will talk to you about the benefits of remaining smoke-free and will provide you with information about quitting smoking. You will be offered up to 8 weeks of tobacco cessation (quitting) counseling, which may include nicotine replacement therapy. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment. You may not want to take part because you think there will not be enough compensation.

You can read a list of potential risks below in the Possible Risks section of this consent.

There will be no cost for you to participate in this study.

You may choose not to take part in this study. You are not being offered treatment for smoking in this study. If you are seeking immediate treatment for smoking, please let the study staff know and they will help you find a treatment program.

Information about quitting smoking can be found by visiting the National Cancer Institute's website (www.smokefree.gov) or by calling their national Smoking Quitline: 1-877-44U-QUIT.

1. STUDY DETAILS

Screening Tests
Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will help the study staff decide if you are eligible:

- You will complete questionnaires about your demographics (age, gender, race, and so on), your physical and emotional health, and your smoking behavior. These questionnaires should take about 30 minutes to complete.
- You will also complete a questionnaire that will ask you how much you are willing to pay for cigarettes. This should take about 10-15 minutes.
- If you can become pregnant, urine may be collected for a pregnancy test at the study clinic, or you may be given a pregnancy test to complete at home. If you complete the test at home, you may be asked to take a picture of the test results and send it to the study team by text or email. To take part in this study, you must not be pregnant or breastfeeding.

A member of the study staff will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. The study staff may decide after the screening that it is not in your best interest to take part in this study or the study chair may decide you cannot take part.

Up to 196 participants will be enrolled in this study. All will take part at MD Anderson.

Length of Study
If you are found eligible to take part in this study, you will have 4 in-person and/or virtual visits over 6 weeks. Each visit may last about 2 hours. You will have 1 telephone visit about 30 days after you final in-person or virtual visit. This phone call will last about 10 minutes. You will be taken off study if you develop serious medical problems, intolerable side effects occur, you are not able to follow the study directions, or you become pregnant. Your participation may also be stopped by the study chair at any time for any reason.

Your participation on this study will be over after the telephone visit.

Smoking Schedule

There are 3 phases to this study: Phase 1 (Weeks 1-2), Phase 2 (Weeks 3-4), and Phase 3 (Weeks 5-6).

During **Phase 1**, you will be asked to smoke your usual cigarette brand as you normally would.

During **Phases 2 and 3**, you will be asked to use ("vape") only the e-cigarettes provided to you. You will vape either regular e-cigarettes or no nicotine content e-cigarettes during Weeks 3-4 (Phase 2) and then switch to whichever one you have not yet received for Weeks 5-6 (Phase 3). Neither you nor the study staff will know the order in which you are receiving the regular and no nicotine content e-cigarettes. However, if needed for your safety, the study staff will be able to find out what you are receiving.

At the start of Phase 2, you will be trained on how to use the study e-cigarettes. This training should take about 30 minutes.

Around 3 days after the start of Phases 2 and 3, the study staff may contact you to make sure you are not having any problems with the study products. This phone call should take about 5-15 minutes.

Study Visits

At the end of Phases 1, 2, and 3 (about every 2 weeks):

- You will complete questionnaires about mood, nicotine withdrawal symptoms, smoking behavior, and your opinion of the study e-cigarettes. These questionnaires will take about 50 minutes to complete. You may complete these questionnaires electronically (by text or email) before your visit.
- You will complete a questionnaire about breathing symptoms including coughing, wheezing, phlegm production, and shortness of breath.
- You will also complete a questionnaire that will ask you how much you are willing to pay for regular cigarettes and/or the study e-cigarettes. This should take about 10-15 minutes.
- Urine will be collected for testing for substances that are related to tobacco at the study clinic, or you may be asked to collect and mail back your urine sample in a prepaid collection kit.

You will receive instructions on how to use your personal smartphone to answer questions about your nicotine cravings and mood, and to log your daily smoking activity every day for up to 42 days. It should take about 15-20 minutes each day to complete these questions. If study reports show that you have not completed any questions for at least 2 days in a row, study staff may call you to see if there is a problem.

