Official Title: The Impact of Menthol and Mint E-liquid Bans on Menthol Cigarette Smokers
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Wake Forest Baptist Health

Department of Social Sciences and Health Policy

MARKETPLACE STUDY

Informed Consent Form to Participate in Research
Rachel Denlinger-Apte, PhD MPH - Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand how the availability of tobacco and nicotine products affects purchasing decisions. You are invited to be in this study because you smoke cigarettes and are 21 years of age or older. Your participation in this research will involve 6 virtual visits and 3 in-person visits and last about one month.

Participation in this study will involve providing breath and urine samples, answering surveys on the computer or your smartphone with video camera, and shopping for tobacco and nicotine products from a virtual store. You will receive the tobacco and nicotine products you purchased from the virtual store to use at home for 7 days. All research studies involve some risks. A risk to this study that you should be aware of is breach of confidentiality. There is the possibility that you may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include smoking cessation programs. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Rachel Denlinger-Apte. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you smoke cigarettes and are 21 years of age or older. Your participation is voluntary. Please take your time in making your decision as to whether you want to participate. Ask the study staff to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand how the availability of tobacco and nicotine

products affects purchasing decisions by people who smoke cigarettes. This information will help the Food and Drug Administration (FDA) and other regulatory agencies decide how to regulate tobacco and nicotine products to improve public health in the U.S.

In this study, you will complete several online shopping trips. During each online shopping trip, you will buy 7-days' worth of tobacco and nicotine products that you would like to use in the real world using store credit given to you by the study (not your own money). The computer will randomly (like the flip of a coin) pick one of those virtual shopping trips and you will be given the tobacco and nicotine products you purchased during that virtual shopping to use at home for the next 7 days.

How Many People Will Take Part in the Study?

80 people at Wake Forest School of Medicine will take part in this study. We may need to screen as many as 100 because some people will not qualify to be included in the study.

What Is Involved in the Study?

If you agree to be in this study, we will first need to find out if you qualify for the study. To see if you qualify, we will do the following screening steps.

Virtual Visit 1

You will be interviewed or asked to complete surveys on the computer or your smartphone that ask personal questions about your medical and tobacco use history, and interest in quitting. After you complete all measures, our research staff will review the information to see if you qualify. If you do qualify, you will complete more questionnaires about your smoking patterns, mood and opinions about other tobacco and nicotine products and tobacco control policies.

Participants will receive payment for completing the virtual visits.

Your participation in this screening interview is voluntary, which means that you can stop the visit at any time.

In-Person Lab Visit 1

People who qualify for the study will attend a short in-person visit at the Tobacco Control Center of Excellence located in the Innovation Quarter (Downtown Winston-Salem). You will be required to wear a mask when interacting with research staff. If you do not have a mask, one will be given to you to wear. We will check your body temperature. If you have a fever, you will be dismissed and rescheduled for 30 days later.

If you do not have a fever, you will provide a breath sample and have the option to sample tobacco and nicotine products.

Participants with child-bearing potential will complete a urine pregnancy test.

Virtual Visit 2-5

Virtual Visit 2 will be completed between 1-21 days after completing In-Person Visit 1. Virtual Visits 2-5 will be conducted four days in a row. You will be interviewed or asked to complete surveys on the computer that ask about your mood and recent smoking patterns.

Then, you will complete several online shopping trips. Each shopping trip will have differences in product prices or availability. The following tobacco and nicotine products will be available:

- Your usual brand cigarettes
- E-cigarettes or vaping devices
- Nicotine gum

For each shopping trip, you will be given store credit to buy 7-days' worth of tobacco and nicotine products. You want to make sure you are buying tobacco and nicotine products that you want to use in the real world. The computer will randomly (like the flip of a coin) pick one of your virtual shopping trips and you will receive the tobacco and nicotine products you purchased during that virtual shopping trip to use at home for the next 7 days. Those are the only tobacco and nicotine products you should use between In-Person Visits 2 and 3. You will need to keep track of all the tobacco and nicotine products you use at home and bring empty cigarette packs/e-liquid cartridges/nicotine gum blister packs.

You do not have to buy any tobacco or nicotine products during the virtual shopping trips. If you do not buy any tobacco and nicotine products, you will receive your store credit as cash at Visit 6. However, you will only receive the store credit if you do not use any tobacco or nicotine products between In-Person Visits 2 and 3.

You will receive payment for completing the visit.

In-Person Lab Visit 2

In-Person Lab Visit 2 will be completed up to 48 hours after completing Virtual Visit 5. You will be required to wear a mask when interacting with research staff. If you do not have a mask, one will be given to you to wear. We will check your body temperature. If you have a fever, you will be dismissed and rescheduled for 30 days later.

You will provide a breath sample and will be given the products you purchased during the virtual shopping trip. You will also receive a urine collection cup and instructions for sample collection.

