Title: **Tobacco Cessation at FDNY**

NCT05997225
ID: **2023-14980**
IRB Approval Date: **01/16/2025**

World Trade Center Health Program at the Fire Department of the City of New York (FDNY)
Individual Information and Consent Form

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

You are being asked to join this research study.
The title of the study is: Preventing Lung Cancer through Tobacco Cessation at FDNY

The study is being done under the supervision of:

Principal Investigators: Dr. David Goldfarb and Dr. Shadi Nahvi
Office Address: 9 Metrotech Center Brooklyn, NY 11201
Telephone #: 718-403-4413
Protocol #: 2023-14980

DO I HAVE TO TAKE PART IN THIS RESEARCH STUDY?

- Your participation is voluntary. This means that you decide whether you want to join the study or not after speaking with the researcher, or other members of the research team.
- If you decide to take part, you will be asked to sign this consent form. Your signature means that you agree to be a participant in this research. In the event you are unable to sign the consent form, but you still wish to participate, you may also give the person administering the informed consent your expressed verbal consent.
- After reading this form and discussing what it says, you should ask all the questions you want to ask. We encourage you to take as much time as you need to decide.
- If you do not understand some of the terms used in this form, ask the person who is discussing the study with you to give any additional information that may make this easier to understand.
- You do not have to consent to participate in the study immediately, or ever. You may choose to think about it or discuss the information with family or friends before you decide.
- You will be given a copy of this form whether or not you agree to participate in this study. Do not sign the form unless you have had all your questions answered and understand exactly what is involved.
- If you decide to take part, you are still free to withdraw at any time without giving a reason. This will not affect your care.

STUDY SPECIFICS

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

- You have been asked to participate in this study because you are enrolled in the Fire Department of the City of New York (FDNY) World Trade Center (WTC) Chest CT program (CT), you previously consented to WTC-related research, and you smoke cigarettes.
- You will be one of approximately 220 people who will be participating in this study. If you agree to take part in this study, you will have a medical evaluation to be sure that you qualify for the study.
- As part of this study, you were randomized and recruited based off your previous responses to questionnaires where you had indicated as being someone who smokes.

WHY IS THIS RESEARCH STUDY BEING DONE?

- Although participants in the FDNY WTCHP CT screening program have access to a free tobacco cessation program, over 1/3 of those people continue to smoke.
- Cigarette smoking is a leading cause of disease and death in the US.

- Many effective treatments exist to help people quit smoking, but people who smoke often don't use medications, or don't use medications long enough to get their full benefit.
- All participants in this study will receive a medication called varenicline. The medicine was approved by the U.S. Food and Drug Administration (FDA) in 2006 for use in helping people to quit smoking. Varenicline works by blocking nicotine receptors in the brain. When people smoke while taking varenicline, it blocks the cigarette's enjoyable effects; it also reduces the craving and other symptoms associated with withdrawing from nicotine. Varenicline may help you reduce your nicotine use, even if you are not ready to quit.
- The purpose of this study is to test the effectiveness of a strategy specifically designed to address the challenges of getting people to start and succeed with tobacco treatment.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

- By previously providing informed consent to FDNY WTC-related research, you had an equal chance (50% or 1-in-2 chance) of being assigned to one of two treatment groups.
- One group will be offered quit-smoking medication (varenicline) and quit-smoking counseling with a treatment plan individually tailored to their health information. If you are assigned to this group, you have the ability to opt out.
- One group will receive an invitation to participate in a quit-smoking program, and to receive quit-smoking medication (varenicline) and quit-smoking counseling.
- Regardless of which group you are assigned to, we will review your medical conditions to confirm that it is safe for you to take varenicline. If we determine that you are potentially eligible for this study, you will be scheduled to meet with the with our research coordinator.
- The study team will complete a screening checklist for eligible participants to allow for clearance/prescription of varenicline. The checklist includes items about your general and mental health, such as renal function and alcohol use, that were measured and/or reported during previous FDNY WTCHP medical monitoring exams. Eligibility will be confirmed after the above data is reviewed by our tobacco treatment specialist and clinical coordinator in consultation with the co-PI, Dr. Shadi Nahvi.
- You will be asked to take varenicline for a total of 16 weeks. You will receive the standard dose of varenicline: 0.5 mg once a day for days 1-3, 0.5 mg twice a day for days 4-7, and 1 mg twice a day after that.
    - We recommend that you try and quit smoking four weeks after you start taking varenicline. That's your target quit date. You'll then continue varenicline for an additional 12 weeks after your target quit date.
- You will be in the study for 28 weeks. You will take medication for 16 weeks.
    - All study visits will be conducted via video conferencing.
    - You will schedule your counseling sessions with a member of the research study team.
    - This will be followed by your baseline visit (i.e., week 0).
    - Subsequent research study visits will take place 2, 4, 8, 12, 16, and 28 weeks after your baseline visit.
    - Each research study visit will last about 10 minutes.
    - All visits include questionnaires, a timeline follow-back assessment of past 30-day tobacco use, and varenicline adherence.
    - The questionnaires will include questions about your cigarette smoking, your drug and alcohol use, your mood and mental health, if you are taking your medications, and any medication side effects that you may be having. You do not have to answer any questions that you do not want to.

  - Urine cotinine levels will be obtained at the baseline visit (to assess baseline nicotine consumption) and at each visit when you report abstinence. These tests are conducted for research purposes, only.
  - NO HIV (AIDS), illicit drug or alcohol testing will be performed on any research subject as part of this study. We will not conduct genetic testing.
- Medications may cause a reaction that, if not treated promptly, could be serious. It is important that you report all symptoms, reactions, and other complaints to the research study doctor. If you do not feel well at any time, call your doctor or the research study doctor immediately. Please refer to the text below for additional information.
- No audio or video recording will be done.

WHAT ARE THE POSSIBLE SIDE EFFECTS, DISCOMFORTS, RISKS, OR INCONVENIENCES I CAN EXPECT FROM BEING IN THIS RESEARCH STUDY?

The risks of participation in this trial are: 1) inconvenience of attending research visits, 2) possible discomfort with answering questions related to the research, 3) discomfort related to quitting smoking, and 4) risks associated with the use of the medication varenicline.

Here is an explanation of each of these types of risks:

- Telehealth visit privacy: Privacy of video encounters. Participants will be notified that video encounters (telehealth) use a HIPAA protected application and will not be recorded. The study coordinator and Tobacco Treatment Specialist will confirm with participants that they are in a private location prior to initiating study visits.
- Discomfort with the research assessments: It is possible that the survey questions might make you feel anxious. You may choose to withdraw from the study if you find the questions upsetting, or you may choose not to answer the questions.
- Risks related to quitting smoking: When people quit smoking and withdraw from nicotine, they can experience symptoms including anger, irritability, anxiety, difficulty concentrating, hunger, depression and trouble sleeping. Weight gain is also possible. There is also the risk of continuing or going back to smoking.
- You may experience side effects related to varenicline treatment. However, these side effects might occur whether or not you participate in the study. Here is a list of the known side effects associated with the medication varenicline:

MOST COMMON SYMPTOMS:

- Nausea: In large studies of varenicline, 28-33% of people reported nausea. In most cases it was mild to moderate, and only 3% of people stopped taking varenicline because of nausea.
- Insomnia was reported by 14-20% of people taking varenicline.
- Headaches were reported by 13-16% of people taking varenicline.
- Abnormal dreams were reported by 10-14% of people taking varenicline.
- These symptoms are common for people who are withdrawing from nicotine, regardless of whether they are taking medication.

OTHER COMMON SYMPTOMS (reported in 5-15% of people taking varenicline):

- Vomiting

- Gas
- Constipation
- Upset stomach/indigestion
- Change in taste/abnormal taste
- Dry mouth
- Change in appetite

RARE SYMPTOMS (reported in less than 5% of people taking varenicline):

- Dizziness
- Fatigue
- Upper Respiratory Disorders (such as trouble breathing or runny nose)
- Skin conditions (such as rash or itching)

VERY RARE SYMPTOMS (reported in less than 1% of people taking varenicline):

- Convulsions

POTENTIAL CARDIOVASCULAR DISEASE RISKS:

- In a study of patients with cardiovascular disease (including heart attack, peripheral arterial vascular disease, or stroke) receiving varenicline, there was a small, increased risk of certain cardiovascular events compared to people receiving placebo. These included heart attack (2% in subjects receiving varenicline v 0.9% in subjects receiving placebo), need for heart stents or bypass surgery (2.3% with varenicline v 0.9% with placebo), and new diagnosis of peripheral vascular disease or admission to the hospital for treatment of peripheral vascular disease (1.4% with Varenicline v 0.9% with placebo).

POTENTIAL PSYCHIATRIC RISKS:

- Research studies of patients with depression, bipolar disorder, and schizophrenia, taking varenicline found no increase in their mental health symptoms.
- Tobacco cessation, treated or untreated, can lead to mental health symptoms such as anxiety or depression. This study protocol is designed to ensure that any such symptoms are quickly identified and if they occur voluntary referrals to our mental health counselors are available.
- In addition to the risks listed above, there is the risk that the drug may not work for you, and that you might continue smoking. There is also the possibility that you will have a reaction that is currently not known and not expected.

USING VARENICLINE WITH ALCOHOL

Varenicline may change the way alcohol affects your system. In March 2015, the FDA issued a Drug Safety Communication describing cases of increased intoxicating effects of alcohol (Increased drunkenness), including aggressive behavior or amnesia (having no memory of things that happened) in healthy individuals. In studies of individuals with alcohol problems using varenicline, there have been reports of varenicline making alcohol-related nausea, headaches, and sleep-related problems worse. As per FDA recommendations, we advise all subjects to reduce the amount of alcohol they consume until they know whether varenicline affects their tolerance of alcohol.

ARE THERE LIKELY TO BE ANY BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

- There may or may not be direct medical benefit to you from being in this research study.
- Varenicline treatment has been shown to help smokers quit.
- There are significant health benefits to quitting smoking, including a reduction in the chance of developing lung disease, heart disease or cancer.
- In addition, the information learned from this study may, in the future, benefit other WTC responders with the same medical condition.

WILL I BE PAID FOR BEING IN THE STUDY?

For attending and completing all research visits and pill counts, you will receive a total of $210 in cash reimbursements for the entire study. For each fully completed regular research visit (Weeks 0, 2, 4, 8, 12, 16, 24) you will receive up to $30 in cash reimbursements.

- If you are asked to pay a copayment when you pick up medications at the pharmacy, we will reimburse the cost of copayments with documentation (pharmacy receipt).

Confidentiality

We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely because the study team takes confidentiality of your information seriously. Your research records will be kept confidential, and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The FDNY Data Center data warehouse and FDNY Data Center servers are limited with password protected access and individual access is granted to data. All individuals with access to the data are both HIPAA and CITI trained for privacy, security, and research conduct. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them.
- the organization that funded the research (NIOSH)
- groups that review research (the Albert Einstein College of Medicine Office of Human Research Affairs).

These people who receive your health information, may share your information with others without your permission, if required by law. But all these groups have agreed to keep your information confidential to the best of their abilities.

- There are some exceptions to us maintaining your confidentiality. If you are in danger to yourself (i.e., suicidal) or to anyone else (i.e., homicidal) we will report these circumstances to a mental health provider or physician for evaluation and/or referral.
- As this research involves a medication, the FDA may inspect our research records and medical records.
- All these groups have been requested to keep your name private.

WILL THERE BE ANY COSTS TO ME?

- There will be no costs to you for participating in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If any questions arise related to this research project, or you believe you have any injury related to this study, you can call Dr. Prezant at 718-999-2696, Dr. Goldfarb at 718-403-4413, or Dr. Nahvi at 718-920-5379. You may also call Tyrone Moline, our Study Coordinator, at 718-403-4422.
- After hours, in the event of any emergency, contact 911.
- If you have any further questions regarding your rights as a research subject, you may also call the Manager of The Albert Einstein College of Medicine Committee on Clinical Investigations at (718) 430-2253, Monday through Friday between 9 AM and 5 PM.

PARTICIPANT: FOR FUTURE CONTACT, PLEASE SELECT YOUR CHOICES BELOW

I consent to be contacted in the future to learn about:

_____ New research protocols that I may wish to join. General information about research findings.

_____ I DO NOT AGREE TO BE CONTACTED IN THE FUTURE, EVEN IF THE RESULTS MAY BE IMPORTANT TO MY HEALTH OR MY FAMILY'S HEALTH.

Your wish does not constitute a guarantee that you will be contacted.

CAN I BE ASKED TO STOP PARTICIPATING IN THIS STUDY BEFORE THE STUDY IS FINISHED?

- You may be withdrawn from the study at any time if the researcher feels that it would be in your best interest not to continue participating.

MAY I STOP THE STUDY AT ANY TIME?

- Your participation in this study is voluntary and you may withdraw from the study at any time without giving a reason.
- If you agree to participate and withdraw later, some of your information may have already been entered into the study and that will not be removed.
- Your treatment by doctors and staff at the institution(s) involved in this study, now and in the future, will not be affected in any way if you agree to participate and withdraw later.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS RESEARCH STUDY?

- Your participation in this study is voluntary.
- You do not waive any of your legal rights by participating in this research study.

Informed Consent Signature Page

The following is a list of items we discussed about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate.

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- Any costs and payments.
- I can discontinue participating in the study at any time without penalty.
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- All written and published information will be reported as group data with no reference to my name.

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigators listed on top of the page 1 of this consent form. If a member of the research team cannot be reached, or you want to talk to someone other than those working on the study, you may contact the Albert Einstein College of Medicine Office of Human Research Affairs at (718) 430-8817 or irb@einsteinmed.edu.

A description of this clinical trial will be available on 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 website site at any time.

____ I have read the consent form.

I understand that I am entitled to and will be given a copy of this signed release form. If you are unable to sign, but expressed verbally your desire to participate, you will also receive a copy of this form.

By consenting to participate, I give my authorization for the uses and disclosures of my protected health information as described above.

When you consent, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date