Final Telephone visit (about 30 days following the end of Phase 3;

- Study staff will call you about 30 days after you complete Phase 3 to check for ongoing and new side effects.

Other Information

- The study staff may contact you by text message and/or unencrypted email to remind you about study visits and procedures if you choose to receive non-secured communications.
- You should vape only the e-cigarettes assigned to you during Phases 2 and 3 and use only the e-cigarette cartridges provided to you by the study staff. For safety reasons, you must not use any cartridge for more than 1 day.
- If you smoke other cigarettes during the study, or use other nicotine products like nicotine gum, you can still be in the study. However, it is important that you tell the study staff about any non-study e-cigarettes, cigarettes, tobacco, or nicotine products that you use.
- This study is not a treatment program. However, if you want to stop smoking or using e-cigarettes entirely, you may still take part in the study. If you decide to quit during or after the study, the study staff will refer you to the MD Anderson smoking cessation program. In this program, you will be provided with up to 8 weeks of free smoking cessation treatment, which may include nicotine replacement therapy and smoking cessation counseling. Alternatively, the staff can refer you to an MD Anderson smoking cessation research study or provide you with information about stopping smoking and referrals to local treatment programs. If you decide to quit, you can choose whether you want to take home your assigned study e-cigarettes. However, having cigarettes or e-cigarettes in your possession during your quit attempt could make it difficult for you to refrain from smoking or vaping.
- Quitting smoking can greatly improve your health. However, changes in your smoking can lead to changes in the levels of drugs you are taking. Please make sure to tell the study staff about all the drugs you take. Quitting smoking may change how your body processes certain medications. If you quit smoking and are taking certain medications regularly (medications to treat asthma or diabetes, for example), discuss this with your regular doctor to determine if a change in these medications is needed.
- The amount of nicotine in the study e-cigarettes provided to you may be lower/higher than your normal brand of cigarettes.
- **You must not share the study e-cigarette or e-cigarette cartridges with anyone**.
- **You should not give or lend the e-cigarette and cartridges to other people. You should store them in a safe location outside the reach of children.**
- Once your participation in the study is complete, you must **return** to study staff (in-person or mailed back using a prepaid collection kit) the e-cigarette device and all used and unused e-cigarette cartridges that were assigned to you.
- You must not engage in study procedures (such as completing a survey) or interact/meet with study staff while operating a vehicle or heavy equipment/machinery.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study chair. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after the study procedures are stopped, but in some cases side

effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped taking part in the study. Tell the study staff about any side effects you may have, even if you do not think they are related to the study procedures.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact the study chair or staff. The only risk of these questionnaires is your loss of privacy if other people find out the results.

Smoking cigarettes can lead to the following medical problems:

- **Cardiovascular Disease**: heart disease, heart attack, stroke, heart and/or blood vessel disease, reduced blood flow, weakness in the walls of arteries (possible serious bleeding)
- **Respiratory Diseases**: Emphysema, lung inflammation, and difficulty breathing due to lung damage
- **Cancers:** Lung cancer, bladder, cervical, esophageal, kidney, larynx, mouth, pancreatic, throat, stomach cancers, and acute myeloid leukemia
- **Other Health Risks:** Infertility, early delivery, stillbirth, low birth weight, sudden infant death syndrome (SIDS), lower bone density in postmenopausal women, and increased risk for hip fracture in women
- **Death**

Smoking and nicotine can affect the cardiovascular system, which may result in changes in blood pressure and/or heart rate. Smoking and nicotine can affect a person’s mood and emotions and are associated with psychiatric disorders including major depressive disorder, general anxiety disorder, bipolar disorder, and eating disorders.

Smoking during pregnancy can lead to miscarriage, preterm delivery, stillbirth, low birth weight, problems with the placenta, birth defects such as cleft palate, sudden infant death syndrome (SIDS), and early childhood behavioral problems. If you are pregnant, you will not be able to take part in this study.