Virtual Visit 6

Virtual Visit 6 will be completed 7 days after In-Person Lab Visit 2. You will be interviewed or asked to complete surveys about your mood and recent smoking patterns. You will also complete one final virtual shopping trip.

As part of this research study, you will be audio recorded. This is being done to understand more about your experiences in the study and how you made purchasing decisions during the virtual shopping task. You may request the recording be stopped at any time during the interview. You can also withdraw your consent to use and disclose the audiotape before it is used. You will not be able to inspect, review, or approve the audiotapes before they are used in this study.

Please choose one of the following regarding the use and disclosure of the audiotape used in this research study:

_____ I would like the audiotapes of me to be destroyed once their use in this study is finished.

____ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

In-Person Lab Visit 3

In-Person Lab Visit 3 will take place up to 48 hours after Virtual Visit 6. On the morning of In-Person Lab Visit 3, you will collect your first morning void urine to bring into the lab. This urine will be stored at the Wake Forest Tobacco Control Center of Excellence. In the future, research on your urine sample will be analyzed to measure chemicals in cigarettes and other tobacco and nicotine products. You will also bring all used and unused tobacco and nicotine products with you to the visit.

You will be required to wear a mask when interacting with research staff. If you do not have a mask, one will be given to you to wear. We will check your body temperature. If you have a fever, you will be dismissed from the study.

If you do not have a temperature, we will collect a breath sample for carbon monoxide exposure. We will collect your used and unused tobacco and nicotine products as well as your urine sample. You will receive payment for completing the visit.

STORAGE OF BIOLOGICAL SPECIMENS

If you agree to participate in this study, we will collect a urine sample from you to use for future research. This sample will be kept and may be used in future research to learn more the chemicals in cigarettes and other tobacco products. Your first morning void urine sample will be collected at home and brought to the lab. The sample will be stored at the Wake Forest Tobacco Control Center of Excellence and it will be given only to researchers approved by Dr. Denlinger-Apte. An Institutional Review Board (IRB) must also approve any future research study using your urine sample. In order to participate in this study, you must be willing to provide this sample for future research.

The research that may be performed with your urine sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your urine sample will not be given to you or your doctor. The results will not be put in your medical record. The research using your urine sample will not affect your care.

Your urine sample will be used only for research and will not be sold. The findings from this

research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

Your urine sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be an assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

____YES you may contact me about future research studies
____NO I do not want to be contacted about future research studies.

How Long Will I Be in the Study?

You will be in the study for about one month. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

Survey Questions

You will be asked questions about your medical history, tobacco, drug and alcohol use, and mood. Answering these kinds of questions may make some people feel uncomfortable. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Breach of Confidentiality

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. However, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

Reproductive Risks

If you are pregnant (as indicated by a positive pregnancy test) trying to become pregnant, or breastfeeding, you will not be eligible to participate in the study.

If female participants choose to be sexually active, they are asked to use an appropriate "double barrier" method of birth control (such as female use of a diaphragm, intrauterine device (IUD), or

contraceptive sponge in addition to male use of a condom), or should be using prescribed "birth control" pills, injections, or implants.

Cigarettes

All cigarettes are harmful to a person's health and can lead to the following medical problems:

a) Heart and blood vessel disease: Heart disease, heart attack, stroke, peripheral vascular disease (PVD), reduced blood circulation, abdominal aortic aneurysm;
b) Lung disease: Emphysema, asthma, bronchitis, tuberculosis and chronic airway obstruction (COPD);
c) Cancer: Lung, bladder, liver, colon, cervical, esophageal, kidney, larynx, mouth, pancreatic, throat, stomach cancers and acute myeloid leukemia;
d) Diabetes;
e) Immune function, rheumatoid arthritis;
f) Other health risks: Infertility, tubal pregnancy, sudden infant death syndrome (SIDS), birth defects, lower bone density in postmenopausal women, and increased risk for hip fracture in women, male sexual dysfunction, vision problems and age-related macular degeneration;
g) Smoking and nicotine can affect your heart and blood vessels which may result in changes in blood pressure and/or heart rate;
h) Death.

E-cigarettes or Vaping devices

Long term health effects of vaping devices are not known since little research has been done on these products. There is a notice from the FDA regarding the safety of this product that says they do not know whether e-cigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using these products. Some of the samples tested have low but detectable levels of toxic chemicals.

The most common side effects are changes in taste, mucus in throat/sinus, dry mouth, dry cough, throat irritation, sore throat, mouth ulcers, dizziness, headache, seizures, and nausea. If you experience loss of consciousness, memory lapse, change in mental status, confusion, tremor, shaking, or seizure, please stop use of e-cigarette (or other nicotine products) and promptly notify study staff. Although uncommon, there have been rare occasions where the batteries in vaping devices have exploded and injured users.

While not harmless water vapor, vaping devices generally contain fewer toxins than smoked tobacco products. Vaping devices can overheat and present a burn risk if the device is turned on repeatedly. Be careful if storing the device in a place where the button might be accidentally pressed often, like your pocket. Defective cartridges, tanks or devices may leak e-liquid. If this should happen, wash the exposed area to remove the e-liquid immediately. On rare occasions, allergic reactions have occurred after using vaping devices.

The Centers for Disease Control and Prevention (CDC) and FDA are investigating recent reports of serious lung disease associated with use of vaping devices. Many of the incidences are related to vaping cannabis oil. FDA has advised consumers to avoid buying vaping products on the

street and refrain from using THC oil or modifying/adding any substance to products purchased at stores. If you use e-cigarette/vaping products and experience any symptoms such as cough, shortness of breath or chest pain, nausea, vomiting or diarrhea seek prompt medical attention.

If any of these side effects mentioned above occur, please notify the research staff ([redacted] or in emergency situations after hours: [redacted]).

The liquid in e-cigarettes (often called e-liquid or e-juice) can contain nicotine that can cause harm and possible death if the e-liquid or the refill cartridges containing e-liquid are eaten.
KEEP ALL VAPING DEVICES, E-LIQUIDS, AND CARTRIDGES AWAY FROM CHILDREN AND PETS

Nicotine Gum
Side effects of the nicotine gum may occur. These include mouth and throat irritation or sores, hiccups, feeling dizzy or lightheaded, upset stomach, vomiting, heartburn, diarrhea and high blood pressure. Using nicotine gum may aggravate the jaw joint or dental work. You should not use the gum if you have dentures. If any of these side effects mentioned above occur, please notify the research staff [redacted]). If these side effects are serious, stop using the nicotine product right away.

Nicotine Withdrawal Symptoms
You may have symptoms of nicotine withdrawal if you do not use any other tobacco or nicotine products during the study. These symptoms may include: craving tobacco, irritability, frustration or anger, anxiety, restlessness, sleep problems, trouble with concentration, depressed or sad mood, constipation, dizziness, coughing, nausea, sore throat and increased appetite or weight gain. These feelings can be uncomfortable but are low risk.

Too Much Nicotine
Combining tobacco and nicotine products or using too much of any one product may lead to headache, dizziness, shakiness, nausea, vomiting or diarrhea, weakness and fast heartbeat. If any of these side effects mentioned above occur, please notify the research staff ([redacted]). If these side effects are serious, stop using the nicotine product right away.

Continued use of dual tobacco products
There is a risk you may keep using other tobacco products along with smoking after the study is over. We will encourage you to quit tobacco use and we will provide referral information for you if you are using any tobacco products.

Worsening of Mental Health Symptoms
Smoking and nicotine can affect a person's mood and emotions. For people with mental health conditions, it is possible that changes in nicotine or tobacco use could have a negative effect on mental health conditions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

There are no additional costs to you by participating in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The National Cancer Institute, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elder abuse and neglect or intended harm to yourself or others.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $155 if you complete all the scheduled study visits. You will be paid $30 for

completing Virtual Visit 1, $15 per visit for completing Virtual Visits 2-6 and a $50 bonus for completing all study procedures. If you withdraw for any reason from the study before completion you will be paid the allotted amount for each complete study visit.

If you do not qualify today for the study, you will be paid $20 for your time.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.
The schedule below shows what you will receive if you complete all parts of this month-long study.

Virtual Visit 1	$30 ($20 if ineligible)
Virtual Visit 2	$15
Virtual Visit 3	$15
Virtual Visit 4	$15
Virtual Visit 5	$15
Virtual Visit 6	$15
Completion Bonus	$50
Total:	**$155**

Payment will be made using a prepaid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Cancer Institute. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.
You do not give up any legal rights as a research participant by signing this consent form.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: medical history, smoking status, current medications, collection of your exhaled breath, saliva, and urine.

We will make every effort to keep your Protected Health Information private. We will store Protected Health Information in a cabinet in a locked office or on a password protected computer.

You will not be directly identified in any publication or presentation that may result from this study. Your personal health information and information that may identify you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products or procedures.

Some of the people, agencies and businesses that may receive and use your health information

are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Rachel Denlinger-Apte that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Rachel Denlinger-Apte
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. You will be given any additional information if we become aware of anything that may affect your willingness to continue to participate in the study.

This study may be enrolling students from the Wake Forest University and Wake Forest University Medical Center campuses. In addition to your rights as a research participant noted in the previous section, as a student, you are under no obligation to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, or assignments. You will not be pressured into participating in this research study by any statements or implied statements that your grades, performance evaluations or assignments will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration or study staff to make decisions regarding the status of your medical benefits. If you have questions regarding your enrollment in the study and your status as a medical student, please contact the Office of Student Services for additional information.

Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with other without additional consent.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Rachel Denlinger-Apte at telephone number [redacted] or after hours at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature (Date/Time, am/pm): _____

Person Obtaining Consent (Printed):_____

Person Obtaining Consent (Date/Time, am/pm):_____ \