For more information about the harmful effects of smoking and the benefits of quitting, please visit the Centers for Disease Control and Prevention (CDC) website: http://www.cdc.gov/tobacco/, the National Cancer Institute's website: www.smokefree.gov or call the National Cancer Institute's Smoking Quitline: 1-877-44U-QUIT.

The study e-cigarettes have been procured through the National Institute on Drug Abuse and the Food and Drug Administration has reviewed the study protocol.

Smoking **withdrawal symptoms** can include anger, irritability, frustration, anxiousness, nervousness, depressed mood or sadness, desire or craving for a cigarette, difficulty concentrating, increased appetite, hunger, weight gain, insomnia, sleep problems, awakening at night, restlessness, impatience, constipation, dizziness, coughing, daydreaming or nightmares, nausea, and sore throat.

It is possible that if you return to smoking your usual brand of cigarette at the end of the study you may experience mild nausea, dizziness, and lightheadedness.

e-Cigarette Side Effects
The short and long-term risks of using e-cigarettes are currently unknown. However, the following side effects have been seen in people using e-cigarettes:

• chest pain • fever • fatigue/tiredness • dizziness • headache • seizures • nausea/vomiting	• diarrhea • taste changes • dehydration • increased mucus in the throat/sinuses • dry mouth • sore throat	• mouth blisters/sores • difficulty breathing • shortness of breath • dry cough • dependence on nicotine

If stored improperly (in a pocket or where the device can turn on accidentally), overheating of the device may occur, which presents a minor burn risk.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets.

The National Institute of Drug Abuse has received a Certificate of Confidentiality from the federal government, which will help them protect the privacy of research participants. The Certificate protects against the involuntary release of information about participants collected during the course of covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the participant or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the participant or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review National Institute of Drug Abuse records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: If you are able to become pregnant, you must use birth control while on the study. Acceptable forms of birth control include hormonal methods (such as birth control pills, patches, implants, injections, or vaginal ring); barrier methods (such as condoms, diaphragms, sponge, or cervical cap with spermicide); or intrauterine devices (IUDs).

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell the study chair right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or National Institute on Drug Abuse for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

All protocol procedures and tests will be paid for by the study.

The total amount of compensation that you could receive for this study is up to $522. You may receive $25 for completing each in-person or virtual visit (up to $100). You may receive up to $40 for completing study questionnaires before each visit ($10 per instance). You may also receive $2/instance for completing once daily smartphone assessments (up to $84) and $2/day for completing random smartphone assessments (up to $168). You will not receive compensation for completing the final telephone visit as no research assessments are collected.

You may receive a $50 incentive at the end of both Phases 2 and 3 when you return all used and unused e-cigarette cartridges (up to $100 bonus). No partial incentives will be paid. You must return 100% of all cartridges given to you (used and unused) to be eligible for this bonus incentive.

Participants will receive $30 at the end of study participation for using their personal smartphone devices and personal data plans for study-related assessments. Alternatively, ff you were loaned a smartphone to use throughout the study, you will receive the $30 payment for returning the phone to our lab at the end of your participation. The study staff will provide the materials necessary to mail the phone back to us.

You will receive your study compensation on a reloadable Bank of America Card. If you lose your card, you will have to pay a $5.00 replacement fee.

You will also receive parking vouchers or a metro card, if needed.

Additional Information

4. You may ask the study chair (Dr. Jason D. Robinson, at 713-792-0919) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, National Institute on Drug Abuse, or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if you are unable to follow study directions or if the study is stopped.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: National Institute on Drug Abuse.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and National Institute on Drug Abuse and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples or data at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

Genetic Research

Research samples collected from you as part of this study may be used for genetic research, but will not include whole genome sequencing.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - National Institute on Drug Abuse, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - NJOY, LLC and any future sponsors and/or licensees of the study technology
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed. Your study data will be labeled with a special code instead of your name or other identifying information. Only the researchers working on this study will have access to the list that can link you to your code. This information will be stored on a password-protected computer during the study and for 7 years after the end of the study.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT