Title: Tobacco Cessation at FDNY

NCT05997225
ID: **2023-14980**
IRB Approval Date: **07/18/2025**

1. Background/significance

Smoking continues to be the leading preventable cause of death and disease in the U.S.,[1] accounting for nearly one in five deaths annually.[2] Over 55% of smokers attempt to quit each year, yet under 10% are successful.[3] Despite the success of chest computed tomography (CT) lung cancer screening programs, tobacco cessation remains the most effective tool in the battle against not only lung cancer, but all tobacco-related diseases.[4, 5] Tobacco cessation rates, however, remain low, even among smokers at high-risk for lung cancer and other tobacco-related diseases, and despite participation in CT screening programs.[6] Although tobacco use in the U.S. and at the Fire Department of the City of New York (FDNY) has declined,[7-9] current tobacco use remains disproportionately high among participants in CT screening programs.

To date, little is known about the optimal treatment components to engage and enhance cessation outcomes among smokers participating in CT screening.[5, 10] Most CT screening programs offer only the bare minimum – a referral to a quit line with or without over-the-counter nicotine replacement treatment (NRT). The current FDNY Standard Care tobacco cessation program consists of cessation counseling plus NRT,[11] although varenicline without preloading has also occasionally been used. Notwithstanding referrals to this no-cost cessation program, 36% of FDNY World Trade Center (WTC) participants in CT lung cancer screening are current smokers.

Tobacco cessation research in the general population (not just restricted to those in CT screening) highlights key challenges among smokers – engaging in tobacco treatment and achieving abstinence. Cessation slows smoking-related declines in lung function and reduces the risk of lung cancer.[12, 13] It is particularly critical for WTC-exposed responders who smoke because a high proportion of the FDNY WTC-exposed workforce has diagnoses of respiratory conditions that can be exacerbated by tobacco use. WTC-exposed FDNY responders (firefighters and EMS) lost, on average, 20% of lung function after September 11, 2001, and >20% developed new-onset obstructive airways disease. We have previously shown in the FDNY WTC Health Program (WTCHP) cohort that the risk of accelerated lung function decline over time was highest among current smokers and that tobacco cessation was associated with reductions in the rate of decline.[14]

Professional societies recommend, and the Centers for Medicare and Medicaid Services (CMS) require, that tobacco cessation counseling be part of chest computed tomography (CT) lung cancer screening programs. Despite the need, little is known about how to optimize cessation rates among current smokers undergoing CT screening.[4] For WTCHP responders who continue to smoke, novel strategies are needed to engage them in evidence-based smoking cessation treatment.

The current tobacco treatment default, in which patients must opt-in to cessation treatment and are only offered counseling and pharmacotherapy when deemed ready to quit, results in missed opportunities to engage smokers into treatment.[15] Previous studies of opt-out enrollment in cessation treatment suggest that an opt-out tobacco treatment strategy substantially increases engagement and cessation rates compared with traditional opt-in approaches.[16-18] Using CT results as a motivational tool has shown promise in pilot studies.[19-23] The optimal approach and success of using CT coupled with spirometry results to motivate tobacco cessation however remains unknown.[4] Research has provided conflicting evidence on the effect of physiological feedback[24-29], including spirometry.[30] This provides an impetus for testing the hypothesis that discussing spirometry and CT scans during tobacco counseling improves smoking cessation.

Individual components of tobacco cessation therapies, such as opt-out enrollment, tailored biofeedback, and Varenicline pre-loading, have been successful in some circumstances, but have never been studied as a as a single, full intervention package. For example, no tobacco cessation programs for CT patients in an occupational health service have utilized opt-out enrollment to smokers, regardless of their readiness to quit. Further, while guidelines exist for determining CT lung cancer screening eligibility criteria,[31-35] all have identified an underlying risk condition in current smokers – high nicotine dependence, which correlates well with predicting those most likely to avoid or struggle with tobacco cessation.[36] Given high nicotine dependence in current smokers enrolled in CT screening, novel, intensive cessation strategies could provide an important evidence base to broaden tobacco treatment for this and other vulnerable groups.

2. Study Design

This is a randomized trial among retired FDNY WTCHP responders eligible for our FDNY WTCHP CT screening program to test the effects of **Enhanced Care** (opt-out enrollment, tailored counseling based on CT and spirometry results, and varenicline with preloading) against **Standard Care** (opt-in enrollment, standard cessation counseling without CT tailoring, and varenicline with preloading) in the engagement of high-risk smokers in cessation treatment and the achievement of tobacco abstinence. The study includes participants who smoke despite participation in our CT screening program and prior referral to our typical NRT-based cessation program, as defined by National Clinical Cancer Network Group 2 and CMS CT eligibility + WTC-exposure. This

trial addresses the challenges of engaging and optimizing cessation outcomes among high-risk current smokers undergoing CT screening and will define specific factors that can be leveraged to improve the success of Tobacco Cessation Programs that would be generalizable to all WTCHP cohorts.

The objectives of this study are as follows:

Aim 1: To compare **enrollment** (proportion participating in first visit with our tobacco treatment specialist) in the FDNY WTCHP Tobacco Cessation Program by Standard Care vs. Enhanced Care methods.

Aim 1a: To evaluate demographic and clinical characteristics associated with FDNY Tobacco Cessation Program enrollment. Using data from FDNY WTCHP databases, we will explore sociodemographic (gender, age, race, firefighter vs. EMS) and clinical characteristics [PTSD, depression, quality of life (SF-12) and lung function (spirometry), number of prior quit attempts, Fagerström Test for Nicotine Dependence scores and CT results] associated with Program enrollment.

Aim 2: To compare **outcomes** (retention to study end-date, varenicline and counseling adherence and tobacco abstinence rates) in the FDNY Tobacco Cessation Program by Standard Care vs. Enhanced Care methods.

Aim 2a: To evaluate demographic and clinical characteristics associated with FDNY Tobacco Cessation Program outcomes. Using data from FDNY WTCHP databases and from questionnaires administered during 7 video visits (e.g., assessment of past 30-day tobacco use), we will explore the above noted sociodemographic and clinical characteristics associated with the tobacco treatment outcomes of retention, intervention adherence and tobacco cessation.

Only those individuals who previously agreed to be contacted for future physical health research studies under the umbrella protocol (Einstein IRB #07-09-320 titled "Medical Surveillance in New York City Fire Department Employees Exposed to Dust During the World Trade Center Collapse") are eligible to be randomized. Participants will be randomly assigned to either **Enhanced Care** or **Standard Care** after their eligibility for future studies from protocol #07-09-320 has been confirmed. A copy of this previously approved consent form has been included in Appendix 4. We will employ a parallel arm study design. It is not feasible to blind participants to their respective treatment assignment for this behavioral intervention. Participants in **both** study arms will be offered varenicline initiated 4 weeks prior to their target quit date ("preloading") followed by 12 weeks of varenicline treatment. Dr. David Prezant, an investigator on this study, will prescribe varenicline through the WTCHP pharmacy benefit plan manager (Express Scripts), thereby achieving the lowest cost to this grant, as the cost of varenicline will be borne by the WTCHP Pharmacy Benefit Plan. Drs. Goldfarb and Prezant will be tracking prescriptions. Tobacco counseling for both arms (tailored to spirometry/CT results or not), will occur at baseline, and at weeks 2, 4, 8, 12, and 16. Similarly, research assessments will also occur at baseline and at weeks 2, 4, 8, 12 and 16, with final visits at 12 weeks post end of treatment (EOT) at 28 weeks. To avoid differential bias, the number of the visits will be identical for both arms and all visits will be individual telehealth visits (audio + video). Urine testing will be performed at the beginning of the study to assess baseline nicotine consumption, as well as at each subsequent visit for biochemical verification. We will test urine for nicotine, cotinine, 3-OH-Cotinine, Nornicotine, Norcotinine, and Anabasine. As these are telehealth visits, the tests will be collected at the Quest lab location nearest to each participant's residence as is routine in the FDNY WTCHP. These services will be provided to participants at no cost. Participants will be compensated with a $30 gift card for each visit.

Enhanced Care will include opt-out enrollment in the FDNY Tobacco Cessation Program, as well as counseling with tailored feedback based on CT and lung function spirometry values **previously** gathered as part of the WTCHP Medical Surveillance protocol (Einstein IRB #07-09-320). These data will be used as part of counseling sessions to create a "reachable, teachable moment." Participants in the **enhanced care** group will first get a letter outlining the trial and the opportunity to opt out of the free WTCHP Tobacco Cessation Program. Then, the research coordinator will make proactive outreach for cessation treatment for those who do not opt out. Following that, study protocols will be discussed, and informed consent to receive the **enhanced care** will be obtained for those who remain interested in participating. Participants who express a desire to **not** participate in the study after being contacted will not be included and ***will not*** be contacted again.

Standard Care will include opt-in enrollment, and brief counseling. A separate letter will explain to participants randomized to the standard care group that they have been randomly selected to be a part of the study and must contact the research coordinator to be included and receive the free therapeutic services. These individuals will be given normal tobacco cessation counseling. While the counselor will not bring up prior

spirometry or CT scan results during sessions until individuals bring them up, if they do, the counselor will emphasize the adverse effects of smoking regarding these exams. Because the effectiveness of this bundled intervention is **truly unknown**, particularly regarding tailored counseling in this occupational cohort, clinical equipoise will be preserved. If participants contact the research coordinator on their own initiative, study methods will be discussed, and informed consent will be sought for those who remain interested. Participants who do not contact the research coordinator will not be included in the study and **will not** be asked to be part of the study at any point in the future.

Randomization. Randomization will be conducted in a 1:1 ratio. To minimize bias in treatment allocation, a data analyst on the WTCHP research team, who has no contact with study participants, will assign participants to each treatment arm via computer-generated randomization.[37, 38] The team will be notified of randomized assignment and allocation will be stored in a password-protected file. Letters from the FDNY WTCHP will be sent to the estimated 320 persons, with 160 receiving the opt-in Standard Care letter and 160 the opt-out Enhanced Care letter.

Eligibility determination. We have developed a checklist to determine participant eligibility which we will use at participants' first encounter. Eligibility will be confirmed after an assessment of medical and psychiatric eligibility in consultation with MPI Dr. Shadi Nahvi and Dr. David Prezant. This checklist includes a review of basic metabolic panel to assess renal function (EGFR <30), and assessment of psychiatric and alcohol use disorders (defined as an AUDIT score >15), using standardized instruments. Exclusion criteria for the study include use of varenicline in last 30 days, psychiatric instability (exacerbations in prior 3 months; current suicidal ideation or attempt, psychiatric hospitalizations in past year); or seizures. The intake interview includes an assessment of psychiatric disorders using standardized instruments, including: (1) mental health screening instruments for PTSD (PCL-17),[39-41] depression (CES-D),[42, 43] and (2) the Columbia Suicide Severity Rating Scale, a valid, sensitive instrument for assessment of suicidal ideation.[44] We have experience with these instruments as they are regularly used in our FDNY WTCHP research. Individuals who report suicidal ideation with plan or intent will be referred for immediate evaluation (see Human Subjects section); those with exclusionary psychiatric symptoms not receiving psychiatric care will be referred to our WTC counseling unit.

Visits will occur at baseline (week 0) and at weeks 2, 4, 8, 12, 16, with a final, post-intervention visit 12-weeks post EOT (week 28) (Table 1). To avoid differential bias, the number of the visits will be identical for both arms, and all visits will be individual telehealth visits. All visits include questionnaires (see measures section, below, for content), a timeline follow back assessment of past 30-day tobacco use, and varenicline adherence. Participants will be provided a link to sign into by the Bureau of Technology Development and Systems. Urine metabolite levels will be measured prior to the baseline visit (to assess baseline nicotine consumption) and prior to each counseling visit. As these are telehealth visits, the urine cotinine will be collected at the Quest lab location nearest to each participant's residence. Participants will be reimbursed $30 per visit. Study visits are to occur with a ±1 week window from the date of the last counselling session, or from the date of study enrollment. A flow of study participation can also be found below in Figure 1, with Figure 2 outlining the timing of study visits, once participants have enrolled into the study.

Participant tracking and retention. We have extensive experience recruiting and retaining persons in our FDNY WTCHP (>80%) and in our research studies. Tobacco treatment will continue to use telehealth visits due to the stated preference of those in treatment. Along with Matt Bars (our tobacco treatment specialist), Dr. Prezant, Co-Director of the FDNY WTCHP and Director of its CT program and the research coordinator, Tyrone Moline, will maintain contact with participants to optimize recruitment and retention to study end-date. For tracking and retention, at enrollment we will verify our records of participant's address, phone number, email. Contact info will be updated at all visits. We will ask whether we can leave phone, text, or email messages and how we should identify ourselves (name or as "FDNY WTC Tobacco Program").

Varenicline distribution and medication adherence: Pill Counts. All participants will receive 16 weeks of varenicline, including preloading. We selected varenicline because it is the most efficacious single medication for tobacco cessation,[45-47] and allows intensification of treatment from the nicotine replacement therapy that is traditionally offered in the WTCHP Tobacco Cessation Program. Dr. Prezant will prescribe varenicline through the WTCHP pharmacy benefit plan manager (Express Scripts), thereby achieving the lowest cost to this study, as the cost of varenicline will be borne by the WTCHP Pharmacy Benefit Plan. We will use pill counts as the

primary measure of varenicline adherence, using established measures. Pill count adherence will be analyzed continuously, defined as # pills taken /# prescribed. Pill count is an objective measure that has been shown to correlate with electronic monitors and varenicline plasma levels.

Brief individual cessation counseling. All participants will undergo structured, brief individual cessation counseling sessions, **with or without** tailoring based on CT results, at baseline and weeks 2, 4, 8, 12 and 16. If CT results are positive (nodules, bronchial wall thickening, emphysema, COPD, etc.) we will motivate by teaching that becoming tobacco free can lead to reductions/resolution of nodules (especially ground-glass nodules) and bronchial wall thickening; and, cessation also decreases progression of emphysema and COPD as well as the risk for heart attacks, strokes and many forms of cancer. If spirometry (obtained annually as part of the WTCHP medical) shows accelerated decline rates (>2x normal aging) or dysfunction (e.g., COPD or interstitial lung disease), we will motivate by teaching that cessation can slow progression. If the CT or spirometry results are unremarkable, we will emphasize that becoming tobacco free is the best way to gain control over future health. Counseling in both arms will also be consistent with Public Health Service Clinical Practice Guidelines,[48] and will assist with problem solving and skills training regarding tobacco cessation. We chose this approach because 1) brief advice has been shown to increase the likelihood of smoking cessation,[49] and is easily implemented in clinical settings; 2) there is a dose-response between the number of counseling encounters and cessation success;[48] and 3) allows comparability with other CT-based cessation interventions.[19] All counseling will be conducted by the same certified tobacco treatment specialist, who will not perform outcome assessments. Consistent with our usual procedures,[50] our treatment specialist will demonstrate adherence to a fidelity checklist before starting and continuing counseling. The counselor will also use a clinic behavioral checklist during enhanced care sessions (Appendix 6).

We will compare enrollment (participation in a visit with our tobacco treatment specialist (Aim 1), treatment outcomes (retention to study end-date, adherence, and biochemically verified abstinence (Aim 2), and evaluate sociodemographic and clinical characteristics associated with each (Aims 1a and 2a).

This is the first randomized trial of smoking cessation treatment (Standard vs. Enhanced Care) in the context of an occupational health service CT lung cancer screening program. Our target population consists entirely of heavy, high-risk current smokers meeting NCCN2 and CMS criteria for CT screening[51] (age ≥50 years old; ≥20 pack-year history OR 20-year duration), who nonetheless continue to smoke. A recent study demonstrated that new lung cancer screening guidelines that use a 20-year smoking duration requirement instead of a 20-pack-year requirement would allow more people to qualify for screening.[51] This change also addresses racial disparities in screening eligibility between Black and White individuals. Additionally, smoking duration is easier to calculate and may be a more precise measure of smoking exposure compared to pack-years. Thus we have expanded the NCCN2 criteria to include 20-year smoking history (regardless of if they self-reported 20-pack years). This trial will capitalize on CT eligibility as a “reachable, teachable moment” to provide opt-out enrollment and motivational interviewing along with varenicline treatment in the FDNY Tobacco Cessation program and assess its efficacy. These **combined program elements** can move the traditional tobacco treatment paradigm toward an approach that has been successfully used in the treatment of other chronic diseases.[15, 52]

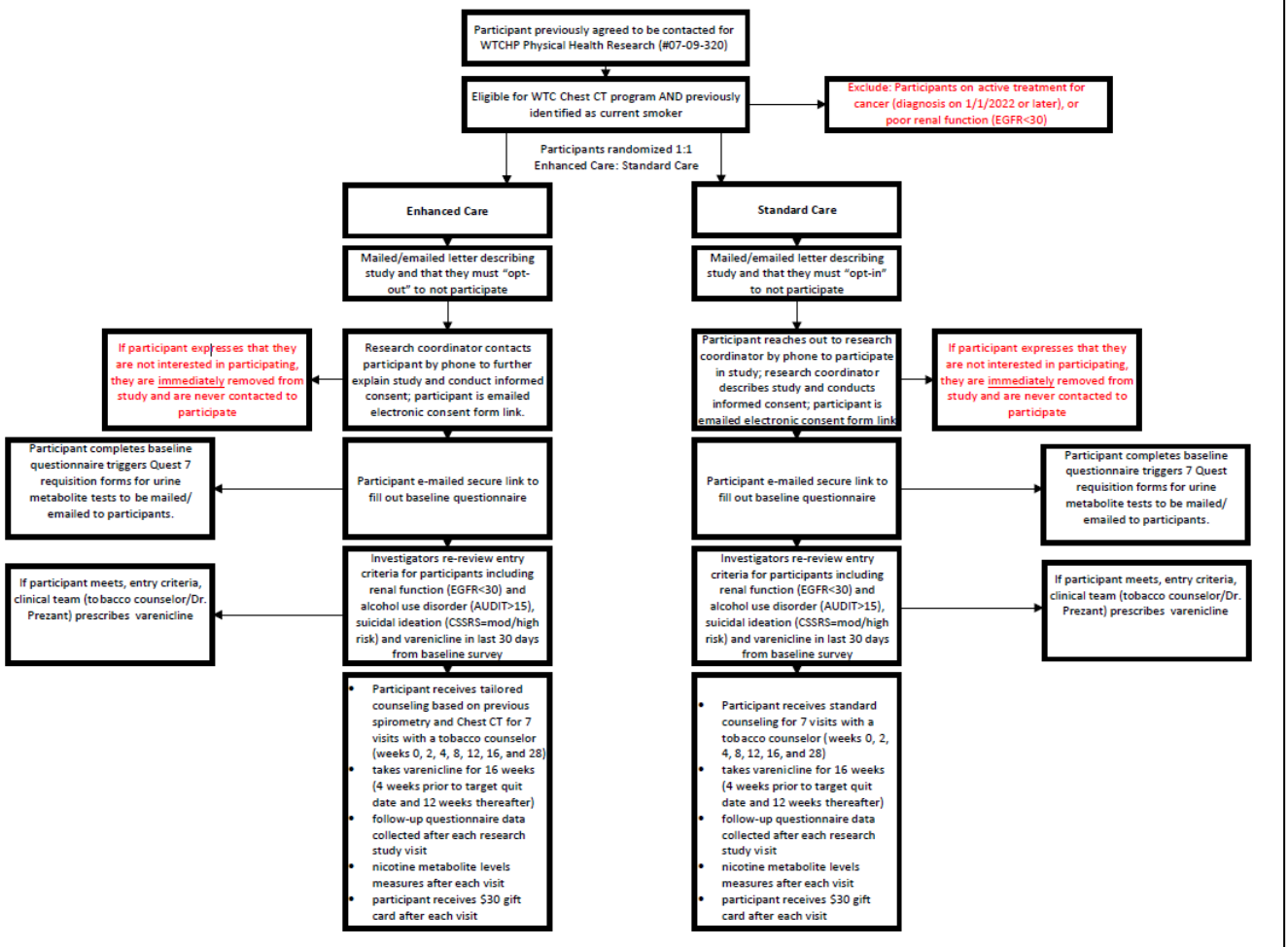
Our overarching objective is to develop and test an effective, scalable intervention with potential to reach high-risk smokers undergoing CT lung cancer screening who have not engaged in or succeeded with traditional tobacco treatment approaches. We will test an **Enhanced Care** intervention specifically designed to address multiple challenges to tobacco treatment engagement and success. **First**, we will test opt-out enrollment in cessation treatment. **Second**, proactive counseling will leverage the "reachable, teachable moment" of CT screening[5, 53] to motivate cessation through individually tailored messaging tied to CT results and lung function spirometry. **Third**, we will offer varenicline pre-loading to all enrollees, regardless of study arm, in which varenicline is initiated 4 weeks prior to target quit date. This approach is associated with decreased pre-quit tobacco-associated reward and double the rate of abstinence compared with standard varenicline treatment.[54] The use of alternative NRTs (i.e., gums, patches, lozenges, nasal sprays) will be tailored to each study participant. These will be provided during counseling sessions, as needed, and will be tracked by the tobacco counselor and the study team.

Table 1. Patient Timeline by treatment arm: **Enhanced Care (E)** and Standard Care (S)	**Enrollment**		**Baseline (Week 0)**		**Week 2**		**Week 4**		**Week 8**		**Week 12**		**Week 16**		**Week 28**	
	S	**E**	**S**	**E**	**S**	**E**	**S**	**E**	**S**	**E**	**S**	**E**	**S**	**E**	**S**	**E**
Enrollment																
320 people randomized to receive recruitment letter (160 per arm)	X	X														
Opt-out enrollment with counseling: Letter describing opt-out enrollment in free WTCHP Tobacco Cessation Program for CT. Proactive outreach by Research Coordinator for cessation		X														

treatment for those who do not opt-out. Study procedures explained and informed consent conducted. Upon outreach, participants who express that they do not wish to be part of the study will not be included and will not be contacted again.									
Opt-in enrollment with counseling: Letter and free WTCHP Tobacco Cessation Program. Patient initiates contact for tobacco cessation treatment	X								
Treatment visits									
Counseling: Brief individual counseling sessions by telehealth delivered by certified tobacco treatment specialist. Focused on tobacco cessation skills training based on Public Health Service guidelines, along with personalized biofeedback addressing CT & spirometry results, varenicline support and lung cancer risk reduction (to leverage motivation of positive CT findings or enhance motivation if negative CT)			X		X		X		X		X		X
Counseling: Brief individual counseling sessions by telehealth delivered by our certified tobacco treatment specialist. Focused on tobacco cessation skills training based on Public Health Service guidelines and varenicline support. CT results NOT discussed.		X		X		X		X		X		X	
Varenicline dosing: Both groups: 0.5mg daily x 3 days, followed by 0.5mg twice daily x 4 days, followed by 1mg twice daily thereafter.		X*	X*	X*	X*	X	X	X	X	X	X	EOT	
Self-administered questionnaires: Both groups - Patients will complete web-based questionnaires		X	X	X	X	X	X	X	X	X	X	X	X
Urine collection													
Both groups - Urine to be collected at Quest Diagnostics		X	X	X	X	X	X	X	X	X	X	X	X
* Varenicline preloading: Varenicline initiated four weeks prior to target quit date (TQD) followed by 12 weeks of varenicline post-TQD, for a total of 16 weeks of treatment, to reduce pre-cessation smoking enjoyment and increase tobacco abstinence													

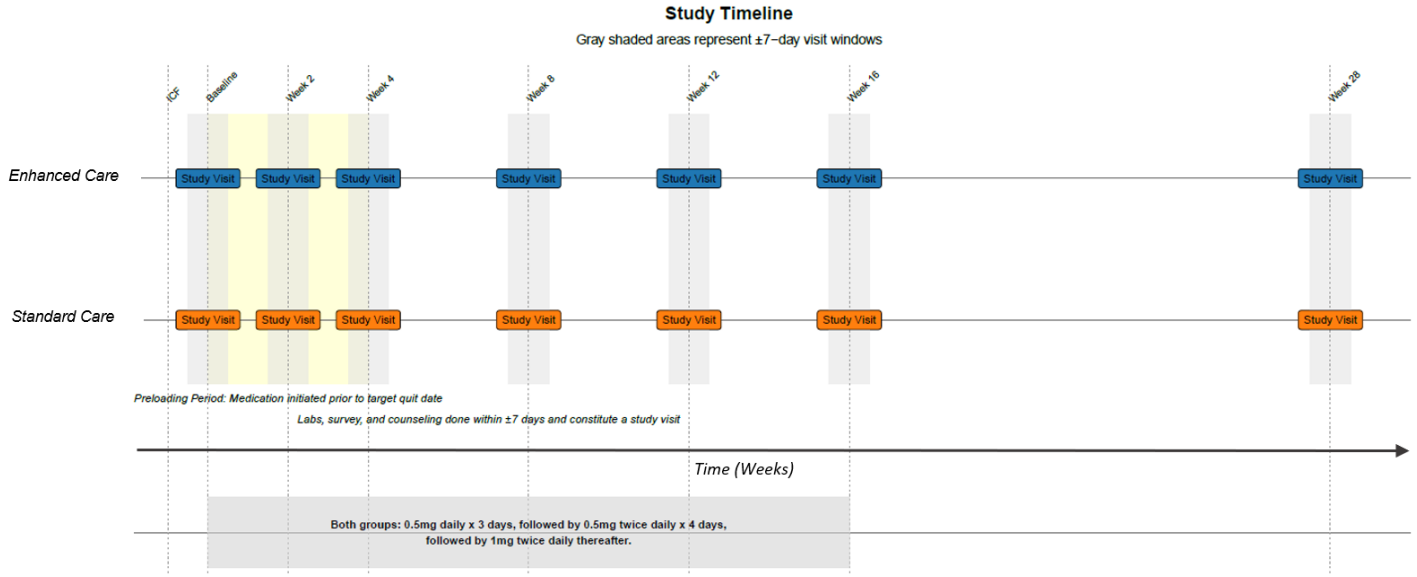
The FDNY WTCHP has succeeded in maintaining the cohort integrity. In the 18-month period pre-pandemic, nearly 12,000 members completed their monitoring visit. While visit rates slowed during the pandemic, they have now nearly returned to our pre-pandemic baseline. **Program** – The need is clear – over one-third of CT eligible FDNY members are heavily tobacco dependent and require a novel approach to cessation; **Expected effects**- we expect to engage more smokers and show better varenicline adherence leading to improved cessation

Figure 1: Flow diagram of participants enrollment



outcomes in the Enhanced Care vs. Standard Care group. **Intervention activities** include opt-out enrollment and outreach by tobacco treatment specialist using CT and spirometry results to motivate smokers toward care. **Evaluation design** – Using intention to treat analyses, we will evaluate enrollment and cessation outcomes in each arm, as per the specific aims. Correlates to be explored: sociodemographic and clinical characteristics as defined by validated screening measures for PTSD, depression, quality of life (SF-12) and lung function (spirometry). Number of prior quit attempts (if available), Fagerström Test for Nicotine Dependence scores and CT results will also be compared. Urine metabolite levels will be obtained at the baseline visit to assess baseline nicotine consumption and for biochemical verification of abstinence at subsequent visits.

Figure 2. Study visit timeline for enrolled participants.



3. Study Population

The FDNY cohort is part of the NIOSH federally funded WTCHP; the cohort consists of firefighters and EMS providers who were employed by NYC and reported being at the WTC site at least one day between 9/11/2001 and 7/25/2002. Demographic and identifying information including gender, race, date of birth, full social security number and full name are securely stored within the FDNY WTCHP data warehouse. Nearly 80% of the WTC-exposed FDNY workforce of 15,706 is currently retired. This retiree cohort consists of 85% firefighters and 15% EMS, with a current median age of 63 for firefighters and 58 for EMS. Most are male: 99% of firefighters and 80% of EMS. Nearly all (97%) were present at the WTC site during the first two weeks after the disaster, with 16% present at the time of the collapse of the buildings. The FDNY WTCHP Clinical Center of Excellence (CCE) provides medical monitoring (including lung function as measured by spirometry and self-administered physical and mental health questionnaires) every 12 to 18 months, treatment, and tobacco cessation at fully equipped health clinics and via telehealth. All tobacco treatment visits for this study will be done via telehealth (audio with video on GoToMeeting, Doximity, and Microsoft Teams platform).

An analyst from the FDNY WTCHP research team will identify all participants who are currently in the FDNY WTCHP CT lung cancer screening program who self-reported smoking, with or without nodules on CT, but without lung cancer. Participation in the trial will be independent of pension decisions, WTC Victim Compensation or WTCHP benefits. To further ensure that participants feel no undue inducement to participate in an employer-based program, we will restrict the sample to the FDNY WTCHP smokers who are currently retired. Participants will be randomized into the enhanced care and standard care treatment arms and recruitment letters from the FDNY WTCHP will be sent to potential participants.

- Inclusion
  - Enrolled in FDNY WTCHP
  - Retired
  - Age ≥ 50 years old

- Self-reported current smoker
- 20 pack-year smoker OR 20-year smoking duration

- Exclusion
  - Reduced renal function: eGFR <30
  - Undergoing active cancer treatment, as defined by diagnosis on 1/1/2022 or later
  - After completing baseline survey:
    - Using varenicline in last 30 days
    - Endorsing suicidal ideations: moderate or high risk on C-SSRS
    - Screened for alcohol use disorder AUDIT>15

4. Participant Recruitment

Participants had to have previously agreed to be contacted for World Trade Center-related physical health research studies as part of WTCHP protocol (#07-09-320) to be eligible for randomization. Randomization will occur prior to recruitment. More information about the informed consent process can be found below in section 5. After the study population is identified and participants are randomized to each group (i.e., enhanced care and standard care groups), the study team will send participants a recruitment letter, either mailed or by email. For participants randomized to the enhanced care group with counseling, the letter will explain that as part of this research study they have been randomly selected to be part of the group with opt-out enrollment. In addition, the letter will describe the clinical services being provided to participants. Proactive outreach will be initiated via phone by the research coordinator, Tyrone Moline, **one month** after the letter is sent out. If participants wish to participate in the study, the research coordinator will explain the study procedures, risks, and benefits to all participants and conduct the informed consent process. Participants will not be included in the intervention if they declare that they do not want to be a part of the study or if the research coordinator is unable to contact them. They will NOT be contacted again.

For participants randomized to the standard care group (opt-in), a separate letter will explain that they have been randomly selected to be a part of the study and must contact the research coordinator in order to be included and receive the clinical services. If participants do not reach out to the research coordinator, they will not be included in the study.

Both the enhanced care and standard care recruitment letters can be found in Appendix 5.

5. Informed Consent

All eligible participants have already **agreed to be contacted for future research** and signed our general FDNY WTC physical consent research consent form under the aforementioned WTCHP Medical Surveillance umbrella protocol (IRB #07-09-320). This allows us to use their data for recruitment purposes *only* (i.e., to confirm smoking history and enrollment in the FDNY Chest CT program). A copy of the IRB-approved consent form from protocol #07-09-320 can be found in Appendix 4. This first stage is used to identify patients for randomization to either the enhanced care or standard care treatment arms. The waiver of consent for recruitment (i.e., the randomization process) has been previously described in other research.[52] Once the cohort who already agreed to be contacted for future research is identified, recruitment materials will be sent out.

Eligible WTCHP participants who consented to future research contact will be randomly assigned to treatment arms. At enrollment (defined as first encounter with our Research Coordinator), potentially eligible participants will complete an electronic informed consent process including discussion of study procedures, risks, and benefits. We will explain that participation in the trial is **voluntary**, limited to current retirees and will not impact pensions, WTC Victim Compensation or WTCHP benefits or care. The informed consent will be administered by phone by the research coordinator. At the same time, participants **will be provided a link to an electronic version of the consent form** developed in collaboration with the FDNY Bureau of Technology Development & Systems, so that they can review the consent while the study is explained to them over the phone. This consent form can be found in Appendix 1. The research coordinator will also have a script that will adequately explain the study's risks and benefits (Appendix 3). Phone scripts for each study arm can be found below. Participants will be able to sign electronically. To facilitate an easier and more inclusive consent, particularly for participants with limited access to or with comfort using digital technology, interested participant unable to access and sign the electronic version of the consent form will be able to provide

their verbal consent, as administered by the research coordinator over the phone. By utilizing verbal phone consent in this special case, we aim to improve participant engagement and retention for this important study seeking tobacco cessation for a high-risk cohort of World Trade Center-exposed responders. Upon providing verbal consent, participants will be sent confirmation with a consent form including the information discussed during their call. A record of the verbal consent will also be documented in the participant's study file, with details of the conversation and confirmation of the consent.

6. Risks and Benefits
Risks to Human Subjects

Human Subjects Involvement, Characteristics, and Design
This proposed study is a randomized control trial of Standard vs. Enhanced Care for Tobacco Cessation. The source population for this study will include retired WTC exposed, smokers (n=320), participating in the FDNY WTCHP CT lung cancer screening program, who previously consented to future research contact as part of the FDNY WTC Health Program (WTCHP). Demographic and exposure data for the proposed study will be obtained from the FDNY WTCHP Data Center. Treatment adherence, cessation outcomes and additional study variables will be obtained via web-based surveys at each study visit.

Study Procedures, Materials, and Potential Risks
The following are the potential risks to subjects posed by participation in the research.

Physical Risks: The risks of the study include: 1) inconvenience of attending telehealth visits, 2) discomfort associated with self-administered surveys 3) risks related to quitting smoking and 4) risks related to varenicline use. These risks will be discussed with potential participants during the informed consent process.

Alternatives, including not participating in the study, and receiving varenicline from medical providers, will be described to participants during the informed consent process.

Telehealth visit privacy: Privacy of video encounters. Participants will be notified that video encounters use a HIPAA protected telehealth application (GoToMeeting, Microsoft Teams and Doximity) and will not be recorded. The Tobacco Treatment Specialist will confirm with participants that they are in a private location prior to initiating study visits.

Telehealth and research study inconveniences: This study requires that participants have telehealth visits with our tobacco treatment specialist at baseline and at 6 more follow-up visits. Study participants will also complete screening, and a web-based questionnaire at all visits. At follow-up visits where the participant reports abstinence, participants will be asked to go to their nearest Quest laboratory so that urine specimens will be analyzed for biochemical verification of abstinence. Study staff will be available to facilitate Quest appointments, if needed. These inconveniences are appreciated for by providing a nominal $30/visit upon the conclusion of each study visit. Additionally, participants will be informed during the informed consent process that they can choose to withdraw at any time without consequence.

Discomfort associated with research interviews: Surveys will assess health status, medication adherence and other sensitive topics. It is unlikely that survey questions would be uncomfortable for participants, because they have experience answering these instruments during their annual monitoring exams. Participants will be told that they may choose to stop the interview or withdraw from the study if they find the questions troubling. Participants also have access to medical and counseling staff at FDNY.

Risks related to quitting smoking: Risks related to quitting smoking include nicotine withdrawal symptoms, including anger, irritability, anxiety, difficulty concentrating, hunger, depression, and insomnia; possible weight gain; and the possibility of going back to smoking. These symptoms are decreased among smokers receiving varenicline treatment for smoking cessation compared to placebo controls.

Risks related to varenicline use: As in Dr. Nahvi's prior trials,[55, 56] at weeks 2, 4, 8, 12 and 16, we will evaluate adverse events in 2 ways: 1) structured questionnaire assessing specific symptoms reported in varenicline in

clinical trials, and 2) open-ended review of treatment-emergent symptoms. Criteria for discontinuation of varenicline will include: adverse events probably or definitely attributable to varenicline. In phase 3 trials of varenicline, side effects from varenicline included nausea (28-33%), insomnia (14-20%), headache (13-14%) and abnormal dreams (10-14%).[52, 57, 58] Nausea was mostly mild to moderate, diminished over time, and resulted in treatment discontinuation in approximately 3% of participants. Vomiting, gas, constipation, indigestion, dyspepsia, dry mouth, and change in appetite were described in 5-15% of people taking varenicline. In Dr. Nahvi's randomized, placebo-controlled trial of varenicline among methadone maintenance treatment patients, we observed significantly higher rates of nausea (51% v 27%) and constipation (40% v 18%) among varenicline-treated subjects compared to controls.[56] In post-marketing. varenicline surveillance, neuropsychological changes, new or worsening seizures, cardiovascular events, increased intoxicating effects of alcohol, accidental injuries (e.g., traffic accidents), angioedema and hypersensitivity reactions, and skin reactions have been reported.

Psychiatric risk potential: Extensive research supports the safety of varenicline, even among persons with mental illness and substance use disorders,[47, 59-66] which prompted the FDA to remove the black box warning about varenicline-associated adverse events in Dec. 2016. Our psychiatric eligibility criteria are adapted from the EAGLES trial, a randomized trial including over 4,000 smokers with psychiatric disorders which showed no significant association between neuropsychiatric adverse effects and varenicline treatment.[47]

Exclusions include: psychiatric instability: exacerbation of their psychiatric condition in prior 6 months; significant change in psychiatric treatment in prior 3 months; current suicidal ideation or past year suicide attempt or psychiatric hospitalization in past year. At baseline screening, individuals endorsing suicidal ideation with plan or intent will be prompted an additional question asking the best method to contact them. An automatic notification will then be sent to a list of designated FDNY Counseling Service Unit clinicians with the individuals contact information provided, prompting immediate outreach.

Seizures have been described among individuals taking varenicline. We will thus exclude individuals with history of seizure and will describe this risk to potential participants during the informed consent process. Cardiovascular risk potential. Varenicline may be associated with a small increase in risk of cardiovascular events.[97,98] In a randomized trial among patients with stable cardiovascular disease, there were slightly higher rates of nonfatal myocardial infarction, coronary revascularization, and peripheral vascular disease among varenicline-treated participants compared to placebo participants; these differences were small and not statistically significant.[97] In addition, a meta-analysis of selected varenicline clinical trials that has been critiqued for trial selection and statistical methods that could bias toward false-positive findings[99-101] described a small absolute increase in the risk of serious adverse cardiovascular events among varenicline group participants.[98] By contrast, a subsequent meta-analysis, including all published randomized trials of varenicline, and focused on the period of varenicline exposure, found no significant increase in serious cardiovascular events associated with varenicline.[99] Similarly, in a meta-analysis of randomized, controlled trials of nicotine replacement therapy, bupropion or varenicline that reported cardiovascular disease outcomes, there was no clear evidence of increased risk of major adverse cardiovascular events with varenicline.[102]

Potential alcohol interaction. In March 2015, the FDA published a Drug Safety Communication describing a potential alcohol interaction with varenicline. Adverse reactions described by individuals who drank alcohol during treatment with varenicline included decreased tolerance to alcohol, including increased drunkenness, unusual or aggressive behavior, or having no memory of things that happened. Human laboratory studies and clinical trials of varenicline among persons with alcohol use disorders have described potentiation of aversive effects of alcohol including dysphoria and nausea; mild to moderate gastrointestinal, neurologic, and sleep-related adverse effects; and few serious adverse events.[103-109] Our own experience has found these side effects to be minimal and none to be serious. Therefore, we will not exclude persons who meet current criteria for alcohol use but will monitor them throughout the study and will discontinue varenicline among subjects who experience alcohol-related unanticipated or serious adverse events. Varenicline is a pregnancy category C drug. There are no adequate studies for determining infant risk when using varenicline during breastfeeding. As this study is limited to retirees, none are pregnant or breast feeding. No clinically meaningful pharmacokinetic drug-drug interactions have been identified between varenicline and digoxin, warfarin, transdermal nicotine, bupropion, cimetidine, or metformin.

ii. Risks of Information Being Stored: Unless otherwise requested by the participant, health information previously collected from the medical records will be kept confidential. Nonetheless, there is always the risk that it may be accessed by individuals not associated with this study. To prevent unauthorized access, the records will be maintained in password-protected files. All data transfers will be made via secure electronic means using encryption. Our Data Center is approved by NIOSH/CDC as meeting all NIST Moderate level security standards.

iii. Psychological Risk. Some may feel stressed by being in a study. Trained FDNY mental health counselors are available to all participants and our clinical coordinator and tobacco treatment specialist have training and experience in mental health counseling. Our FDNY WTCHP Counseling Unit is available for any person experiencing difficulties.

iv. Social, Financial or Legal Risks. We are taking multiple steps to ensure that participants face no social, financial, or legal risks from participation. First, we are restricting enrollment to only those FDNY WTCHP participants who are retired**.** Second, lack of participation in the trial will have no impact on individuals' care through the FDNY World Trade Center Health Program, their access to smoking cessation treatment, their FDNY pensions, or their other benefits. Finally, no individual results will be available to the participants' past employer(s), insurers, pension, or any other benefits plan. As such, there are no current or future social, financial, or legal risks.

v. Risks of Undue Influence. As an employee health service, there is potential risk that FDNY WTCHP participants will feel obligated to participate in this study. We will ensure participant autonomy at all stages of the research protocol. Specifically, we will (1) restrict the sample to include only retirees. (2) We will only reach out to those FDNY WTCHP participants who have previously provided written consent for future research contact. (3) We will seek IRB approval for a waiver of consent for the randomization process. (4) With IRB approval, the recruitment letter will offer those randomized to the Enhanced Care group the opportunity to **opt out** of the proposed tobacco treatment intervention; (5) only those who choose not to opt out will receive proactive outreach by the Tobacco Treatment Specialist. (6) Those who are randomized to the Standard Care group will have to choose to participate and indicate that choice by making the active decision to reach out to the Tobacco Treatment Specialist. (7) At enrollment (defined as first encounter with our Tobacco Treatment Specialist), potentially eligible participants will complete a written informed consent process including discussion of study procedures, risks, and benefits. (8) We will explain that participation in the trial is voluntary, participants can choose not to participate at any time, and that the decision to participate or decline to participate will not impact pensions, WTC Victim Compensation or WTCHP benefits or care.

7. Data analysis

Measures.

Sociodemographic and occupational factors will be assessed at baseline, and include age, gender, race/ethnicity, and service (EMS or Fire service).

Baseline tobacco use and clinical characteristics will include cigarettes smoked per day, pack-years smoked, duration and number of prior quit attempts,[67, 68] menthol use,[69] and, Fagerstrom Test for Nicotine Dependence[70], motivation to quit,[71-73] smoking cessation self-efficacy,[74] and from WTCHP monitoring exam database PTSD (PCL-17),[39-41] depression (CES-D),[42, 43] quality of life (SF-12),[75] spirometry and CT results.

Other covariates will be assessed at each visit, and include use of other cessation medications; cessation motivation;[71-73] cessation self-efficacy,[74] tobacco-associated reward;[76] other tobacco use, including electronic cigarettes,[77, 78] cigars, little cigars, and cigarillos.[79]

Adverse effects. As in Dr. Nahvi's prior trials,[80, 81] at weeks 2, 4, 8, 12 and 16, we will evaluate adverse events in 2 ways: 1) structured questionnaire assessing specific symptoms reported with varenicline in clinical trials, and 2) open-ended review of treatment-emergent symptoms. Criteria for discontinuation of varenicline include adverse events probably or definitely attributable to varenicline.

Enrollment is operationalized as the participation in a first visit with our tobacco treatment specialist.

Retention will be assessed at study end date (week 28 visit).

Adherence. We will use pill counts as the primary measure of varenicline adherence, using established measures. Pill count adherence will be analyzed continuously, defined as # pills taken / # prescribed. Pill count is an objective measure that has been shown to correlate with electronic monitors and varenicline plasma levels. As in prior studies, we will categorize medication adherence rates from 100%-120% as 100% adherence (e.g., subjects mistakenly took extra pills), and rates below zero as 0% (e.g., subjects added pills to the bottle but did

not remove any pills). We will similarly assess adherence with number of counseling visits attended as a continuous variable.

Tobacco abstinence. Tobacco use will be assessed using the timeline follow back method (TLFB), which uses calendar prompts to assess self-reported daily patterns.[82-86] The TLFB method is highly sensitive to whether, and how much, people smoke.[86, 87] We will evaluate the dichotomous outcome of achieving biomarker-verified (e.g., urine cotinine < 20 ng/mL) 7-day point prevalence abstinence (yes or no) at the end of each treatment arm time period (16 weeks) using logistic regression models. Point-prevalence abstinence from cigarettes is defined as no smoking ("not even a puff") during a specific prior interval (usually the last 7 or 30 days). We chose 7-day point prevalence abstinence because it is a standard, biomarker-verifiable measure of tobacco abstinence,[88] is highly correlated with measures of 30-day prolonged abstinence,[88-91] and allows comparison with prior trials.[81, 92, 93] Though point-prevalence abstinence is less predictive of life-long abstinence than prolonged or continuous abstinence,[88, 90, 91] it has several advantages as an outcome measure. First, in self-reported measures, it is less subject to recall bias because it assesses a shorter timeframe. Second, it is less likely to be influenced by missing data such as when a participant is temporarily difficult to schedule for an assessment, but then returns to treatment or follow-up.[94] Third, biochemical verification is more likely to be valid with 7-day point-prevalence abstinence than prolonged or continuous abstinence.[95] Finally, point-prevalence abstinence will more accurately reflect abstinence status for smokers who do not quit immediately, or have one or more early lapses, but then go on to refrain from smoking in the long term.[94]

Self-reported abstinence will be biochemically verified with urine testing. Because nicotine is rapidly metabolized, the primary proximate metabolite of nicotine, cotinine, is the most commonly measured biomarker of nicotine intake.[96, 97] Cotinine is a reliable, highly specific measure of nicotine uptake with a significantly longer half-life than nicotine,[96] and is associated with lung cancer risk, independent of smoking intensity or duration.[98] Urine cotinine levels will be obtained at baseline visit (to assess baseline nicotine consumption) and at all follow up appointments when participants report abstinence. We will use a cotinine level < 20 ng/mL to verify abstinence.[97] As these are telehealth visits, the urine cotinine will be collected at a Quest location near each participant. Participants in the WTCHP are routinely asked to use Quest for laboratory tests, and study staff can assist participants to find a location or schedule an appointment when necessary.

A full description of the proposed survey measures can be found in Appendix 2.

Analytic Plan:

General Approach. We will review data using descriptive summaries to ensure recorded values are within appropriate ranges, and check for outliers and abnormal values. We will then carry out the following analyses, by aim**.**

Aim 1 Analyses. Using intention-to-treat analyses, we will compare **enrollment** (first visit attendance with our tobacco treatment specialist) in FDNY's Tobacco Cessation Program: Standard vs. Enhanced Care arms.

Aim 1. To evaluate sociodemographic and clinical characteristics associated with FDNY Tobacco Cessation Program enrollment, we will conduct analyses using data from FDNY WTCHP databases. In models controlling for treatment group and potential confounders, we will explore standard sociodemographic, occupational (service [EMS or Firefighter]) and clinical characteristics (CT results, spirometry (from most recent WTCHP medical), PTSD, depression, quality of life [SF-12], number of prior quit attempts, Fagerstrom Test for Nicotine Dependence) associated with the dichotomous outcome of Tobacco Treatment Program enrollment (yes/no). We will also review the EMR for previous quit attempts and participation in the *original* FDNY tobacco cessation program to see if this influences participation in the current program.

Power (Aim 1). Using PASS 15,[99] we used a conservative estimate of an enrollment proportion of 25% in Standard Care based on a trial of tobacco cessation, [100] given the lack of a similar study population in prior work. We require ≥45% enrollment in the Enhanced Care arm to have 80% power at α=.05 significance level (2-sided) to detect a significant difference between the arms, an estimate that is well within the reported range for enrollment to health intervention programs;[101, 102] a diabetes behavioral trial reported 38% vs. 13% for opt-out vs. opt-in enrollment,[84] respectively, and an influenza vaccination study in an occupational health setting reported 92% vs. 21%.[85]

Aim 2 Analyses. Among Program enrollees, we will compare **outcomes** (abstinence rate, retention to study end-date and intervention adherence) by Standard vs. Enhanced Care arms.

Aim 2a. To evaluate standard demographic, occupational and clinical characteristics associated with outcomes of tobacco abstinence, retention to study end-date and medication and counseling adherence, we will conduct analyses using data from FDNY WTCHP databases and study visits. We will also construct models

controlling for treatment group and potential confounders to further explore these characteristics and their associations with treatment outcomes as the primary outcome is abstinence rate. To test the relative importance of Standard vs. Enhanced Care as a predictor of tobacco abstinence, we will conduct a multivariable logistic analysis adjust for pre-specified covariates (e.g., PTSD, depression) and variables that differ between groups ($p \leq 0.10$) in univariate analyses. We will compare differences between the Standard Care and Enhanced Care in retention (# and % counseling sessions completed) varenicline adherence from cotinine-verified 7-day point prevalence abstinence at treatment end, and at post-intervention follow up.

Power (Aim 2). Using PASS 15,[99] and assuming a cessation proportion of 14% in the Standard Care arm from a trial of tobacco cessation,[100] we will require ≥47% cessation in the Enhanced Care to have 80% power at $\alpha = .05$ significance level (2-sided) to detect a significant difference between the arms.[101-103]

Exploratory analyses. In exploratory analyses we will evaluate the impact of adherence to varenicline, and to counseling sessions on abstinence and assess the impact of Enhanced Care vs. Standard Care on motivation to quit.

Missing data. While we expect close to 100% outcome ascertainment for the primary outcome of enrollment, we will perform sensitivity analyses to assess the potential impact of informative low enrollment or loss to follow-up. If needed, multiple imputation will be used to assess the potential impact of low enrollment, loss to follow-up or missing covariate data. We will consider missing abstinence data[104] and missing biochemical verification of abstinence as smoking.

Potential Limitations

Intervention. We recognize that we will not be able to separate out the effects of intervention elements (opt-out enrollment, enhanced vs. standard counseling) to estimate the impact of each individually on smoking cessation. We believe that for an CT cohort all components are essential and that separating them out would not represent our "real-world" use. The FDNY Tobacco Cessation Program has seen over 900 members since 2001 and is eager to address the unmet needs of the high-risk smokers in CT screening.

Outcomes for Specific Aim 2. We acknowledge that we may not have the power to reach statistical significance, but we anticipate our findings will support a larger, collaborative study involving all WTCHP Clinical Centers of Excellence and if successful, provide a model that will have major public health impact by offering a blueprint for other programs (WTC and non-WTC; occupational and non-occupational).

Psychological factors mediating engagement and smoking cessation. Multiple psychological factors may mediate the relationship between the proposed intervention and its outcomes, enrollment and tobacco abstinence. Our sample size, though within the scope of an R21 award, will not provide sufficient power to test the mediational effects of psychological factors including motivation to quit,[105] tobacco-associated reward,[45, 46, 106, 107] and tobacco cessation self-efficacy.[105] We will evaluate these factors in exploratory analyses.

8. Data quality control and database management

Collection of data: Demographic and clinical data will be provided by the FDNY WTC Data Center, and these data are obtained from the FDNY's Human Resources Information System (HRIS) with the self-administered questionnaire data incorporated into the FDNY WTC Data Center database and data warehouse. Data from each study visit and lab results will be incorporated into the FDNY Clinical Center of Excellence medical record which then populates the FDNY Data Center database and data warehouse. This study collects data through questionnaires at the beginning and end of each visit, biochemical verification of cotinine and other metabolites, and adherence to varenicline. All other clinical data, such as CT scans and spirometry readings, had already been collected independent of this study and were already stored in the FDNY data warehouse.

Analysis of data: All data will be accessed through SAS (SAS Institute, Cary, North Carolina) either as an Oracle dataset, SAS dataset or Excel data files. All analyses will then be conducted in SAS, Stata, or R.

Storage of data: All data, including the final analytic data files and data dictionaries are stored in the FDNY Data Center Data Warehouse. All data are backed up regularly as part of the FDNY Data Center Disaster Recovery Plan.

Data Security: The FDNY Data Center data warehouse and FDNY Data Center servers are limited with password protected access and individual access is granted to data. Archived data are saved to an encrypted password protected external hard drive stored in a locked cabinet in a locked office. All individuals with access

to the data are both HIPAA and CITI trained for privacy, security, and research conduct. NIOSH/CDC have approved the FDNY Data Center as meeting moderate level NIST security requirements.

Sharing of data: Researchers and others interested in tobacco cessation for heavy, high-risk smokers will certainly find these data useful. The final aggregate analytic data files and data dictionaries will be available to health researchers and others upon request, as stated in the sharing plans for the FDNY Data Center (sharing plan is provided as a Data Sharing Plan). Depending on the request, either limited datasets or de-identified full datasets will be provided when the request is approved by the FDNY WTCHP's Data Center and Clinical Center of Excellence. Approval also requires researchers to obtain IRB approval from the researcher's institution. Thirty days following the completion of the current proposal, the final data files will be available for release to health researchers if requested. All final data files will contain limited information with a unique study identifier but no names, addresses, dates of birth, or death retained in these files. Datasets containing all IRB approved data will then be provided to researchers.

All data created from the described measures will be stored in the FDNY Data Center Data Warehouse on the FDNY DC Server. Access to the FDNY DC Data Warehouse is limited with password protection and individual access restrictions. Archived data will be saved to an encrypted password protected external hard drive stored in a locked cabinet in a locked office. All individuals with access to the data will be both HIPAA and CITI trained for privacy, security, and research conduct. As part of the FDNY DC Server, all data are regularly backed up as part of the FDNY Data Center Disaster Recovery Plan. Data for all Aims, including the final analytic data files and corresponding data dictionaries will remain in the FDNY Data Center Data Warehouse or on the FDNY DC server. Once stored, all data will be accessed through SAS (SAS Institute, Cary, North Carolina) either as an Oracle dataset, SAS dataset or Excel data files. All analyses will then be conducted in SAS, Stata, or R.

The final aggregate analytic data files and data dictionaries will additionally be made available to health researchers and others upon request, as stated in the sharing plans for the FDNY Data Center. Depending on the request, either limited datasets or de-identified full datasets will be provided when the request is approved by the FDNY WTCHP's Data Center and Clinical Center of Excellence. Approval will also require researchers to obtain IRB approval from the researcher's institution. Thirty days following the completion of the current proposal, the final data files will be available for release to health researchers if requested. All final data files will contain limited information with a unique study identifier but no names, addresses, dates of birth, or death retained within these files.

9. Data Safety Monitoring

The Montefiore Einstein Comprehensive Cancer Center Data Safety and Monitoring Committee (DSMC) will be the DSMC of record. The DSMC will perform data and safety monitoring for this study. The primary functions of the MECC DSMC are to provide oversight for all MECC interventional clinical trials, including: (1) review/ensure protocol compliance with dose escalation and expansion in phase I trials, (2) review/ensure protocol compliance for all aspects of phase I, II, and phase III trials, (3) review all reportable internal serious adverse event reports, investigator alerts, action letters, and other reportable safety reports , and (4) review all internal and external audit and monitoring reports, and (5) implement early stopping rule milestones as appropriate for the degree of risk in the particular clinical trial.

An Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the subject's participation in the research. Adverse events related to the study drug will be assessed using CTCAE version 5.

Serious adverse events are defined as those which result in death, are life-threatening (e.g., Suicidal ideation), inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

Protections Against Risk. Throughout the proposed study, Drs. Prezant and Nahvi will be responsible for continual medical oversight of patients. All participants will be given oral and written instructions about management of adverse medication effects and emergency contact information prior to initiating medication

therapy. Adverse events will be assessed at each visit by asking participants about symptoms that emerged or worsened since the start of medication treatment, whether they were thought to be related to study medication. Participants will be asked about treatment-emergent symptoms using both a structured interview and open-ended questions. We will assess for the presence of specific symptoms reported among ≥5 % of participants receiving varenicline in published research, including (but not limited to) nausea, constipation, headache, insomnia, abnormal dreams. We chose the threshold of 5% as the majority of published varenicline studies did not report symptoms that occurred in <5% of participants.

Psychiatric symptoms and suicidal ideation will be assessed at baseline using the Columbia Suicide Severity Rating Scale, a valid, sensitive instrument for assessment of suicidal ideation.

If participants meet diagnostic criteria for any new DSM-V Axis I diagnoses, or report suicidal ideation, it will trigger immediate clinical intervention. We will address the potential alcohol-varenicline interaction with a multi-pronged approach. First, we will warn potential participants of this risk during the informed consent process. As per FDA recommendations, we will advise subjects to reduce the amount of alcohol they consume until they know whether varenicline affects their tolerance of alcohol. Finally, we will explicitly query about alcohol use when documenting treatment-emergent adverse effects and discontinue varenicline for alcohol-related unanticipated or serious adverse events. Patients who experience varenicline-related serious adverse events will be withdrawn from the study.

Criteria for discontinuation of varenicline will include serious adverse events, probably or definitely attributable to varenicline, or pregnancy.

Adverse events will be documented in case report forms and on an adverse event log, followed up to resolution or end of study. Data will be integrated into the in-house FDNY electronic health record. An aggregate table of adverse events will be submitted to the DSMC upon review of the trial not in real time.

All SAEs must be reported within 24 hours of awareness to the sponsor and DSMC except for those SAEs that the protocol or other documents (e.g., Investigator's Brochure, packet insert) identifies as not needing immediate reporting. The initial reports will be followed promptly by detailed, written reports. The initial and follow-up reports will identify subjects by unique code number assigned to the trial subjects rather than by patient identifiers.

Ethics/Human Subjects Safety and Record Management. All analysis will use limited datasets to protect patient confidentiality.

Vulnerable Subjects
Pregnant Women, Fetuses, and Neonates or Children: Fetuses, Neonates, and/or children are not included in this study. Prisoners are not included in this study.

10. References

1. U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General.* 2020.
2. Redfield RR, Hahn SM, Sharpless NE. Redoubling Efforts to Help Americans Quit Smoking — Federal Initiatives to Tackle the Country's Longest-Running Epidemic. *N Engl J Med*. Oct 22 2020;383(17):1606-1609. doi:10.1056/NEJMp2003255
3. Creamer MR, Wang TW, Babb S, et al. Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018. *MMWR Morb Mortal Wkly Rep*. 2019;68(45):1013-1019.
4. Iaccarino JM, Duran C, Slatore CG, Wiener RS, Kathuria H. Combining smoking cessation interventions with LDCT lung cancer screening: A systematic review. *Preventive medicine*. Apr 2019;121:24-32. doi:10.1016/j.ypmed.2019.02.016
5. Slatore CG, Baumann C, Pappas M, Humphrey LL. Smoking behaviors among patients receiving computed tomography for lung cancer screening. Systematic review in support of the U.S. preventive services task force. *Annals of the American Thoracic Society*. May 2014;11(4):619-27. doi:10.1513/AnnalsATS.201312-460OC
6. Borondy Kitts AK, McKee AB, Regis SM, Wald C, Flacke S, McKee BJ. Smoking cessation results in a clinical lung cancer screening program. *Journal of thoracic disease*. Jul 2016;8(Suppl 6):S481-7. doi:10.21037/jtd.2016.03.11
7. Bars MP, Banauch GI, Appel D, et al. "Tobacco Free With FDNY": the New York City Fire Department World Trade Center Tobacco Cessation Study. *Chest*. Apr 2006;129(4):979-87. doi:10.1378/chest.129.4.979
8. Fire Department of the City of New York World Trade Center Health Program Data Center. *Annual Health Surveillance Report*. 2020.
9. Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults - United States, 2019. *MMWR Morb Mortal Wkly Rep*. Nov 20 2020;69(46):1736-1742. doi:10.15585/mmwr.mm6946a4
10. Cadham CJ, Jayasekera JC, Advani SM, et al. Smoking cessation interventions for potential use in the lung cancer screening setting: A systematic review and meta-analysis. *Lung Cancer*. Sep 2019;135:205-216. doi:10.1016/j.lungcan.2019.06.024
11. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *British journal of addiction*. Sep 1991;86(9):1119-27. doi:10.1111/j.1360-0443.1991.tb01879.x
12. Tønnesen P, Pisinger C, Hvidberg S, et al. Effects of smoking cessation and reduction in asthmatics. *Nicotine Tob Res*. Feb 2005;7(1):139-48. doi:10.1080/14622200412331328411
13. Godtfredsen NS, Vestbo J, Osler M, Prescott E. Risk of hospital admission for COPD following smoking cessation and reduction: a Danish population study. *Thorax*. Nov 2002;57(11):967-72. doi:10.1136/thorax.57.11.967
14. Aldrich TK, Vossbrinck M, Zeig-Owens R, et al. Lung Function Trajectories in World Trade Center-Exposed New York City Firefighters Over 13 Years: The Roles of Smoking and Smoking Cessation. *Chest*. 2016/06/01/ 2016;149(6):1419-1427. doi:https://doi.org/10.1016/j.chest.2015.10.067
15. Richter KP, Ellerbeck EF. It's time to change the default for tobacco treatment. *Addiction*. Mar 2015;110(3):381-386. doi:10.1111/add.12734
16. Amato KA, Reid ME, Bansal-Travers M, et al. Patient Cessation Activity after Automatic Referral to a Dedicated Cessation Support Service. *Journal of smoking cessation*. Jun 2018;13(2):78-86. doi:10.1017/jsc.2017.7
17. Nahhas GJ, Wilson D, Talbot V, et al. Feasibility of Implementing a Hospital-Based "Opt-Out" Tobacco-Cessation Service. *Nicotine Tob Res*. Aug 1 2017;19(8):937-943. doi:10.1093/ntr/ntw312
18. Nolan M, Ridgeway JL, Ghosh K, Martin D, Warner DO. Design, implementation, and evaluation of an intervention to improve referral to smoking cessation services in breast cancer patients. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*. Jun 2019;27(6):2153-2158. doi:10.1007/s00520-018-4486-5
19. Taylor KL, Hagerman CJ, Luta G, et al. Preliminary evaluation of a telephone-based smoking cessation intervention in the lung cancer screening setting: A randomized clinical trial. *Lung Cancer*. Jun 2017;108:242-246. doi:10.1016/j.lungcan.2017.01.020
20. Hagerman CJ, Tomko CA, Stanton CA, et al. Incorporating a Smoking Cessation Intervention into Lung Cancer Screening Programs: Preliminary Studies. *J Psychosoc Oncol*. 2015;33(6):703-23. doi:10.1080/07347332.2015.1082171

21. Ashraf H, Saghir Z, Dirksen A, et al. Smoking habits in the randomised Danish Lung Cancer Screening Trial with low-dose CT: final results after a 5-year screening programme. *Thorax*. Jun 2014;69(6):574-9. doi:10.1136/thoraxjnl-2013-203849
22. Brain K, Carter B, Lifford KJ, et al. Impact of low-dose CT screening on smoking cessation among high-risk participants in the UK Lung Cancer Screening Trial. *Thorax*. Oct 2017;72(10):912-918. doi:10.1136/thoraxjnl-2016-209690
23. Pozzi P, Munarini E, Bravi F, et al. A combined smoking cessation intervention within a lung cancer screening trial: a pilot observational study. *Tumori*. May-Jun 2015;101(3):306-11. doi:10.5301/tj.5000282
24. Bovet P, Perret F, Cornuz J, Quilindo J, Paccaud F. Improved smoking cessation in smokers given ultrasound photographs of their own atherosclerotic plaques. *Preventive medicine*. Feb 2002;34(2):215-20. doi:10.1006/pmed.2001.0976
25. Buffels J, Degryse J, Decramer M, Heyrman J. Spirometry and smoking cessation advice in general practice: a randomised clinical trial. *Respir Med*. Nov 2006;100(11):2012-7. doi:10.1016/j.rmed.2006.02.014
26. Deane K, Stevermer JJ, Hickner J. Help smokers quit: tell them their "lung age". *J Fam Pract*. Sep 2008;57(9):584-6.
27. Lerman C, Orleans CT, Engstrom PF. Biological markers in smoking cessation treatment. *Semin Oncol*. Aug 1993;20(4):359-67.
28. McBride CM, Halabi S, Bepler G, et al. Maximizing the motivational impact of feedback of lung cancer susceptibility on smokers' desire to quit. *J Health Commun*. Jul-Sep 2000;5(3):229-41. doi:10.1080/10810730050131406
29. Rodondi N, Bovet P, Hayoz D, Cornuz J. The Impact of CAROtid plaque Screening on Smoking (CAROSS) cessation and control of other cardiovascular risk factors: Rationale and design of a randomized controlled trial. *Contemp Clin Trials*. Sep 2008;29(5):767-73. doi:10.1016/j.cct.2008.03.001
30. Westerdahl E, Engman KO, Arne M, Larsson M. Spirometry to increase smoking cessation rate: A systematic review. journal article. *Tobacco Induced Diseases*. 2019;17(April)doi:10.18332/tid/106090
31. Aberle DR, Adams AM, Berg CD, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med*. Aug 4 2011;365(5):395-409. doi:10.1056/NEJMoa1102873
32. Moyer VA. Screening for lung cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of internal medicine*. Mar 4 2014;160(5):330-8. doi:10.7326/m13-2771
33. Tammemägi MC, Katki HA, Hocking WG, et al. Selection criteria for lung-cancer screening. *N Engl J Med*. Feb 21 2013;368(8):728-36. doi:10.1056/NEJMoa1211776
34. Wood DE, Kazerooni EA, Baum SL, et al. Lung Cancer Screening, Version 3.2018, NCCN Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network : JNCCN*. Apr 2018;16(4):412-441. doi:10.6004/jnccn.2018.0020
35. Bach PB, Kattan MW, Thornquist MD, et al. Variations in lung cancer risk among smokers. *Journal of the National Cancer Institute*. Mar 19 2003;95(6):470-8. doi:10.1093/jnci/95.6.470
36. Rojewski AM, Tanner NT, Dai L, et al. Tobacco Dependence Predicts Higher Lung Cancer and Mortality Rates and Lower Rates of Smoking Cessation in the National Lung Screening Trial. *Chest*. Jul 2018;154(1):110-118. doi:10.1016/j.chest.2018.04.016
37. Hedden SL, Woolson RF, Malcolm RJ. Randomization in substance abuse clinical trials. *Substance abuse treatment, prevention, and policy*. Feb 6 2006;1:6. doi:10.1186/1747-597x-1-6
38. Stout RL, Wirtz PW, Carbonari JP, Del Boca FK. Ensuring balanced distribution of prognostic factors in treatment outcome research. *J Stud Alcohol Suppl*. Dec 1994;12:70-5. doi:10.15288/jsas.1994.s12.70
39. Blanchard EB, Jones-Alexander J, Buckley TC, Forneris CA. Psychometric properties of the PTSD Checklist (PCL). *Behaviour research and therapy*. Aug 1996;34(8):669-73. doi:10.1016/0005-7967(96)00033-2
40. Ruggiero KJ, Del Ben K, Scotti JR, Rabalais AE. Psychometric properties of the PTSD Checklist-Civilian Version. *Journal of traumatic stress*. Oct 2003;16(5):495-502. doi:10.1023/a:1025714729117
41. Chiu S, Webber MP, Zeig-Owens R, et al. Performance characteristics of the PTSD Checklist in retired firefighters exposed to the World Trade Center disaster. *Ann Clin Psychiatry*. May 2011;23(2):95-104.
42. Radloff LS. The CES-D Scale:A Self-Report Depression Scale for Research in the General Population. *Applied Psychological Measurement*. 1977;1(3):385-401. doi:10.1177/014662167700100306
43. Chiu S, Webber MP, Zeig-Owens R, et al. Validation of the Center for Epidemiologic Studies Depression Scale in screening for major depressive disorder among retired firefighters exposed to the World Trade Center disaster. *J Affect Disord*. Mar 2010;121(3):212-9. doi:10.1016/j.jad.2009.05.028

44. Posner K, Brown GK, Stanley B, et al. The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *The American journal of psychiatry*. Dec 2011;168(12):1266-77. doi:10.1176/appi.ajp.2011.10111704
45. Gonzales D, Rennard SI, Nides M, et al. Varenicline, an alpha4beta2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Sustained-Release Bupropion and Placebo for Smoking Cessation: A Randomized Controlled Trial. *JAMA*. Jul 5 2006;296(1):47-55. doi:10.1001/jama.296.1.47
46. Jorenby D, Hays JT, Rigotti NA, et al. Efficacy of Varenicline, an alpha4beta2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation: A Randomized Controlled Trial. *JAMA*. Jul 5 2006;296(1):56-63. doi:10.1001/jama.296.1.56
47. Anthenelli RM, Benowitz NL, West R, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial. *Lancet (London, England)*. Jun 18 2016;387(10037):2507-20. doi:10.1016/s0140-6736(16)30272-0
48. Fiore M, Jaen C, Baker T, et al. A clinical practice guideline for treating tobacco use and dependence: 2008 update. A U.S. Public health service report. *American Journal of Preventive Medicine*. 2008;35:158 - 176.
49. Lancaster T, Stead LF. Physician advice for smoking cessation. *Cochrane Database of Systematic Reviews*. Oct 18 2004;(4):CD000165. doi:10.1002/14651858.CD000165.pub2
50. Reid MS, Fallon B, Sonne S, et al. Smoking cessation treatment in community-based substance abuse rehabilitation programs. *Journal of Substance Abuse Treatment*. Jul 2008;35(1):68-77. doi:10.1016/j.jsat.2007.08.010
51. Potter AL, Xu NN, Senthil P, et al. Pack-Year Smoking History: An Inadequate and Biased Measure to Determine Lung Cancer Screening Eligibility. *J Clin Oncol*. Mar 27 2024:JCO2301780. doi:10.1200/JCO.23.01780
52. Faseru B, Ellerbeck EF, Catley D, et al. Changing the default for tobacco-cessation treatment in an inpatient setting: study protocol of a randomized controlled trial. journal article. *Trials*. August 14 2017;18(1):379. doi:10.1186/s13063-017-2119-9
53. McBride CM, Emmons KM, Lipkus IM. Understanding the potential of teachable moments: the case of smoking cessation. *Health Educ Res*. Apr 2003;18(2):156-70. doi:10.1093/her/18.2.156
54. Hajek P, McRobbie HJ, Myers KE, Stapleton J, Dhanji AR. Use of varenicline for 4 weeks before quitting smoking: decrease in ad lib smoking and increase in smoking cessation rates. *Arch Intern Med*. Apr 25 2011;171(8):770-7. doi:10.1001/archinternmed.2011.138
55. Nahvi S, Adams TR, Ning Y, Zhang C, Arnsten JH. Effect of varenicline directly observed therapy versus varenicline self-administered therapy on varenicline adherence and smoking cessation in methadone-maintained smokers: a randomized controlled trial. *Addiction*. Apr 2021;116(4):902-913. doi:10.1111/add.15240
56. Nahvi S, Ning Y, Segal KS, Richter KP, Arnsten JH. Varenicline efficacy and safety among methadone maintained smokers: a randomized placebo-controlled trial. *Addiction*. Sep 2014;109(9):1554-63. doi:10.1111/add.12631
57. Jorenby DE, Hays JT, Rigotti NA, et al. Efficacy of varenicline, an alpha4beta2 nicotinic acetylcholine receptor partial agonist, vs placebo or sustained-release bupropion for smoking cessation: a randomized controlled trial. *JAMA*. Jul 5 2006;296(1):56-63. doi:10.1001/jama.296.1.56
58. Tonstad S, Tonnesen P, Hajek P, et al. Effect of maintenance therapy with varenicline on smoking cessation: a randomized controlled trial. *JAMA*. Jul 5 2006;296(1):64-71. doi:10.1001/jama.296.1.64
59. Anthenelli RM, Morris C, Ramey TS, et al. Effects of varenicline on smoking cessation in adults with stably treated current or past major depression: a randomized trial. *Annals of internal medicine*. Sep 17 2013;159(6):390-400. doi:10.7326/0003-4819-159-6-201309170-00005
60. Evins AE, Cather C, Pratt SA, et al. Maintenance treatment with varenicline for smoking cessation in patients with schizophrenia and bipolar disorder: a randomized clinical trial. *JAMA*. Jan 8 2014;311(2):145-54. doi:10.1001/jama.2013.285113
61. Hughes JR. Varenicline as a Cause of Suicidal Outcomes. *Nicotine Tob Res*. Jan 2016;18(1):2-9. doi:10.1093/ntr/ntu275
62. McClure JB, Swan GE, Jack L, et al. Mood, side-effects and smoking outcomes among persons with and without probable lifetime depression taking varenicline. *J Gen Intern Med*. May 2009;24(5):563-9. doi:10.1007/s11606-009-0926-8

63. Pachas GN, Cather C, Pratt SA, et al. Varenicline for Smoking Cessation in Schizophrenia: Safety and Effectiveness in a 12-Week, Open-Label Trial. *J Dual Diagn*. 2012;8(2):117-125. doi:10.1080/15504263.2012.663675
64. Smith RC, Amiaz R, Si TM, et al. Varenicline Effects on Smoking, Cognition, and Psychiatric Symptoms in Schizophrenia: A Double-Blind Randomized Trial. *PLoS One*. 2016;11(1):e0143490. doi:10.1371/journal.pone.0143490
65. Stapleton JA, Watson L, Spirling LI, et al. Varenicline in the routine treatment of tobacco dependence: a pre-post comparison with nicotine replacement therapy and an evaluation in those with mental illness. *Addiction*. Jan 2008;103(1):146-54. doi:10.1111/j.1360-0443.2007.02083.x
66. Williams JM, Anthenelli RM, Morris CD, et al. A randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of varenicline for smoking cessation in patients with schizophrenia or schizoaffective disorder. *J Clin Psychiatry*. May 2012;73(5):654-60. doi:10.4088/JCP.11m07522
67. Farkas AJ, Pierce JP, Zhu S-H, et al. Addiction versus stages of change models in predicting smoking cessation. *Addiction*. Sep 1996;91(9):1271-1280.
68. de Dios MA, Anderson BJ, Caviness CM, Stein MD. Early Quit Days Among Methadone-Maintained Smokers in a Smoking Cessation Trial. *Nicotine & Tobacco Research*. June 20, 2014 2014;16(11):1463-9. doi:10.1093/ntr/ntu099
69. Smith CJ, Levy I, Sabin CA, Kaya E, Johnson MA, Lipman MCI. Cardiovascular disease risk factors and antiretroviral therapy in an HIV-positive UK population.[erratum appears in HIV Med. 2004 Jul;5(4):314]. *HIV Medicine*. Mar 2004;5(2):88-92. doi:10.1111/j.1468-1293.2004.00191.x
70. Heatherton T, Kozlowski L, Frecker R, Fagerström K. The Fagerström Test of Nicotine Dependence: A revision of the Fagerström tolerance questionnaire. *British journal of addiction*. 1991;86:1119-1127.
71. Curry S, Wagner EH, Grothaus LC. Intrinsic and extrinsic motivation for smoking cessation. *Journal of consulting and clinical psychology*. Jun 1990;58(3):310-6. doi:10.1037//0022-006x.58.3.310
72. Curry SJ, Grothaus L, McBride C. Reasons for quitting: intrinsic and extrinsic motivation for smoking cessation in a population-based sample of smokers. *Addictive behaviors*. Nov-Dec 1997;22(6):727-39. doi:10.1016/s0306-4603(97)00059-2
73. Payne TJ, Chen C-I, Baker CL, Shah SN, Pashos CL, Boulanger L. National Ambulatory Medical Care Survey: Tobacco intervention practices in outpatient clinics. *Psychology of Addictive Behaviors*. Sep 2012;26(3):644-648. doi:10.1037/a0026910
74. Abrams DB, Niaura R, Brown RA, Emmons KM, Goldstein MG, Monti PM. *The Tobacco Dependence Treatment Handbook: A Guide to Best Practices*. Guilford Press; 2003.
75. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. Mar 1996;34(3):220-33. doi:10.1097/00005650-199603000-00003
76. Cappelleri JC, Bushmakin AG, Baker CL, Merikle E, Olufade AO, Gilbert DG. Confirmatory factor analyses and reliability of the modified cigarette evaluation questionnaire. *Addictive behaviors*. May 2007;32(5):912-23. doi:10.1016/j.addbeh.2006.06.028
77. Stein MD, Caviness CM, Grimone K, Audet D, Borges A, Anderson BJ. E-cigarette knowledge, attitudes, and use in opioid dependent smokers. *J Subst Abuse Treat*. May 2014;52:73-7. doi:10.1016/j.jsat.2014.11.002

10.1016/j.jsat.2014.11.002. Epub 2014 Nov 20.
78. Shah PA, Nahvi S, Brisbane M, Blackstock O, Cunningham CO. Interest in Smoking Cessation and Prior Cessation Attempts Among Patients Receiving Office-based Buprenorphine Treatment. presented at: 2014 Society of General Internal Medicine Annual Meeting; April 2014; San Diego, CA.
79. Sterling K, Berg CJ, Thomas AN, Glantz SA, Ahluwalia JS. Factors Associated With Small Cigar Use Among College Students. *American Journal of Health Behavior*. May 2013;37(3):325-333. doi:10.5993/ajhb.37.3.5
80. Nahvi S, Adams TR, Ning Y, Zhang C, Arnsten JH. Effect of varenicline directly observed therapy versus varenicline self-administered therapy on varenicline adherence and smoking cessation in methadone-maintained smokers: a randomized controlled trial. *Addiction*. Aug 28 2020 [epub ahead of print];doi:10.1111/add.15240
81. Nahvi S, Ning Y, Segal K, Richter K, Arnsten J. Varenicline efficacy and safety among methadone maintained smokers: a randomized placebo-controlled trial. *Addiction*. Sep 2014;109(9):1554-1563. doi:10.1111/add.12631

82. Sobell LC, Brown J, Leo GI, Sobell MB. The reliability of the Alcohol Timeline Followback when administered by telephone and by computer. *Drug & Alcohol Dependence*. Sep 1996;42(1):49-54. doi:10.1016/0376-8716(96)01263-x
83. Fals-Stewart W, O'Farrell TJ, Freitas TT, McFarlin SK, Rutigliano P. The timeline followback reports of psychoactive substance use by drug-abusing patients: psychometric properties. *Journal of Consulting & Clinical Psychology*. Feb 2000;68(1):134-44. doi:10.1037//0022-006x.68.1.134
84. DeMarce JM, Burden JL, Lash SJ, Stephens RS, Grambow SC. Convergent validity of the Timeline Followback for persons with comorbid psychiatric disorders engaged in residential substance use treatment. *Addictive behaviors*. 8// 2007;32(8):1582-1592. doi:http://dx.doi.org/10.1016/j.addbeh.2006.11.015
85. Sobell LC, Sobell MB. *Timeline Followback user's guide: A calendar method for assessing alcohol and drug use*. Addiction Research Foundation; 1996.
86. Brigham J, Lessov-Schlaggar CN, Javitz HS, McElroy M, Krasnow R, Swan GE. Reliability of Adult Retrospective Recall of Lifetime Tobacco Use. *Nicotine & Tobacco Research*. February 1, 2008 2008;10(2):287-299. doi:10.1080/14622200701825718
87. Japuntich SJ, Piper ME, Leventhal AM, Bolt DM, Baker TB. The effect of five smoking cessation pharmacotherapies on smoking cessation milestones. *Journal of consulting and clinical psychology*. Feb 2011;79(1):34-42. doi:10.1037/a0022154
88. Hughes JR, Keely JP, Niaura RS, Ossip-Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. *Nicotine Tob Res*. Feb 2003;5(1):13-25.
89. Clark MA, Gorelick JJ, Sicks JD, et al. The Relations Between False Positive and Negative Screens and Smoking Cessation and Relapse in the National Lung Screening Trial: Implications for Public Health. *Nicotine Tob Res*. Jan 2016;18(1):17-24. doi:10.1093/ntr/ntv037
90. Velicer WF, Prochaska JO. A comparison of four self-report smoking cessation outcome measures. *Addictive behaviors*. Jan 2004;29(1):51-60. doi:10.1016/s0306-4603(03)00084-4
91. Velicer WF, Prochaska JO, Rossi JS, Snow MG. Assessing outcome in smoking cessation studies. *Psychological Bulletin*. Jan 1992;111(1):23-41. doi:10.1037/0033-2909.111.1.23
92. Stein MD, Weinstock MC, Herman DS, Anderson BJ, Anthony JL, Niaura R. A smoking cessation intervention for the methadone-maintained. *Addiction*. Apr 2006;101(4):599-607. doi:10.1111/j.1360-0443.2006.01406.x
93. Stein MD, Caviness CM, Kurth ME, Audet D, Olson J, Anderson BJ. Varenicline for smoking cessation among methadone-maintained smokers: A randomized clinical trial. *Drug and Alcohol Dependence*. 2013;133(2):486-493.
94. Hughes JR, Carpenter MJ, Naud S. Do point prevalence and prolonged abstinence measures produce similar results in smoking cessation studies? A systematic review. *Nicotine Tob Res*. Jul 2010;12(7):756-62. doi:10.1093/ntr/ntq078
95. Benowitz NL, Bernert JT, Foulds J, et al. Biochemical Verification of Tobacco Use and Abstinence: 2019 Update. *Nicotine Tob Res*. Oct 1 2019;22(7):1086-1097. doi:10.1093/ntr/ntz132
96. Wang L, Bernert JT, Benowitz NL, et al. Collaborative Method Performance Study of the Measurement of Nicotine, Its Metabolites, and Total Nicotine Equivalents in Human Urine. *Cancer Epidemiology Biomarkers & Prevention*. Sep 2018;27(9):1083-1090. doi:10.1158/1055-9965.epi-17-1127
97. Benowitz NL, Bernert JT, Foulds J, et al. Biochemical Verification of Tobacco Use and Abstinence: 2019 Update. *Nicotine Tob Res*. Oct 1 2020;22(7):1086-1097. doi:10.1093/ntr/ntz132
98. Yuan JM, Butler LM, Stepanov I, Hecht SS. Urinary tobacco smoke-constituent biomarkers for assessing risk of lung cancer. *Cancer research*. Jan 15 2014;74(2):401-11. doi:10.1158/0008-5472.can-13-3178
99. Version 15. NCSS, LLC; 2017. ncss.com/software/pass
100. Hammett PJ, Lando HA, Erickson DJ, et al. Proactive outreach tobacco treatment for socioeconomically disadvantaged smokers with serious mental illness. *J Behav Med*. Jun 2020;43(3):493-502. doi:10.1007/s10865-019-00083-8
101. Aysola J, Tahirovic E, Troxel AB, et al. A Randomized Controlled Trial of Opt-In Versus Opt-Out Enrollment Into a Diabetes Behavioral Intervention. *Am J Health Promot*. Mar 2018;32(3):745-752. doi:10.1177/0890117116671673
102. Chapman GB, Li M, Colby H, Yoon H. Opting in vs opting out of influenza vaccination. *JAMA*. Jul 7 2010;304(1):43-4. doi:10.1001/jama.2010.892
103. Scholz JR, Abe TO, Gaya PV, et al. Cue restricted smoking increases quit rates with varenicline. *Tob Prev Cessat*. 2021;7:33. doi:10.18332/tpc/133570

104. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction*. Mar 2005;100(3):299-303. doi:10.1111/j.1360-0443.2004.00995.x
105. Hughes JR, Rennard SI, Fingar JR, Talbot SK, Callas PW, Fagerstrom KO. Efficacy of varenicline to prompt quit attempts in smokers not currently trying to quit: a randomized placebo-controlled trial. *Nicotine Tob Res*. Oct 2011;13(10):955-64. doi:10.1093/ntr/ntr103
106. Cinciripini PM, Robinson JD, Karam-Hage M, et al. Effects of varenicline and bupropion sustained-release use plus intensive smoking cessation counseling on prolonged abstinence from smoking and on depression, negative affect, and other symptoms of nicotine withdrawal. *JAMA psychiatry*. May 2013;70(5):522-33. doi:10.1001/jamapsychiatry.2013.678
107. Lu W, Chappell K, Walters JA, et al. The effect of varenicline and nicotine patch on smoking rate and satisfaction with smoking: an examination of the mechanism of action of two pre-quit pharmacotherapies. *Psychopharmacology (Berl)*. Mar 24 2017;234(13):1969-1976. doi:10.1007/s00213-017-4604-y

Appendix contents

1. Informed Consent (current study)

2. Questionnaire data (including adverse event checklist)

2A. Baseline

2B. Follow-up

3. Informed consent phone script (current study)

4. General FDNY WTCHP Physical Health Consent (previously approved by AECOM IRB #07-09-320)

5. Recruitment materials

5A. Enhanced care: Opt-out letter

5B. Standard Care: Opt-in letter

1. Informed Consent (current study)

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.
- 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. Participant selection was conducted **prior** to informed consent for the present study. However, as noted above, participation is voluntary.
- 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.
- You were randomized and recruited for this study based on previous responses to questionnaires in which you indicated that you smoked.

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.
    - Varenicline will be prescribed by Dr. David Prezant, WTCHP director and co-Investigator on this study. Drs. Goldfarb and Prezant will be tracking varenicline prescriptions.
    - 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.
- Other choices.
- 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.

By signing this release form, I give my authorization for the uses and disclosures of my protected health information as described above.

When you sign this form, 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

2. Questionnaire data (including adverse event checklist)

2A. Baseline

Lung Cancer Prevention through Tobacco Cessation at FDNY – Survey

Eligibility preface:

Thank you for participating in the FDNY tobacco cessation program. This questionnaire was created to help us better understand the effects of your health and tobacco use. Additionally, before we begin, we must ensure that it is safe for you to participate, including whether it is safe for you to take the medication varenicline. Findings from this study may provide a model that will have major public health impact by offering a blueprint for other programs serving high-risk smokers. Most critically, we believe that findings from this study may help you and other first responders who were exposed to the World Trade Center disaster.

Enrolment Eligibility Questions

Q No: 1

Category: Eligibility

Question**: Have you ever in the past 30 days taken the medicine Varenicline (aka. Chantix)?**

Choice1 **=> ###:** Yes **=> 2**

Choice2 **=> ###**: No **=> 2**

Multiple Choice: No

Current Tobacco Use

Q No: 2

Category: Current Tobacco Use

Question: **Have you smoked ANY cigarettes, even a puff, in the last 4 weeks?**

Choice 1 => #### => Yes => 3

Choice 2 => #### => No => 3

Multiple choice: No

Q No: 3

Category: Current Tobacco Use

Question: **On the average, how many cigarettes do you now smoke a day?**

Cigarettes per day: 0-140 range => 4

Single number

Q No: 4

Category: Current Tobacco Use

Past-month Timeline Follow Back (TLFB) Smoking Assessment (baseline and each visit):

Example: Programmed to previous 30 day

Using the following calendar, to the best of your ability, please try to indicate on which days in the past month you have smoked cigarettes, if any. On only the days when you smoked cigarettes, please indicate how many you smoked. Even one or two puffs counts as a smoked cigarette. We know this may be hard to remember exactly, but please try to complete it as accurately as you can to the best of your ability. If you did not smoke, please put a 0 for the first available day on the calendar.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

Q No: 5

Category: Current Tobacco Use

Question: **Is your usual cigarette brand menthol or non-menthol?**

Choice 1 => #### => Menthol => 6

Choice 2 => #### => Non-menthol => 6

Choice 3 => #### => No usual Brand => 6

Choice 3 => #### => Don't know/refuse to answer => 6

Prev Ques to this grid:

Multiple choice: No

Cigarette alternatives

Q No: 6

Category: Cigarette alternatives

Question: **In the past 30 days, have you used an e-cigarette (even one or two puffs)?**

Choice 1 => #### =>Yes => 7

Choice 2 => #### => No => 8

Choice 3 => #### => Don't know/refuse to answer => 8

Prev Ques to this grid:

Multiple choice: No

Q No: 7

Category: Cigarette alternatives

Question: **Do you now use e-cigarettes (even one or two puffs)?**

Choice 1 => #### => Every day => 8

Choice 2 => #### => Some days=> 8

Choice 3 => #### => Not at all => 8

Choice 4 => #### Don't know/refuse to answer => 8

Prev Ques to this grid:

Multiple choice: No

Q No: 8

Category: Cigarette alternatives

Question: **In the past 30 days, have you smoked cigars, cigarillos or little cigars (even one or two puffs)?**

Choice 1 => #### =>Yes => 9

Choice 2 => #### => No => 10

Choice 3 => #### => Don't know/refuse to answer => 10

Multiple choice: No

Q No: 9

Category: Cigarette alternatives

Question: **Do you now smoke cigars, cigarillos, or little cigars (even one or two puffs)?**

Choice 1 => #### => Every day => 10

Choice 2 => #### => Some days=> 10

Choice 3 => #### => Not at all => 10

Choice 4 => #### Don't know/refuse to answer => 10

Multiple choice: No

Smoking History (baseline only)

Q No: 10

Category: Smoking History

Question**: How old were you when you FIRST started to smoke regularly?**

Choice 1 => #### => *Select number 6 - 80* => 11

Choice 2 => #### => Don’t know/refuse to answer => 11

Q No: 11

Category: Smoking History

Question**: Thinking back over the years you have smoked regularly, about how many cigarettes did you usually smoke each day?**

Choice 1 => #### => *Select number 1 - 80* => 12

Choice 2 => #### => Don’t know/refuse to answer => 12

Multiple choice: No

Fagerstrom Test for Nicotine Dependence (baseline only)

Q No: 12

Category: FTND

Question: **How soon after you wake up do you smoke your first cigarette?**

Choice 1 => #### => Within 5 minutes => 13

Choice 2 => #### => 6 to 30 minutes => 13

Choice 3 =>#### => 31 to 60 minutes => 13

Choice 4 => #### => After 60 minutes => 13

Multiple choice: No

Q No: 13

Category: FTND

Question: **Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, at the movies)?**

Choice 1 => #### => Yes=> 14

Choice 2 => #### => No => 14

Multiple choice: No

Q No: 14

Category: FTND

Question: **Which cigarette would you hate most to give up?**

Choice 1 => #### => The first one in the morning => 15

Choice 2 => #### => Any other => 15

Multiple choice: No

Q No: 15

Category: FTND

Question: **How many cigarettes do you smoke per day?**

Choice 1 => #### => 10 or less => 16

Choice 2 => #### => 11 – 20 => 16

Choice 3 =>#### => 21 – 30 => 16

Choice 4 => #### => 31 or more => 16

Multiple choice: No

Q No: 16

Category: FTND

Question: Do you smoke more frequently during the first hours after waking than during the rest of the day?

Choice 1 => #### => Yes => 17

Choice 2 => #### => No => 17

Multiple choice: No

Q No: 17

Category: FTND

Question: **Do you smoke when you are so ill that you are in bed most of the day?**

Choice 1 => #### => Yes => 18

Choice 2 => #### => No => 18

Multiple choice: No

Prior Quit Attempts (baseline)

Q No: 18

Category: Prior Quit Attempts

Question: **Have you EVER stopped smoking for one day or longer BECAUSE YOU WERE TRYING TO QUIT SMOKING?**

Choice 1 => #### => Yes => 19

Choice 2 => #### => No => 22

Choice 3 => #### => Don't know/refuse to answer => 22

Multiple choice: No

Q No: 19

Category: Prior Quit Attempts

Question: **During the PAST 12 MONTHS, have you stopped smoking for one day or LONGER BECAUSE YOU WERE TRYING TO QUIT SMOKING?**

Choice 1 => #### => Yes => 20

Choice 2 => #### => No => 20

Choice 3 => #### => Don't know/refuse to answer => 20

Multiple choice: No

Q No: 20

Category: Prior Quit Attempts

Question: Of all the times you have tried to quit smoking, how long was the longest period that you stayed off cigarettes? **PLEASE ENTER IN YEARS**. If your response is less than 1 year, please approximate to the best of your ability with a decimal (e.g., 6 months = 0.5).

Choice 1 => #### => ENTER NUMBER => 21

Q No: 21

Category: Prior Quit Attempts

Question: How long did you actually stay off cigarettes the LAST TIME you stopped smoking? **PLEASE ENTER IN YEARS**. If your response is less than 1 year, please approximate to the best of your ability with a decimal (e.g., 6 months = 0.5).

Choice 1 => #### => ENTER NUMBER => 21

Cessation Self-Efficacy (baseline only)

Q No: 22

Category: Cessation Self-Efficacy

Question: **Using a scale of 1 to 10, where 1 is not at all confident and 10 is extremely confident, how confident are you that you could quit smoking completely?**

Select number* range: 1- 10 => 23

Cessation Motivation (baseline only)

Q No: 23

Category: Cessation Motivation

Question: **Using a scale of 1 to 10, where 1 is not at all important and 10 is extremely important, how important is it to you that you quit smoking completely?**

Choice: Select number* range: 1- 10 => 24

Modified Cigarette Evaluation Questionnaire (mCEQ) (baseline and follow-up)

Please mark the answer choice that represents how smoking made you feel.

Q No: 24

Category: Tobacco Associated Reward

Question: **Was smoking satisfying?**

Choice 1 => #### => Not at all => 25

Choice2 => #### => Very little => 25

Choice 3 => #### => A little => 25

Choice 4 => #### => Moderately => 25

Choice 5 => #### => A lot => 25

Choice 6 => #### => Quite a lot => 25

Choice 7 => #### => Extremely => 25

Prev Ques to this grid: 23

Multiple Choice: No

Q No: 25

Category: Tobacco Associated Reward

Question: **Did cigarettes taste good?**

Choice 1 => #### => Not at all => 26

Choice2 => #### => Very little => 26

Choice 3 => #### => A little => 26

Choice 4 => #### => Moderately => 26

Choice 5 => #### => A lot => 26

Choice 6 => #### => Quite a lot => 26

Choice 7 => #### => Extremely => 26

Prev Ques to this grid: 23

Multiple Choice: No

Q No: 26

Category: Tobacco Associated Reward

Question: **Did you enjoy the cigarette sensations in your throat and chest?**

Choice 1 => #### => Not at all => 27

Choice2 => #### => Very little => 27

Choice 3 => #### => A little => 27

Choice 4 => #### => Moderately => 27

Choice 5 => #### => A lot => 27

Choice 6 => #### => Quite a lot => 27

Choice 7 => #### => Extremely => 27

Prev Ques to this grid: 23

Multiple Choice: No

Q No: 27

Category: Tobacco Associated Reward

Question: **Did smoking calm you down?**

Choice 1 => #### => Not at all => 28

Choice2 => #### => Very little => 28

Choice 3 => #### => A little => 28

Choice 4 => #### => Moderately => 28

Choice 5 => #### => A lot => 28

Choice 6 => #### => Quite a lot => 28

Choice 7 => #### => Extremely => 28

Prev Ques to this grid: 23

Multiple Choice: No

Q No: 28

Category: Tobacco Associated Reward

Question: **Did smoking make you feel more awake?**

Choice 1 => #### => Not at all => 29

Choice2 => #### => Very little => 29

Choice 3 => #### => A little => 29

Choice 4 => #### => Moderately => 29

Choice 5 => #### => A lot => 29

Choice 6 => #### => Quite a lot => 29

Choice 7 => #### => Extremely => 29

Prev Ques to this grid: 23

Multiple Choice: No

Q No: 29

Category: Tobacco Associated Reward

Question: **Did smoking make you feel less irritable?**

Choice 1 => #### => Not at all => 30

Choice2 => #### => Very little => 30

Choice 3 => #### => A little => 30

Choice 4 => #### => Moderately => 30

Choice 5 => #### => A lot => 30

Choice 6 => #### => Quite a lot => 30

Choice 7 => #### => Extremely => 30

Prev Ques to this grid: 28

Multiple Choice: No

Q No: 30

Category: Tobacco Associated Reward

Question: **Did smoking help you concentrate?**

Choice 1 => #### => Not at all => 31

Choice2 => #### => Very little => 31

Choice 3 => #### => A little => 31

Choice 4 => #### => Moderately => 31

Choice 5 => #### => A lot => 31

Choice 6 => #### => Quite a lot => 31

Choice 7 => #### => Extremely => 31

Prev Ques to this grid: 28

Multiple Choice: No

Q No: 31

Category: Tobacco Associated Reward

Question: **Did smoking reduce your hunger for food?**

Choice 1 => #### => Not at all => 32

Choice2 => #### => Very little => 32

Choice 3 => #### => A little => 32

Choice 4 => #### => Moderately => 32

Choice 5 => #### => A lot => 32

Choice 6 => #### => Quite a lot => 32

Choice 7 => #### => Extremely => 32

Prev Ques to this grid: 28

Multiple Choice: No

Q No: 32

Category: Tobacco Associated Reward

Question: **Did smoking make you dizzy?**

Choice 1 => #### => Not at all => 33

Choice2 => #### => Very little => 33

Choice 3 => #### => A little => 33

Choice 4 => #### => Moderately => 33

Choice 5 => #### => A lot => 33

Choice 6 => #### => Quite a lot => 33

Choice 7 => #### => Extremely => 33

Prev Ques to this grid: 28

Multiple Choice: No

Q No: 33

Category: Tobacco Associated Reward

Question: **Did smoking make you nauseous?**

Choice 1 => #### => Not at all => 34

Choice2 => #### => Very little => 34

Choice 3 => #### => A little => 34

Choice 4 => #### => Moderately => 34

Choice 5 => #### => A lot => 34

Choice 6 => #### => Quite a lot => 34

Choice 7 => #### => Extremely => 34

Prev Ques to this grid: 28

Multiple Choice: No

Q No: 34

Category: Tobacco Associated Reward

Question: **Did smoking immediately relieve your craving for a cigarette?**

Choice 1 => #### => Not at all => 35

Choice2 => #### => Very little => 35

Choice 3 => #### => A little => 35

Choice 4 => #### => Moderately => 35

Choice 5 => #### => A lot => 35

Choice 6 => #### => Quite a lot => 35

Choice 7 => #### => Extremely => 35

Prev Ques to this grid: 33

Multiple Choice: No

Q No: 35

Category: Tobacco Associated Reward

Question: **Did you enjoy smoking?**

Choice 1 => #### => Not at all => 36

Choice2 => #### => Very little => 36

Choice 3 => #### => A little => 36

Choice 4 => #### => Moderately => 36

Choice 5 => #### => A lot => 36

Choice 6 => #### => Quite a lot => 36

Choice 7 => #### => Extremely => 36

Prev Ques to this grid: 33

Multiple Choice: No

Reasons for Quitting

Q No: 36

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because I am afraid that I will get very sick if I don't quit smoking.**

Choice 1 => #### => Not at all true => 37

Choice 2 => #### => A little true => 37

Choice 3 => #### => Moderately true => 37

Choice 4 => #### => Quite true => 37

Choice 5 => #### => Extremely true => 37

Choice 6 => #### => Refuse to answer => 37

Prev Ques to this grid: 35

Multiple choice: No

Q No: 37

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? To prove that I can quit if I really want to.**

Choice 1 => #### => Not at all true => 38

Choice 2 => #### => A little true => 38

Choice 3 => #### => Moderately true => 38

Choice 4 => #### => Quite true => 38

Choice 5 => #### => Extremely true => 38

Choice 6 => #### => Refuse to answer => 38

Prev Ques to this grid: 35

Multiple choice: No

Q No: 38

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because I feel like smoking is hurting my health.**

Choice 1 => #### => Not at all true => 39

Choice 2 => #### => A little true => 39

Choice 3 => #### => Moderately true => 39

Choice 4 => #### => Quite true => 39

Choice 5 => #### => Extremely true => 39

Choice 6 => #### => Refuse to answer => 39

Prev Ques to this grid: 35

Multiple choice: No

Q No: 39

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? To feel in control of my life.**

Choice 1 => #### => Not at all true => 40

Choice 2 => #### => A little true => 40

Choice 3 => #### => Moderately true => 40

Choice 4 => #### => Quite true => 40

Choice 5 => #### => Extremely true => 40

Choice 6 => #### => Refuse to answer => 40

Prev Ques to this grid: 35

Multiple choice: No

Q No: 40

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? To show that I can do other things that are important to me.**

Choice 1 => #### => Not at all true => 41

Choice 2 => #### => A little true => 41

Choice 3 => #### => Moderately true => 41

Choice 4 => #### => Quite true => 41

Choice 5 => #### => Extremely true => 41

Choice 6 => #### => Refuse to answer=> 41

Prev Ques to this grid: 35

Multiple choice: No

Q No: 41

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because I am afraid that smoking will shorten my life.**

Choice 1 => #### => Not at all true => 42

Choice 2 => #### => A little true => 42

Choice 3 => #### => Moderately true => 42

Choice 4 => #### => Quite true => 42

Choice 5 => #### => Extremely true => 42

Choice 6 => #### => Refuse to answer=> 42

Prev Ques to this grid: 40

Multiple choice: No

Q No: 42

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? So other people will stop nagging me.**

Choice 1 => #### => Not at all true => 43

Choice 2 => #### => A little true => 43

Choice 3 => #### => Moderately true => 43

Choice 4 => #### => Quite true => 43

Choice 5 => #### => Extremely true => 43

Choice 6 => #### => Refuse to answer => 43

Prev Ques to this grid: 40

Multiple choice: No

Q No: 43

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? To save money that I spend on cigarettes.**

Choice 1 => #### => Not at all true => 44

Choice 2 => #### => A little true => 44

Choice 3 => #### => Moderately true => 44

Choice 4 => #### => Quite true => 44

Choice 5 => #### => Extremely true => 44

Choice 6 => #### => Refuse to answer => 44

Prev Ques to this grid: 40

Multiple choice: No

Q No: 44

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because someone is making me quit.**

Choice 1 => #### => Not at all true => 45

Choice 2 => #### => A little true => 45

Choice 3 => #### => Moderately true => 45

Choice 4 => #### => Quite true => 45

Choice 5 => #### => Extremely true => 45

Choice 6 => #### => Refuse to answer => 45

Prev Ques to this grid: 40

Multiple choice: No

Q No: 45

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? So I won't burn holes in clothes or furniture.**

Choice 1 => #### => Not at all true => 46

Choice 2 => #### => A little true => 46

Choice 3 => #### => Moderately true => 46

Choice 4 => #### => Quite true => 46

Choice 5 => #### => Extremely true => 46

Choice 6 => #### => Refuse to answer=> 46

Prev Ques to this grid: 40

Multiple choice: No

Q No: 46

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because people I am close to will be mad at me if I don't quit.**

Choice 1 => #### => Not at all true => 47

Choice 2 => #### => A little true => 47

Choice 3 => #### => Moderately true => 47

Choice 4 => #### => Quite true => 47

Choice 5 => #### => Extremely true => 47

Choice 6 => #### => Refuse to answer=> 47

Prev Ques to this grid: 45

Multiple choice: No

Q No: 47

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? So my house or car won't smell.**

Choice 1 => #### => Not at all true => 48

Choice 2 => #### => A little true => 48

Choice 3 => #### => Moderately true => 48

Choice 4 => #### => Quite true => 48

Choice 5 => #### => Extremely true => 48

Choice 6 => #### => Refuse to answer=> 48

Prev Ques to this grid: 45

Multiple choice: No

Exposure

Q No: 48

Category: Exposure

Question: The next series of questions is about problems and complaints that people may experience in relation to WTC and other traumatic life experiences. Indicate below what traumatic experiences you have had that were TERRIBLE, FRIGHTENING or HORRIBLE for you

Choice1 => **915**: Never had a traumatic experience => 50

Choice2 => **1538**: WTC => 49

Choice3 => **2529**: Non-WTC physical assault (shot, stabbed, mugged) => 49

Choice4 => **2530**: Non-WTC exposure to dangerous materials (Bio, Chem, Radiation) => 49

Choice5 => **2531**: Non-WTC witnessed or personally experienced severe accident, injury, or illness => 49

Choice6 => **2532**: Non-WTC unexpected death of relative or close friend or co-worker => 49

Choice7 => **3547**: Non-WTC discovered dead body or body parts => 49

Choice8 => **3596**: COVID-19 pandemic => 49

Choice9 => **3625**: Other disaster or trauma (Not WTC or COVID-19) => 49

Answer choice: Multiple, 1st answer choice negates the rest

Q No.: 49

Category: Exposure

Question: Which traumatic experience was emotionally the most terrible, frightening, or horrible for you?

Choice1 => **1538**: WTC => 50

Choice2 => **2529**: Non-WTC physical assault (shot, stabbed, mugged) => 50

Choice3 => **2530**: Non-WTC exposure to dangerous materials (Bio, Chem, Radiation) => 50

Choice4 => **2531**: Non-WTC witnessed or personally experienced severe accident, injury, or illness => 50

Choice5 => **2532**: Non-WTC unexpected death of relative or close friend or co-worker => 50

Choice6 => **3547** : Non-WTC discovered dead body or body parts => 50

Choice7 => **3596**: COVID-19 pandemic => 50

Choice 8 => **3625**: Other disaster or trauma (Not WTC or COVID-19) => 50

Multiple Choice: No

PTSD

Q No.: 50

Category: PTSD

Question [When answering the following questions please think about your most stressful experience. You have indicated that as ANSWER FROM Q No: 49]. **IN THE PAST MONTH, have you been bothered by repeated, disturbing memories, thoughts, or images of the stressful experience?**

Choice1 => **571**: Not at all => **51 (1)**

Choice2 => **1401**: A little bit => **51 (2)**

Choice3 => **1402**: Moderately => **51 (3)**

Choice4 => **1403**: Quite a bit => **51 (4)**

Choice5 => **1404**: Extremely => **51 (5)**

Prev Ques to this grid: 49

Multiple Choice: No

Q No : 51

Category: PTSD

Question: **IN THE PAST MONTH, have you been bothered by repeated, disturbing dreams of the stressful experience?**

Choice1 **=> 571**: Not at all **=> 52 (1)**

Choice2 **=> 1401**: A little bit **=> 52 (2)**

Choice3 **=> 1402**: Moderately **=> 52 (3)**

Choice4 **=> 1403**: Quite a bit **=> 52 (4)**

Choice5 **=> 1404**: Extremely **=> 52 (5)**

Prev Ques to this grid: 49

Multiple Choice: No

Q No : 52

Category: PTSD

Question: **IN THE PAST MONTH, have you been suddenly acting or feeling as if the stressful experience was happening again (as if you were reliving it)?**

Choice1 **=> 571**: Not at all **=> 53 (1)**

Choice2 **=> 1401**: A little bit **=> 53 (2)**

Choice3 **=> 1402**: Moderately **=> 53 (3)**

Choice4 **=> 1403**: Quite a bit **=> 53 (4)**

Choice5 **=> 1404**: Extremely **=> 53 (5)**

Prev Ques to this grid: 49

Multiple Choice: No

Q No: 53

Category: PTSD

Question: **IN THE PAST MONTH, do you feel very upset when something reminded you of the stressful experience?**

Choice1 **=> 571**: Not at all **=> 54 (1)**

Choice2 **=> 1401**: A little bit **=> 54 (2)**

Choice3 **=> 1402**: Moderately **=> 54 (3)**

Choice4 **=> 1403**: Quite a bit **=> 54 (4)**

Choice5 **=> 1404**: Extremely **=> 54 (5)**

Prev Ques to this grid: 49

Multiple Choice: No

Q No: 54

Category: PTSD

Question: **IN THE PAST MONTH, have you been having physical reactions (e.g., heart pounding, trouble breathing, sweating) when something reminded you of the stressful experience?**

Choice1 **=> 571**: Not at all **=> 55 (1)**

Choice2 **=> 1401**: A little bit **=> 55 (2)**

Choice3 **=> 1402**: Moderately **=> 55 (3)**

Choice4 **=> 1403**: Quite a bit **=> 55 (4)**

Choice5 **=> 1404**: Extremely **=> 55 (5)**

Prev Ques to this grid: 53

Multiple Choice: No

Q No: 55

Category: PTSD

Question: **IN THE PAST MONTH, have you been avoiding thinking about or talking about the stressful experience or avoiding having feelings related to the incident?**

Choice1 **=> 571**: Not at all **=> 56 (1)**

Choice2 **=> 1401**: A little bit **=> 56 (2)**

Choice3 **=> 1402**: Moderately **=> 56 (3)**

Choice4 **=> 1403**: Quite a bit **=> 56 (4)**

Choice5 **=> 1404**: Extremely **=> 56 (5)**

Prev Ques to this grid: 53

Multiple Choice: No

Q No: 56

Category: PTSD

Question: **IN THE PAST MONTH, have you been avoiding activities or situations because they reminded you of the stressful experience?**

Choice1 **=> 571**: Not at all **=> 57 (1)**

Choice2 **=> 1401**: A little bit **=> 57 (2)**

Choice3 **=> 1402**: Moderately **=> 57 (3)**

Choice4 **=> 1403**: Quite a bit **=> 57 (4)**

Choice5 **=> 1404**: Extremely **=> 57 (5)**

Prev Ques to this grid:53

Multiple Choice: No

Q No: 57

Category: PTSD

Question: **IN THE PAST MONTH, have you been having trouble remembering important parts of the stressful experience?**

Choice1 **=> 571**: Not at all **=> 58 (1)**

Choice2 **=> 1401**: A little bit **=> 58 (2)**

Choice3 **=> 1402**: Moderately **=> 58 (3)**

Choice4 **=> 1403**: Quite a bit **=> 58 (4)**

Choice5 **=> 1404**: Extremely **=> 58 (5)**

Prev Ques to this grid: 53

Multiple Choice: No

Q No : 58

Category: PTSD

Question: **IN THE PAST MONTH, have you had a loss of interest in activities you used to enjoy?**

Choice1 **=> 571**: Not at all **=> 59 (1)**

Choice2 **=> 1401**: A little bit **=> 59 (2)**

Choice3 **=> 1402**: Moderately **=> 59 (3)**

Choice4 **=> 1403**: Quite a bit **=> 59 (4)**

Choice5 **=> 1404**: Extremely **=> 59 (5)**

Prev Ques to this grid: 53

Multiple Choice: No

Q No: 59

Category: PTSD

Question: **IN THE PAST MONTH, have you been feeling distant or cut off from other people?**

Choice1 **=> 571**: Not at all **=> 60 (1)**

Choice2 **=> 1401**: A little bit **=> 60 (2)**

Choice3 **=> 1402**: Moderately **=> 60 (3)**

Choice4 **=> 1403**: Quite a bit **=> 60 (4)**

Choice5 **=> 1404**: Extremely **=> 60 (5)**

Prev Ques to this grid: 58

Multiple Choice: No

Q No: 60

Category: PTSD

Question: **IN THE PAST MONTH, have you been feeling emotionally numb or unable to have loving feelings for those close to you?**

Choice1 **=> 571**: Not at all **=> 61 (1)**

Choice2 **=> 1401**: A little bit **=> 61 (2)**

Choice3 **=> 1402**: Moderately **=> 61 (3)**

Choice4 **=> 1403**: Quite a bit **=> 61 (4)**

Choice5 **=> 1404**: Extremely **=> 61 (5)**

Prev Ques to this grid: 58

Multiple Choice: No

Q No: 61

Category: PTSD

Question: **IN THE PAST MONTH, have you been feeling as if your future somehow will be cut short?**

Choice1 **=> 571**: Not at all **=> 62 (1)**

Choice2 **=> 1401**: A little bit **=> 62 (2)**

Choice3 **=> 1402**: Moderately **=> 62 (3)**

Choice4 **=> 1403**: Quite a bit **=> 62 (4)**

Choice5 **=> 1404**: Extremely **=> 62 (5)**

Prev Ques to this grid: 58

Multiple Choice: No

Q No: 62

Category: PTSD

Question: **IN THE PAST MONTH, have you had trouble falling or staying asleep?**

Choice1 **=> 571**: Not at all **=> 63 (1)**

Choice2 **=> 1401**: A little bit **=> 63 (2)**

Choice3 **=> 1402**: Moderately **=> 63 (3)**

Choice4 **=> 1403**: Quite a bit **=> 63 (4)**

Choice5 **=> 1404**: Extremely **=> 63 (5)**

Prev Ques to this grid: 58

Multiple Choice: No

Q No: 63

Category: PTSD

Question: **IN THE PAST MONTH, have you been feeling irritable or having angry outbursts?**

Choice1 **=> 571**: Not at all **=> 64 (1)**

Choice2 **=> 1401**: A little bit **=> 64 (2)**

Choice3 **=> 1402**: Moderately **=> 64 (3)**

Choice4 **=> 1403**: Quite a bit **=> 64 (4)**

Choice5 **=> 1404**: Extremely **=> 64 (5)**

Prev Ques to this grid: 58

Multiple Choice: No

Q No: 64

Category: PTSD

Question: **IN THE PAST MONTH, have you had difficulty concentrating?**

Choice1 **=> 571**: Not at all **=> 65 (1)**

Choice2 **=> 1401**: A little bit **=> 65 (2)**

Choice3 **=> 1402**: Moderately **=> 65 (3)**

Choice4 **=> 1403**: Quite a bit **=> 65 (4)**

Choice5 **=> 1404**: Extremely **=> 65 (5)**

Prev Ques to this grid: 63

Multiple Choice: No

Q No: 65

Category: PTSD

Question: **IN THE PAST MONTH, have you been "superalert" or watchful or on guard?**

Choice1 **=> 571**: Not at all **=> 66 (1)**

Choice2 **=> 1401**: A little bit **=> 66 (2)**

Choice3 **=> 1402**: Moderately **=> 66 (3)**

Choice4 **=> 1403**: Quite a bit **=> 66 (4)**

Choice5 **=> 1404**: Extremely **=> 66 (5)**

Prev Ques to this grid: 63

Multiple Choice: No

Q No: 66

Category: PTSD

Question: **IN THE PAST MONTH, have you been feeling jumpy or easily startled?**

Choice1 **=> 571**: Not at all **=> 71 (1)**

Choice2 **=> 1401**: A little bit **=> 71 (2)**

Choice3 **=> 1402**: Moderately **=> 71 (3)**

Choice4 **=> 1403**: Quite a bit **=> 71 (4)**

Choice5 **=> 1404**: Extremely **=> 71 (5)**

Prev Ques to this grid: 63

Multiple Choice: No

Q No: 67

Category: PTSD

Question: **IN THE PAST MONTH, how much were you bothered by having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?**

Choice1 => **910**: Not at all => **68 (1)**

Choice2 => **911**: A little bit => **68 (2)**

Choice3 => **914**: Moderately => **68 (3)**

Choice4 => **913**: Quite a bit => **68 (4)**

Choice5 => **912**: Extremely => **68 (5)**

Prev Ques to this grid:

Multiple Choice: No

CESD

Q No: 71

Category: Depression CESD

Question: **IN THE PAST MONTH, have you been bothered by things that do NOT usually bother you?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **72 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **72 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **72 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **72 (3)**

Prev Ques to this grid: 66

Multiple Choice: No

Q No: 72

Category: Depression CESD

Question: **IN THE PAST MONTH, have you not felt like eating (poor appetite)?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **73 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **73 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **73 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **73 (3)**

Prev Ques to this grid: 70

Multiple Choice: No

Q No: 73

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt that you could NOT shake off the blues even with the help of family or friends?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **74 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **74 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **74 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **74 (3)**

Prev Ques to this grid: 70

Multiple Choice: No

Q No: 74

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt that you were just as good as other people?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **75 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **75 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **75 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **75 (3)**

Prev Ques to this grid: 70

Multiple Choice: No

Q No: 75

Category: Depression CESD

Question: **IN THE PAST MONTH, have you had trouble keeping your mind on what you were doing?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **76 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **76 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **76 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **76 (3)**

Prev Ques to this grid: 70

Multiple Choice: No

Q No: 76

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt depressed?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **77 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **77 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **77 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **77 (3)**

Prev Ques to this grid: 75

Multiple Choice: No

Q No: 77

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt that everything that you did was an effort?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **78 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **78 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **78 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **78 (3)**

Prev Ques to this grid: 75

Multiple Choice: No

Q No: 78

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt hopeful about the future?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **79 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **79 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **79 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **79 (3)**

Prev Ques to this grid: 75

Multiple Choice: No

Q No: 79

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt that your life had been a failure?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **80 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **80 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **80 (2)**

Choice4 => **1014:** Most or All the Time (5-7 days per week) => **80 (3)**

Prev Ques to this grid: 75

Multiple Choice: No

Q No: 80

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt fearful?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **81 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **81 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **81 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) =>**81 (3)**

Prev Ques to this grid: 75

Multiple Choice: No

Q No: 81

Category: Depression CESD

Question: **IN THE PAST MONTH, has your sleep been restless?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **82 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **82 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **82 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **82 (3)**

Prev Ques to this grid: 80

Multiple Choice: No

Q No: 82

Category: Depression CESD

Question: **IN THE PAST MONTH, have you been happy?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **83 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **83 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **83 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **83 (3)**

Prev Ques to this grid: 80

Multiple Choice: No

Q No: 83

Category: Depression CESD

Question: **IN THE PAST MONTH, have you talked less than usual?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **84 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **84 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **84 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **84 (3)**

Prev Ques to this grid: 80

Multiple Choice: No

Q No: 84

Category: Depression CESD

Question: **IN THE PAST MONTH, have you felt lonely?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **85 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **85 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **85 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **85 (3)**

Prev Ques to this grid: 80

Multiple Choice: No

Q No: 85

Category: Depression CESD

Question: **IN THE PAST MONTH, have people been unfriendly to you?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **86 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **86 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **86 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **86 (3)**

Prev Ques to this grid: 80

Multiple Choice: No

Q No: 86

Category: Depression CESD

Question: **IN THE PAST MONTH, have you enjoyed life?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **87 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **87 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **87 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **87 (3)**

Prev Ques to this grid: 85

Multiple Choice: No

Q No: 87

Category: Depression CESD

Question: **IN THE PAST MONTH, have you had crying spells?**

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **88 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **88 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **88 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **88 (3)**

Prev Ques to this grid: 85

Multiple Choice: No

Q No: 88

Category: Depression CESD

Question: IN THE PAST MONTH, have you felt sad?

Choice1 => **1013**: None or Rarely (less than 1 day per week) => **89 (0)**

Choice2 => **1016**: Some or Little of the Time (1-2 days per week) => **89 (1)**

Choice3 => **1015**: Occasionally or a Moderate Amount of Time (3-4 days per week) => **89 (2)**

Choice4 => **1014**: Most or All the Time (5-7 days per week) => **89 (3)**

Prev Ques to this grid: 85

Multiple Choice: No

Q No: 89

Category: Depression CESD

Question: IN THE PAST MONTH, have you felt that people disliked you?

Choice1 => 1013: None or Rarely (less than 1 day per week) => **90 (0)**

Choice2 => 1016: Some or Little of the Time (1-2 days per week) => **90 (1)**

Choice3 => 1015: Occasionally or a Moderate Amount of Time (3-4 days per week) => **90 (2)**

Choice4 => 1014: Most or All the Time (5-7 days per week) => **90 (3)**

Prev Ques to this grid: 85

Multiple Choice: No

Q No: 90

Category: Depression CESD

Question: IN THE PAST MONTH, have you felt that you could not get "going"?

Choice1 => 1013: None or Rarely (less than 1 day per week) => 91 (0)

Choice2 => 1016: Some or Little of the Time (1-2 days per week) => 91 (1)

Choice3 => 1015: Occasionally or a Moderate Amount of Time (3-4 days per week) => 91 (2)

Choice4 => 1014: Most or All the Time (5-7 days per week) => 91 (3)

Prev Ques to this grid: 85

Multiple Choice: No

SF-12

Q No: 91

Category: QOL SF-12

Question: **GENERALLY, would you say your health is:**

Choice1 => **4636**: Excellent => 92

Choice2 => **4637**: Very Good => 92

Choice3 => **4638**: Good => 92

Choice4 => **4639**: Fair => 92

Choice5 => **4640**: Poor => 92

Prev Ques to this grid:

Multiple Choice: No

Q No: 92

Category: QOL SF-12

Question: **DURING A TYPICAL DAY, does your health limit you in performing moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf?**

Choice1 => **4641**: No, not limited at all => 93

Choice2 => **4642**: Yes, limited a little => 93

Choice3 => **4643**: Yes, limited a lot => 93

Prev Ques to this grid:

Multiple Choice: No

Q No: 93

Category: QOL SF-12

Question: **DURING A TYPICAL DAY, does your health limit you in climbing several flights of stairs?**

Choice1 => **4644**: No, not limited at all => 94

Choice2 => **4645**: Yes, limited a little => 94

Choice3 => **4646**: Yes, limited a lot => 94

Prev Ques to this grid:

Multiple Choice: No

Q No: 94

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time have you accomplished less than you would like with your work or regular daily activities as a result of your PHYSICAL health?**

Choice1 => **4657**: All of the time => 95

Choice2 => **4658**: Most of the time => 95

Choice3 => **4659**: Some of the time => 95

Choice4 => **4660**: A little of the time => 95

Choice5 => **4661**: None of the time => 95

Prev Ques to this grid: 93

Multiple Choice: No

Q No: 95

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time were you limited in the kind of work or other activities as a result of your PHYSICAL health?**

Choice1 => **4662**: All of the time => 96

Choice2 => **4663**: Most of the time => 96

Choice3 => **4664**: Some of the time => 96

Choice4 => **4665**: A little of the time => 96

Choice5 => **4666**: None of the time => 96

Prev Ques to this grid: 93

Multiple Choice: No

Q No: 96

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time have you accomplished less than you would like with your work or regular daily activities as a result of your EMOTIONAL problems (such as feeling depressed or anxious)?**

Choice1 => **4647**: All of the time => 97

Choice2 => **4648**: Most of the time => 97

Choice3 => **4649**: Some of the time => 97

Choice4 => **4650**: A little of the time => 97

Choice5 => **4651**: None of the time => 97

Prev Ques to this grid: 93

Multiple Choice: No

Q No: 97

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time did you do work or other regular daily activities less carefully than usual as a result of your EMOTIONAL problems (such as feeling depressed or anxious)?**

Choice1 => **4652**: All of the time => 98

Choice2 => **4653**: Most of the time => 98

Choice3 => **4654**: Some of the time => 98

Choice4 => **4655**: A little of the time => 98

Choice5 => **4656**: None of the time => 98

Prev Ques to this grid: 93

Multiple Choice: No

Q No : 98

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time have you felt calm and peaceful?**

Choice1 => **4672**: All of the time => 99

Choice2 => **4673**: Most of the time => 99

Choice3 => **4674**: Some of the time => 99

Choice4 => **4675**: A little of the time => 99

Choice5 => **4676**: None of the time => 99

Prev Ques to this grid: 97

Multiple Choice: No

Q No : 99

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time did you have a lot of energy?**

Choice1 => **4677**: All of the time => 100

Choice2 => **4678**: Most of the time => 100

Choice3 => **4679**: Some of the time => 100

Choice4 => **4680**: A little of the time => 100

Choice5 => **4681**: None of the time => 100

Prev Ques to this grid: 97

Multiple Choice: No

Q No : 100

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time have you felt downhearted or depressed?**

Choice1 => **4667**: All of the time => 101

Choice2 => **4668**: Most of the time => 101

Choice3=> **4669**: Some of the time => 101

Choice4 => **4670**: A little of the time => 101

Choice5 => **4671**: None of the time => 101

Prev Ques to this grid: 97

Multiple Choice: No

Q No : 101

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

Choice1 => **4682**: All of the time => 102

Choice2 => **4683**: Most of the time => 102

Choice3 => **4684**: Some of the time => 102

Choice4 => **4685**: A little of the time => 102

Choice5 => **4686**: None of the time => 102

Prev Ques to this grid: 97

Multiple Choice: No

Q No : 102

Category: QOL SF-12

Question: **IN THE PAST MONTH, how much did pain interfere with your normal work (include work both outside the home and housework)?**

Choice1 => **4687**: Not at all => 103

Choice2 => **4688**: A little bit => 103

Choice3 => **4689**: Moderately => 103

Choice4 => **4690**: Quite a bit => 103

Choice5 => **4691**: Extremely => 103

Prev Ques to this grid:

Multiple Choice: No

AUDIT-Alcohol

Q No : 103

Category : Audit Alcohol

Question : DIRECTIONS: The following are some questions about your use of alcoholic drinks (beer, wine, wine coolers, or hard liquor like vodka, gin, or whiskey). When we use the term "drink," we mean a glass of wine, a can or bottle of beer, or a shot of hard liquor alone or in a mixed drink. IN THE PAST YEAR, how often did you have a drink containing alcohol?

Choice1 => 4917: Never => 114 (0)

Choice2 => 4918: Monthly OR LESS => 104 (1)

Choice3 => 4919: 2-4 times A MONTH => 104 (2)

Choice4 => 4920: 2-3 times A WEEK => 104 (3)

Choice5 => 4921: 4 or more times A WEEK => 104 (4)

Prev Ques to this grid:

Multiple Choice: No

Q No : 104

Category : Audit Alcohol

Question : IN THE PAST YEAR, how many drinks containing alcohol have you had on a TYPICAL DAY when you are drinking?

Choice1=> 4922: 0 to 2 drinks => 105 (0)

Choice2 => 4923: 3 or 4 drinks => 105 (1)

Choice3 => 4924: 5 or 6 drinks => 105 (2)

Choice4 => 4925: 7 to 9 drinks => 105 (3)

Choice5 => 4926: 10 or more drinks => 105 (4)

Prev Ques to this grid:

Multiple Choice: No

Q No : 105

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you had six or more drinks on one occasion?

Choice1 => 4927: Never => 106 (0)

Choice2 => 4928: Less than Monthly => 106 (1)

Choice3 => 4929: Monthly => 106 (2)

Choice4 => 4930: Weekly => 106 (3)

Choice5 => 4931: Daily or Almost Daily => 106 (4)

Prev Ques to this grid: 1035

Multiple Choice: No

Q No :106

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you found that you were not able to stop drinking once you had started?

Choice1 => 4932: Never => 107 (0)

Choice2 => 4933: Less than Monthly => 107 (1)

Choice3 => 4934: Monthly => 107 (2)

Choice4 => 4935: Weekly => 107 (3)

Choice5 => 4936: Daily or Almost Daily => 107 (4)

Prev Ques to this grid: 1035

Multiple Choice: No

Q No : 107

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you failed to do what was normally expected from you because of drinking?

Choice1 => 4937: Never => 108 (0)

Choice2 => 4938: Less than Monthly => 108 (1)

Choice3 => 4939: Monthly => 108 (2)

Choice4 => 4940: Weekly => 108 (3)

Choice5 => 4941: Daily or Almost Daily => 108 (4)

Prev Ques to this grid:

Multiple Choice: No

Q No : 108

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you needed a first drink in the morning to "get going" after a heavy drinking session?

Choice1 => 4942: Never => 109 (0)

Choice2 => 4943: Less than Monthly => 109 (1)

Choice3 => 4944: Monthly => 109 (2)

Choice4 => 4945: Weekly => 109 (3)

Choice5 => 4946: Daily or Almost Daily => 109 (4)

Prev Ques to this grid: 1038

Multiple Choice: No

Q No :109

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you had a feeling of guilt or remorse after drinking?

Choice1 => 4947: Never => 110 (0)

Choice2 => 4948: Less than Monthly => 110 (1)

Choice3 => 4949: Monthly => 110 (2)

Choice4 => 4950: Weekly => 110 (3)

Choice5 => 4951: Daily or Almost Daily => 110 (4)

Prev Ques to this grid:

Multiple Choice: No

Q No : 110

Category : Audit Alcohol

Question : IN THE PAST YEAR, how often have you been unable to remember what happened the night before because you had been drinking?

Choice1 => 4952: Never => 111 (0)

Choice2 => 4953: Less than Monthly => 111 (1)

Choice3 => 4954 Monthly => 111 (2)

Choice4 => 4955: Weekly => 111 (3)

Choice5 => 4956: Daily or Almost Daily => 111 (4)

Prev Ques to this grid:

Multiple Choice: No

Q No : 111

Category : Audit Alcohol

Question : Have you or someone else EVER been injured as a result of your drinking?

Choice1 => 4957: No => 112 (0)

Choice2 => 4958: Yes, during the past 12 months => 112 (4)

Choice3 => 4959: Yes, but not during the past 12 months => 112 (2)

Prev Ques to this grid:

Multiple Choice: No

Q No : 112

Category : Audit Alcohol

Question : Has a relative, friend, doctor or other health professional EVER been concerned about your drinking or suggested you cut down?

Choice1 => 4960: No => 113 (0)

Choice2 => 4961: Yes, during the past 12 months => 113 (4)

Choice3 =>4962: Yes, but not during the past 12 months => 113 (2)

Prev Ques to this grid:

Multiple Choice: No

Q No : 113

Category : Audit Alcohol

Question : Have you EVER thought you should quit or cut down on drinking whether or not you actually tried to do it?

Choice1 => 4963: No => 114 (no score)

Choice2 => 4964: Yes, during the past 12 months => 114 (no score)

Choice3 => 4965: Yes, but not during the past 12 months => 114 (no score)

Prev Ques to this grid:

Multiple Choice: No

CSSRS

Criteria to get flagged for CSU (patients need to meet one of the following criteria)

- Participant answers choice 2 (in past month) to Q117 OR
- Participant answers choice 2 (in past month) to Q118 OR
- Participant answers choice 2 (in past month) to Q119 OR
- Participant answers choice 2 (in past month) to Q120 OR
- Participant answers choice 3 (in past 3 months) to Q120 OR

- Participant answers choice 4 (in lifetime) to Q120

Q No: 114

Category: Suicide

Question**: Have any of your blood relatives committed suicide?**

Choice 1 => 5125 => No => 115

Choice 2 => 5126 => Yes => 115

Prev Ques to this grid:

Multiple Choice: No

Q No: 115

Category: C-SSRS

Question: **Have you wished you were dead or wished you could go to sleep and not wake up?**

Choice 1 => 5127 => Never => 116 (0)

Choice 2 => 5128 => Yes, in the past month => 116 (0)

Choice 3 => 5129 => Yes, in the past 3 months => 116 (0)

Choice 4 => 5130 => Yes, in lifetime => 116 (0)

Prev Ques to this grid:

Multiple choice: Yes

Q No: 116

Category: C-SSRS

Question: **Have you actually had any thoughts about killing yourself?**

Choice 1 => 5131 => Never => 120 (0)

Choice 2 => 5132 => Yes, in the past month => 117 (0)

Choice 3 => 5133=> Yes, in the past 3 months => 117 (0)

Choice 4 => 5134 => Yes, in lifetime => 117 (0)

Prev Ques to this grid:

Multiple choice: Yes

Q No: 117

Category: C-SSRS

Question: **Have you thought about how you might do this?**

Choice 1 => 5135 => Never => 118 (0)

Choice 2 => 5136 => Yes, in the past month => 118 (1)

Choice 3 => 5137 => Yes, in the past 3 months => 118 (0)

Choice 4 => 5138 => Yes, in lifetime => 118 (0)

Prev Ques to this grid:

Multiple choice: Yes

Q No: 118

Category: C-SSRS

Question: **Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them?**

Choice 1 => 5139 => Never => 119 (0)

Choice 2 => 5140 => Yes, in the past month => 119 (1)

Choice 3 => 5141 => Yes, in the past 3 months => 119 (0)

Choice 4 => 5142 => Yes, in lifetime => 119 (0)

Prev Ques to this grid:

Multiple choice: Yes

Q No: 119

Category: C-SSRS

Question: **Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?**

Choice 1 => 5143 => Never => 120 (0)

Choice 2 => 5144 => Yes, in the past month => 120 (1)

Choice 3 => 5145 => Yes, in the past 3 months => 120 (0)

Choice 4 => 5146 => Yes, in lifetime => 120 (0)

Prev Ques to this grid:

Multiple choice: Yes

Q No: 120

Category: C-SSRS

Question: **Have you done anything, started to do anything, or prepared to do anything to end your life?**

Choice 1 => 5147 => Never => END (0)

Choice 2 => 5148 => Yes, in the past month => END (1)

Choice 3 => 5149 => Yes, in the past 3 months => END (1)

Choice 4 => 5150 => Yes, in lifetime => END (1)

Prev Ques to this grid:

Multiple choice: Yes

ANYONE WITH SCORING “SUICIDE RISK” an email is sent to Counseling Services Unit.

2B. Follow-up

Lung Cancer Prevention through Tobacco Cessation at FDNY

Follow Up Survey

Current Tobacco Use

Q No: 1

Category: Current Tobacco Use

Question: **In the time since your last study visit, did you at any point smoke any cigarettes (even one or two puffs)?**

Choice 1 => #### => Yes => 2

Choice 2 => #### => No => 5

Multiple choice: No

Q No: 2

Category: Current Tobacco Use

Question: **On the average, how many cigarettes do you now smoke a day?**

Cigarettes per day: 0-140 range => 3

Single number

Q No: 3.

Category: Current Tobacco Use

Past-month Timeline Follow Back (TLFB) Smoking Assessment (baseline and each visit):

Example: Programmed to previous 30 day

Using the following calendar, to the best of your ability, please try to indicate on which days in the past month you have smoked cigarettes, if any. On only the days when you smoked cigarettes, please indicate how many you smoked. Even one or two puffs counts as a smoked cigarette. We know this may be hard to remember exactly, but please try to complete it as accurately as you can to the best of your ability. If you did not smoke, please put a 0 for the first available day on the calendar.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

Q No: 4

Category: Current Tobacco Use

Question: **Is your usual cigarette brand menthol or non-menthol?**

Choice 1 => #### => Menthol => 5

Choice 2 => #### => Non-menthol => 5

Choice 3 => #### => No usual Brand => 5

Choice 3 => #### => Don't know/refuse to answer => 5

Multiple choice: No

Cigarette alternatives

Q No: 5

Category: Cigarette alternatives

Question: **In the past 30 days, have you used an e-cigarette (even one or two puffs)?**

Choice 1 => #### =>Yes => 6

Choice 2 => #### => No => 7

Choice 3 => #### => Don’t know/refuse to answer => 7

Prev Ques to this grid:

Multiple choice: No

Q No: 6

Category: Cigarette alternatives

Question: **Do you now use e-cigarettes?**

Choice 1 => #### =>Every day => 7

Choice 2 => #### => Some days=> 7

Choice 3 => #### => Not at all => 7

Choice 4 => #### Don’t know/refuse to answer => 7

Prev Ques to this grid:

Multiple choice: No

Q No: 7

Category: Cigarette alternatives

Question: **In the past 30 days, have you smoked cigars, cigarillos or little cigars (even one or two puffs)?**

Choice 1 => #### =>Yes => 8

Choice 2 => #### => No => 9

Choice 3 => #### => Don’t know/refuse to answer => 9

Multiple choice: No

Q No: 8

Category: Cigarette alternatives

Question: **Do you now smoke cigars, cigarillos, or little cigars?**

Choice 1 => #### =>Every day => 9

Choice 2 => #### => Some days=> 9

Choice 3 => #### => Not at all => 9

Choice 4 => #### Don't know/refuse to answer => 9

Multiple choice: No

Modified Cigarette Evaluation Questionnaire (mCEQ) (baseline and follow-up)

If you have smoked since you last completed this questionnaire, please mark the number that best represents how smoking makes you feel.

Q No: 9

Category: Tobacco Associated Reward

Question: **Was smoking satisfying?**

Choice 1 => #### => Not at all => 10

Choice2 => #### => Very little => 10

Choice 3 => #### => A little => 10

Choice 4 => #### => Moderately =>10

Choice 5 => #### => A lot => 10

Choice 6 => #### => Quite a lot => 10

Choice 7 => #### => Extremely => 10

Prev Ques to this grid: 8

Multiple Choice: No

Q No: 10

Category: Tobacco Associated Reward

Question: **Did cigarettes taste good?**

Choice 1 => #### => Not at all => 11

Choice2 => #### => Very little => 11

Choice 3 => #### => A little => 11

Choice 4 => #### => Moderately => 11

Choice 5 => #### => A lot => 11

Choice 6 => #### => Quite a lot => 11

Choice 7 => #### => Extremely => 11

Prev Ques to this grid: 8

Multiple Choice: No

Q No: 11

Category: Tobacco Associated Reward

Question: **Did you enjoy the sensations in your throat and chest?**

Choice 1 => #### => Not at all => 12

Choice2 => #### => Very little => 12

Choice 3 => #### => A little => 12

Choice 4 => #### => Moderately => 12

Choice 5 => #### => A lot => 12

Choice 6 => #### => Quite a lot => 12

Choice 7 => #### => Extremely => 12

Prev Ques to this grid: 8

Multiple Choice: No

Q No: 12

Category: Tobacco Associated Reward

Question: **Did smoking calm you down?**

Choice 1 => #### => Not at all => 13

Choice2 => #### => Very little => 13

Choice 3 => #### => A little => 13

Choice 4 => #### => Moderately => 13

Choice 5 => #### => A lot => 13

Choice 6 => #### => Quite a lot => 13

Choice 7 => #### => Extremely => 13

Prev Ques to this grid: 8

Multiple Choice: No

Q No: 13

Category: Tobacco Associated Reward

Question: **Did smoking make you feel more awake?**

Choice 1 => #### => Not at all => 14

Choice2 => #### => Very little => 14

Choice 3 => #### => A little => 14

Choice 4 => #### => Moderately => 14

Choice 5 => #### => A lot => 14

Choice 6 => #### => Quite a lot => 14

Choice 7 => #### => Extremely => 14

Prev Ques to this grid: 8

Multiple Choice: No

Q No: 14

Category: Tobacco Associated Reward

Question: **Did smoking make you feel less irritable?**

Choice 1 => #### => Not at all => 15

Choice2 => #### => Very little => 15

Choice 3 => #### => A little => 15

Choice 4 => #### => Moderately => 15

Choice 5 => #### => A lot => 15

Choice 6 => #### => Quite a lot => 15

Choice 7 => #### => Extremely => 15

Prev Ques to this grid: 13

Multiple Choice: No

Q No: 15

Category: Tobacco Associated Reward

Question: **Did smoking help you concentrate?**

Choice 1 => #### => Not at all => 16

Choice2 => #### => Very little => 16

Choice 3 => #### => A little => 16

Choice 4 => #### => Moderately => 16

Choice 5 => #### => A lot => 16

Choice 6 => #### => Quite a lot => 16

Choice 7 => #### => Extremely => 16

Prev Ques to this grid: 13

Multiple Choice: No

Q No: 16

Category: Tobacco Associated Reward

Question: **Did smoking reduce your hunger for food?**

Choice 1 => #### => Not at all => 17

Choice2 => #### => Very little => 17

Choice 3 => #### => A little => 17

Choice 4 => #### => Moderately => 17

Choice 5 => #### => A lot => 17

Choice 6 => #### => Quite a lot => 17

Choice 7 => #### => Extremely => 17

Prev Ques to this grid: 13

Multiple Choice: No

Q No: 17

Category: Tobacco Associated Reward

Question: **Did smoking make you dizzy?**

Choice 1 => #### => Not at all => 18

Choice2 => #### => Very little => 18

Choice 3 => #### => A little => 18

Choice 4 => #### => Moderately => 18

Choice 5 => #### => A lot => 18

Choice 6 => #### => Quite a lot => 18

Choice 7 => #### => Extremely => 18

Prev Ques to this grid: 13

Multiple Choice: No

Q No: 18

Category: Tobacco Associated Reward

Question: **Did smoking make you nauseous?**

Choice 1 => #### => Not at all => 19

Choice2 => #### => Very little => 19

Choice 3 => #### => A little => 19

Choice 4 => #### => Moderately => Q18

Choice 5 => #### => A lot => 19

Choice 6 => #### => Quite a lot => 19

Choice 7 => #### => Extremely => 19

Prev Ques to this grid: 13

Multiple Choice: No

Q No: 19

Category: Tobacco Associated Reward

Question: **Did smoking immediately relieve your craving for a cigarette?**

Choice 1 => #### => Not at all => 20

Choice2 => #### => Very little => 20

Choice 3 => #### => A little => 20

Choice 4 => #### => Moderately => 20

Choice 5 => #### => A lot => 20

Choice 6 => #### => Quite a lot => 20

Choice 7 => #### => Extremely => 20

Prev Ques to this grid: 18

Multiple Choice: No

Q No: 20

Category: Tobacco Associated Reward

Question: **Did you enjoy smoking?**

Choice 1 => #### => Not at all => 21

Choice2 => #### => Very little => 21

Choice 3 => #### => A little => 21

Choice 4 => #### => Moderately => 21

Choice 5 => #### => A lot => 21

Choice 6 => #### => Quite a lot => 21

Choice 7 => #### => Extremely => 21

Prev Ques to this grid: 18

Multiple Choice: No

Reasons for Quitting

Q No: 21

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting? Because I am afraid that I will get very sick if I don't quit smoking.**

Choice 1 => #### => Not at all true => 22

Choice 2 => #### => A little true => 22

Choice 3 => #### => Moderately true => 22

Choice 4 => #### => Quite true => 22

Choice 5 => #### => Extremely true => 22

Choice 6 => #### => Refuse to answer => 22

Prev Ques to this grid: 20

Multiple choice: No

Q No: 22

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: To prove that I can quit if I really want to.**

Choice 1 => #### => Not at all true => 23

Choice 2 => #### => A little true => 23

Choice 3 => #### => Moderately true => 23

Choice 4 => #### => Quite true => 23

Choice 5 => #### => Extremely true => 23

Choice 6 => #### => Refuse to answer => 23

Prev Ques to this grid: 20

Multiple choice: No

Q No: 23

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: Because I feel like smoking is hurting my health.**

Choice 1 => #### => Not at all true => 24

Choice 2 => #### => A little true => 24

Choice 3 => #### => Moderately true => 24

Choice 4 => #### => Quite true => 24

Choice 5 => #### => Extremely true => 24

Choice 6 => #### => Refuse to answer => 24

Prev Ques to this grid: 20

Multiple choice: No

Q No: 24

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: To feel in control of my life.**

Choice 1 => #### => Not at all true => 25

Choice 2 => #### => A little true => 25

Choice 3 => #### => Moderately true => 25

Choice 4 => #### => Quite true => 25

Choice 5 => #### => Extremely true => 25

Choice 6 => #### => Refuse => 25

Prev Ques to this grid: 20

Multiple choice: No

Q No: 25

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: To show that I can do other things that are important to me.**

Choice 1 => #### => Not at all true => 26

Choice 2 => #### => A little true => 26

Choice 3 => #### => Moderately true => 26

Choice 4 => #### => Quite true => 26

Choice 5 => #### => Extremely true => 26

Choice 6 => #### => Refuse to answer => 26

Prev Ques to this grid: 20

Multiple choice: No

Q No: 26

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: Because I am afraid that smoking will shorten my life.**

Choice 1 => #### => Not at all true => 27

Choice 2 => #### => A little true => 27

Choice 3 => #### => Moderately true => 27

Choice 4 => #### => Quite true => 27

Choice 5 => #### => Extremely true => 27

Choice 6 => #### => Refuse to answer => 27

Prev Ques to this grid: 25

Multiple choice: No

Q No: 27

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: So other people will stop nagging me.**

Choice 1 => #### => Not at all true => 28

Choice 2 => #### => A little true => 28

Choice 3 => #### => Moderately true => 28

Choice 4 => #### => Quite true => 28

Choice 5 => #### => Extremely true => 28

Choice 6 => #### => Refuse => 28

Prev Ques to this grid: 25

Multiple choice: No

Q No: 28

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: To save money that I spend on cigarettes.**

Choice 1 => #### => Not at all true => 29

Choice 2 => #### => A little true => 29

Choice 3 => #### => Moderately true => 29

Choice 4 => #### => Quite true => 29

Choice 5 => #### => Extremely true => 29

Choice 6 => #### => Refuse => 29

Prev Ques to this grid: 25

Multiple choice: No

Q No: 29

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: Because someone is making me quit.**

Choice 1 => #### => Not at all true => 30

Choice 2 => #### => A little true => 30

Choice 3 => #### => Moderately true => 30

Choice 4 => #### => Quite true => 30

Choice 5 => #### => Extremely true => 30

Choice 6 => #### => Refuse => 30

Prev Ques to this grid: 25

Multiple choice: No

Q No: 30

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: So I won't burn holes in clothes or furniture**

Choice 1 => #### => Not at all true => 31

Choice 2 => #### => A little true => 31

Choice 3 => #### => Moderately true => 31

Choice 4 => #### => Quite true => 31

Choice 5 => #### => Extremely true => 31

Choice 6 => #### => Refuse => 31

Prev Ques to this grid: 25

Multiple choice: No

Q No: 31

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: Because people I am close to will be mad at me if I don't quit.**

Choice 1 => #### => Not at all true => 32

Choice 2 => #### => A little true => 32

Choice 3 => #### => Moderately true => 32

Choice 4 => #### => Quite true => 32

Choice 5 => #### => Extremely true => 32

Choice 6 => #### => Refuse => 32

Prev Ques to this grid: 30

Multiple choice: No

Q No: 32

Category: Reasons for Quitting

Question: **How true for you is the following reason for quitting: So my house or car won't smell.**

Choice 1 => #### => Not at all true => 33

Choice 2 => #### => A little true => 33

Choice 3 => #### => Moderately true => 33

Choice 4 => #### => Quite true => 33

Choice 5 => #### => Extremely true => 33

Choice 6 => #### => Refuse => 33

Prev Ques to this grid: 30

Multiple choice: No

Cessation Self-Efficacy

Q No: 33

Category: Cessation Self-Efficacy

Question: **Using a scale of 1 to 10, where 1 is not at all confident and 10 is extremely confident, how confident are you that you could quit smoking completely if you wanted to?**

Choice: Select number* range: 1- 10 => 34

Cessation Motivation

Q No: 34

Category: Cessation Motivation

Question: **Using a scale of 1 to 10, where 1 is not at all important and 10 is extremely important, how important is it to you that you quit smoking completely?**

Choice: Select number* range: 1- 10 => 35

Other medications/Methods to quit

Category: Other medications/Methods to quit (Non-baseline Study visits)

Q No: 35

Category: Smoking

Question: Do you currently use any nicotine replacement therapy products (not e-cigarettes)? Select all that apply

Choice1 => No => 36

Choice2 => Nicotine patches => 36

Choice3 => Nicotine gum => 36

Choice4 => Lozenges => 36

Choice5 => Inhalers => 36

Choice6 => Nasal Sprays => 36

Choice7 => Medication(s) (Chantix, Wellbutrin, etc.) => 36

Answer Choice: 1st answer choice negates the rest

Category: Other medications/Methods to quit (Non-baseline Study visits)

Q No: 36

Category: Smoking

Question: Do you CURRENTLY use any of the following products?

Choice1 => 3699: None, former user => 37

Choice2 => 3197: Pipes => 37

Choice3 => 3199: Cigars => 37

Choice4 => 3164: Chewing Tobacco => 37

Choice5 => 3697: Hookah Pipe => 37

Choice6 => 3698: Electronic Cigarettes (e-cigarettes, vapes, etc.) => 37

Answer Choice: 1st answer choice negates the rest

Adverse events (every study visit)

Q No: 37

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Nausea**

Choice 1 => #### => Yes => 38

Choice 2 => #### => No => 38

Choice 3 => #### => Yes, but resolved => 38

Q No: 38

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Headache**

Choice 1 => #### => Yes => 39

Choice 2 => #### => No => 39

Choice 3 => #### => Yes, but resolved => 39

Q No: 39

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Constipation**

Choice 1 => #### => Yes => 40

Choice 2 => #### => No => 40

Choice 3 => #### => Yes, but resolved => 40

Q No: 40

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Insomnia**

Choice 1 => #### => Yes => 41

Choice 2 => #### => No => 41

Choice 3 => #### => Yes, but resolved => 41

Q No: 41

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Abnormal dreams**

Choice 1 => #### => Yes => 42

Choice 2 => #### => No => 42

Choice 3 => #### => Yes, but resolved => 42

Q No: 42

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Vomiting**

Choice 1 => #### => Yes => 43

Choice 2 => #### => No => 43

Choice 3 => #### => Yes, but resolved => 43

Q No: 43

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Gas**

Choice 1 => #### => Yes => 44

Choice 2 => #### => No => 44

Choice 3 => #### => Yes, but resolved => 44

Q No: 44

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Upset stomach/indigestion**

Choice 1 => #### => Yes => 45

Choice 2 => #### => No => 45

Choice 3 => #### => Yes, but resolved => 45

Q No: 45

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Change in taste, or feelings of abnormal taste**

Choice 1 => #### => Yes => 46

Choice 2 => #### => No => 46

Choice 3 => #### => Yes, but resolved => 46

Q No: 46

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Dry mouth**

Choice 1 => #### => Yes => 47

Choice 2 => #### => No => 47

Choice 3 => #### => Yes, but resolved => 47

Q No: 47

Category: Adverse Symptoms

Question: **Have you had any of the following new symptoms or illnesses since starting varenicline? Change or shift in appetite**

Choice 1 => #### => Yes => END

Choice 2 => #### => No => END

Choice 3 => #### => Yes, but resolved => END

3. Informed consent phone script (current study)

CONSENT SCRIPT
Enhanced care (opt-out) treatment arm

Hello, my name is Ty Moline, and I am a research coordinator with the Bureau of Health Services at the FDNY. Today, I would like to talk with you about participating in our Tobacco Cessation program, and the research study connected to it that will investigate how well the program works. You recently received a letter about it in the mail. We're researching how to better engage people in tobacco cessation treatment so that we can help them quit smoking. Your participation is voluntary and you may opt-out.

Our research study and program are titled "Preventing Lung Cancer Through Tobacco Cessation at FDNY." And today, I'd like to speak about it and give an overview of the study as well as outline the potential risks and benefits of participating, so that you can then make an informed decision on whether or not you would like to participate. Please note that you do not have to participate. Your participation is always voluntary and is always your choice. If you decide you would like to take part, after reviewing this form with me you will be asked to sign this consent form. Your signature means that you agree to be a participant in this program and this research. We encourage you to take as much time as you would like to decide, and that you should ask all the questions that you would like to. Importantly, your decision will not affect your rights or benefits, your access to care, or your pension.

As we go through the consent form if you have any questions, please do not hesitate to bring them up, either anytime with me now, or at any time following this. You may also contact Dr. Shadi Nahvi or Dr. David Goldfarb, the study's Principal Investigators, with their contact information provided below in this form, as well as in the letter that you received from us.

With your permission, may I begin? If you have any questions, please stop me at any time.

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, you previously agreed to be contacted for future WTC-related research studies, and you indicated that you smoke cigarettes as per a recent research questionnaire.

This study is being conducted because, although participants in the FDNY WTCHP CT screening program have access to a free tobacco cessation program, over 1/3 of them continue to smoke. 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.

In this study we plan to offer all participants a free, no-cost clinical service along with a prescription for the medication varenicline to help them reduce smoking. The study's no-cost service will also include telehealth visits with a tobacco cessation treatment specialist.

The drug you will be taking is varenicline, which has been approved by the US Food and Drug Administration and is intended to make it easier for smokers to quit smoking. Varenicline works by blocking nicotine receptors in the brain, so that it makes it easier to quit, both by reducing the effects of nicotine withdrawal and by reducing the nicotine associated reward that somebody feels when smoking.

Now, I would like to direct you know to "What will Happen if I take part in this Research Study?" section on the second page of the from. I'll now walk you through everything that is involved with the research study, so that you can get a better understanding of everything that we'll ask, should you choose to participate.

By previously agreeing to be contacted for future 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. 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 first to confirm that it is safe for you to take varenicline. If we determine that you are potentially eligible for this program and study, you will be scheduled to meet with our tobacco cessation specialist. 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 kidney function and alcohol use, that were measured and/or reported

during your 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.

To elaborate more on what is involved with taking varenicline, as part of the program and study, FDNY Chief Medical Officer Dr. David Prezant or Dr. Shadi Nahvi will provide you with a free prescription for the medication, which you will be asked to take for a total of 16 weeks, 4 of which we recommend will lead up to the target quit date before you quit smoking.

In those first four weeks, you'll start by taking 0.5 mg of varenicline once a day for your first 3 days, then 0.5 mg twice a day for four days, and then 1 mg twice a day after that, up to, and following your quit date for the rest of the duration of the 16-week period.

You will be in the study for 28 weeks, for 16 of which, you will take varenicline.

All study visits will be conducted via video conferencing using the telehealth platform Doximity. 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 program and study visits will take place 2, 4, 8, 12, 16, and 28 weeks after your baseline appointment.

Each research study visit will last about 10 minutes. All visits will include questionnaires, a timeline follow-back assessment of past 30-day tobacco use, and varenicline use.

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. If any of the questions make you uncomfortable, you can ask to pass or not answer them. You do not have to answer any questions that you do not want to.

Around the time of each visit, we will also collect urine samples to validate self-reported cigarette cessation. We will measure cotinine levels at your first appointment and all following sessions if you report smoking abstinence. Cotinine is a byproduct created when your body breaks down nicotine. These tests are conducted for research purposes only and will be done at your convenience at the nearest Quest Diagnostics laboratory. We will order these tests for you and provide you a form to bring to the test. There will be no financial cost for you to do this.

No other procedures will take place, other than those highlighted by me here. For instance, no HIV (AIDS), illicit drug or alcohol testing will be performed on any research participant as part of this study. We will not conduct any form of genetic testing of keep or maintain any biological samples.

No audio or video recording from any of the sessions will be done.

Now, if I can direct you to page 3, I would like to go through the risk and benefits associated with your participation in this study.

The risks of participating in this study include the inconvenience of attending research and program visits, potential discomfort with answering research-related questions, potential discomfort with quitting smoking, and risks associated with the use of the medication varenicline.

Here is further 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 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 uncomfortable or 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:

The most common varenicline symptoms include Nausea, Insomnia, Headaches, Abnormal Dreams. Please note, that these symptoms are also common for people who are withdrawing from nicotine regardless of whether they are taking medication.

Other less common symptoms include, vomiting, gas, constipation, indigestion, abnormal taste, dry mouth and change in appetite. Even more rare symptoms include dizziness, fatigue, upper respiratory disorders, and skin conditions. Incredibly rare symptoms include convulsions.

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).

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.

Now, I would like to review the potential benefits of participating in our program and research study.

There may or may not be direct medical benefit to you from being in this research study.

Varenicline treatment has been shown and proven within the medical literature to help smokers quit.

There are significant health benefits that come with quitting smoking, including a reduction in the chance of developing lung disease, heart and cardiovascular diseases, and various forms of cancer.

In addition, the information learned from this study may, in the future, benefit other WTC responders with the same medical condition, as well as other people trying to quit smoking.

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).

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.

Again, there will be no costs to you for participating in this study.

Again, at any point, now or in the future, if you have any questions that arise related to this research project and health program, 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.

Do you have any other questions about the program and the research study?

CONSENT SCRIPT
Standard care (opt-in) treatment arm

Thank you for reaching out to us regarding our tobacco cessation study. My name is Ty Moline, and I am a research coordinator with the Bureau of Health Services at the FDNY. Today, I will talk with you about participating in our Tobacco Cessation program, and the research study connected to it that will investigate how well the program works. You recently received a letter about it in the mail. We're researching how to better engage people in tobacco cessation treatment so that we can help them quit smoking. Your participation is voluntary.

Our research study and program are titled "Preventing Lung Cancer Through Tobacco Cessation at FDNY." And today, I'd like to speak about it and give an overview of the study as well as outline the potential risks and benefits of participating, so that you can then make an informed decision on whether or not you would like to participate. Please note that you do not have to participate. Your participation is always voluntary and is always your choice. If you decide you would like to take part, after reviewing this form with me you will be asked to sign this consent form. Your signature means that you agree to be a participant in this program and this research. We encourage you to take as much time as you would like to decide, and that you should ask all the questions that you would like to. Importantly, your decision will not affect your rights or benefits, your access to care, or your pension.

As we go through the consent form if you have any questions, please do not hesitate to bring them up, either anytime with me now, or at any time following this. You may also contact Dr. Shadi Nahvi or Dr. David Goldfarb, the study's Principal Investigators, with their contact information provided below in this form, as well as in the letter that you received from us.

With your permission, may I begin? If you have any questions, please stop me at any time.

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, you previously agreed to be contacted for future WTC-related research studies, and you indicated that you smoke cigarettes as per a recent research questionnaire.

This study is being conducted because, although participants in the FDNY WTCHP CT screening program have access to a free tobacco cessation program, over 1/3 of them continue to smoke. 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.

In this study we plan to offer all participants a free, no-cost clinical service along with a prescription for the medication varenicline to help them reduce smoking. The study's no-cost service will also include telehealth visits with a tobacco cessation treatment specialist.

The drug you will be taking is varenicline, which has been approved by the US Food and Drug Administration and is intended to make it easier for smokers to quit smoking. Varenicline works by blocking nicotine receptors in the brain, so that it makes it easier to quit, both by reducing the effects of nicotine withdrawal and by reducing the nicotine associated reward that somebody feels when smoking.

Now, I would like to direct you know to "What will Happen if I take part in this Research Study?" section on the second page of the from. I'll now walk you through everything that is involved with the research study, so that you can get a better understanding of everything that we'll ask, should you choose to participate.

By previously agreeing to be contacted for future 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. 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 first to confirm that it is safe for you to take varenicline. If we determine that you are potentially eligible for this program and study, you will be scheduled to meet with our tobacco cessation specialist. 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 kidney function and alcohol use, that were measured and/or reported during your 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.

To elaborate more on what is involved with taking varenicline, as part of the program and study, FDNY Chief Medical Officer Dr. David Prezant or Dr. Shadi Nahvi will provide you with a free prescription for the medication, which you will be asked to take for a total of 16 weeks, 4 of which we recommend will lead up to the target quit date before you quit smoking.

In those first four weeks, you'll start by taking 0.5 mg of varenicline once a day for your first 3 days, then 0.5 mg twice a day for four days, and then 1 mg twice a day after that, up to, and following your quit date for the rest of the duration of the 16-week period.

You will be in the study for 28 weeks, for 16 of which, you will take varenicline.

All study visits will be conducted via video conferencing using the telehealth platform Doximity. 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 program and study visits will take place 2, 4, 8, 12, 16, and 28 weeks after your baseline appointment.

Each research study visit will last about 10 minutes. All visits will include questionnaires, a timeline follow-back assessment of past 30-day tobacco use, and varenicline use.

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. If any of the questions make you uncomfortable, you can ask to pass or not answer them. You do not have to answer any questions that you do not want to.

Around the time of each visit, we will also collect urine samples to validate self-reported cigarette cessation. We will measure cotinine levels at your first appointment and all following sessions if you report smoking abstinence. Cotinine is a byproduct created when your body breaks down nicotine. These tests are conducted for research purposes only and will be done at your convenience at the nearest Quest Diagnostics laboratory. We will order these tests for you and provide you a form to bring to the test. There will be no financial cost for you to do this.

No other procedures will take place, other than those highlighted by me here. For instance, no HIV (AIDS), illicit drug or alcohol testing will be performed on any research participant as part of this study. We will not conduct any form of genetic testing of keep or maintain any biological samples.

No audio or video recording from any of the sessions will be done.

Now, if I can direct you to page 3, I would like to go through the risk and benefits associated with your participation in this study.

The risks of participating in this study include the inconvenience of attending research and program visits, potential discomfort with answering research-related questions, potential discomfort with quitting smoking, and risks associated with the use of the medication varenicline.

Here is further 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 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 uncomfortable or 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:

The most common varenicline symptoms include Nausea, Insomnia, Headaches, Abnormal Dreams. Please note, that these symptoms are also common for people who are withdrawing from nicotine regardless of whether they are taking medication.

Other less common symptoms include, vomiting, gas, constipation, indigestion, abnormal taste, dry mouth and change in appetite. Even more rare symptoms include dizziness, fatigue, upper respiratory disorders, and skin conditions. Incredibly rare symptoms include convulsions.

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).

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.

Now, I would like to review the potential benefits of participating in our program and research study.

There may or may not be direct medical benefit to you from being in this research study.

Varenicline treatment has been shown and proven within the medical literature to help smokers quit.

There are significant health benefits that come with quitting smoking, including a reduction in the chance of developing lung disease, heart and cardiovascular diseases, and various forms of cancer.

In addition, the information learned from this study may, in the future, benefit other WTC responders with the same medical condition, as well as other people trying to quit smoking.

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).

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.

Again, there will be no costs to you for participating in this study.

Again, at any point, now or in the future, if you have any questions that arise related to this research project and health program, 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.

Do you have any other questions about the program and the research study?

4. General FDNY WTCHP Physical Health Consent (previously approved by AECOM IRB #07-09-320)

FDNY WORLD TRADE CENTER HEALTH PROGRAM
INDIVIDUAL INFORMED CONSENT TO PARTICIPATE IN CLINICAL RESEARCH
AND AUTHORIZATION TO RELEASE PERSONAL HEALTH INFORMATION

TITLE OF STUDY: Medical Surveillance in NYC Fire Department Employees Exposed to Dust during the WTC Collapse

PRINCIPAL INVESTIGATORS:	Dr. D. Prezant	TELEPHONE No.: 718-999-7019
OFFICIAL ADDRESS:	NYC Fire Department World Trade Center Health Program 9 MetroTech Center; Brooklyn, NY 1120 I	IRB PROTOCOL No.:07-09-320

By signing this form you voluntarily agree to participate as a subject in the World Trade Center (WTC) research study referenced above and authorize the principal investigators of the WTC Health Program to use and disclose your protected health information for the research as described below. FDNY is entitled to perform job-related medicals of uniformed employees without their written consent. If you wish NOT to sign this consent and authorization, the FDNY medical will still be performed but, we will not be able to analyze the data for research purposes.

The FDNY WTC Health Program is required by law to protect your health information. The consent and authorization process for the WTC Health Program is monitored by an external independent Institutional Research Review Board (IRB) at Montefiore Medical Center that protects your rights as a research participant and further protects the medical confidentiality of your medical results.

After reading and listening to an explanation of the following information, you should ask all the questions you want to ask. You will be given a copy of this form whether or not you agree to participate in this study.

The following information describes (I) The PURPOSE of the research; (2) The PROCEDURES and DISCLOSURES involved in your participation with the study; (3) The RISKS that you will be taking, if any; (4) The BENEFITS to you or to others that may result; and (5) Any ALTERNATIVE procedures or courses of treatment that may be available.

THE PURPOSE: of this study is to evaluate whether exposure to fire, smoke, dust and other items at the WTC has affected you and other firefighters, emergency medical service workers, officers, civilian FDNY employees and other workers present at the site. FDNY is already assessing your exposure as part of your regular FDNY Bureau of Health Services and/or WTC Health Program medical evaluation, and will continue to do so whether or not you sign this consent. The purpose of this consent is to agree to have your data analyzed, including your data from the WTC Health Program as well as data we will obtain through linkage with the New York State Cancer Registry and other State Cancer Registries. Your consent also allows us to store blood samples for future research.

PROCEDURES AND DISCLOSURES: If you sign consent to be a participant in this study, the WTC Health Program may perform the following tests and disclose results to the WTC Health Program Research Team at Montefiore Medical Center, the Albert Einstein College of Medicine, and the New York University School of Medicine, for the following research purposes:

1. Blood and urine test results to assess cell counts and liver, kidney and metabolic functions.
2. Blood and urine test results to assess exposure to potential toxins (Hepatitis C, heavy metals [ex. lead, beryllium and mercury, etc.], PCBs, dioxins, and other chemicals of potential concern.
3. Blood stored for analysis of proteins to assess inflammation. Blood samples will not be used for genetic studies without your separate consent.
4. Hearing, cardiogram, chest X–ray imaging and pulmonary function tests.
5. Healthcare surveillance questionnaires relevant to your health and job-related exposures including the WTC.
6. Standard clinically accepted specialized diagnostics and treatments for WTC-related or potentially related conditions.
7. Linkage to the New York State Cancer Registry and other State Cancer Registries

NO HIV (AIDS), ILLICIT DRUG OR ALCOHOL TESTING WILL BE PERFORMED ON ANY RESEARCH SUBJECT AS PART OF THIS STUDY.

RISKS: Blood drawing procedure has some risks. Your skin will be carefully cleaned over the arm with alcohol. A needle will be inserted into the vein and 50 ml of blood will be withdrawn using a tube or syringe. Rarely, the vein in which the needle was inserted may become sore, red and/or a temporary, harmless "black and blue" may develop and rarely, fainting.

BENEFITS: If you agree to take part in this study, there may or may not be direct medical benefit to you. The goal of this study is to identify and help prevent or treat health-related problems that might occur in you or other first responders after exposure to the WTC collapse or other disasters. You will receive a copy of results and may share this data with your private physician. This study will not interfere with your normal activities or normal FDNY procedures.

ALTERNATIVES: You may choose not to participate in this study. If you choose not to participate, you will continue to receive medical monitoring and treatment for which you are eligible from the WTC Health Program.

COSTS TO PARTICIPANTS There are no costs to study participants.

5. Recruitment materials

5A. Enhanced care: Opt-out letter

FDNY 911 343 BHS NEVER FORGET
WTC MEDICAL MONITORING PROGRAM
718-999-1858
wtcmed@fdny.nyc.gov

FIRE DEPARTMENT

9 METROTECH CENTER BROOKLYN, N.Y. 11201-3857

DAVID PREZANT, MD 718-999-2696
Chief Medical Officer Fax 718-999-0665
Director World Trade Center Medical Monitoring & Treatment Program
david.prezant@fdny.nyc.gov

9.11 Monitoring and Treatment

DATE

Dear: MEMBER'S NAME

You have been enrolled in our FDNY Tobacco Cessation Program research study

The FDNY World Trade Center (WTC) Health Program is a leader in documenting and treating 9/11-related illnesses. Cigarette smoking remains a leading cause of disease and death in the US. We want to help people quit.

You have been selected because you are a retired FDNY responder (firefighter or EMS provider) who was at the WTC, are enrolled in the FDNY WTC Chest CT program (CT), previously consented to WTC-related research, and indicated on your most recent monitoring exam that you currently smoke cigarettes. As part of your enrollment, we are testing the effectiveness of treatment interventions specifically designed to help individuals *stop* or *reduce their smoking* with minimal discomfort.

You have the access to the following *free* tobacco cessation program services:

- A prescription of Varenicline, a medication approved by the US FDA in 2006 to help people quit smoking **by reducing cravings**.
- 7 free counseling telehealth sessions provided through the FDNY WTC Health Program tobacco cessation program individually tailored based on your chest CT and lung function testing results.
- Nicotine Replacement Therapies, as needed.

Your pension status cannot be affected by participation in this program

Your results will NOT be shared with FDNY, the Pension Board, or any insurance company. This program will be conducted over the course of 28 weeks (7 brief telehealth visits). We strongly encourage and appreciate your participation. We will provide a $30 reimbursement for each visit (for up to a total of $210).

Should you choose to ***opt-out*** of these free clinical services, please call **Tyrone Moline at 718-403-4422 or email tyrone.moline@fdny.nyc.gov.**

We strongly encourage and appreciate your participation.

Thank you and stay safe,



Dr. David Prezant

5B. Standard Care: Opt-in letter

FIRE DEPARTMENT

9 METROTECH CENTER BROOKLYN, N.Y. 11201-3857

DAVID PREZANT, MD 718-999-2696
Chief Medical Officer Fax 718-999-0665
Director World Trade Center Medical Monitoring & Treatment Program
david.prezant@fdny.nyc.gov

WTC MEDICAL MONITORING PROGRAM
718-999-1858
wtcmed@fdny.nyc.gov

DATE

Dear: MEMBER'S NAME

You have been identified as a candidate for our FDNY Tobacco Cessation Program research study

The FDNY World Trade Center (WTC) Health Program is a leader in documenting and treating 9/11-related illnesses. Cigarette smoking remains a leading cause of disease and death in the US. We want to help people quit.

You have been selected because you are a retired FDNY responder (firefighter or EMS provider) who was at the WTC, are enrolled in the FDNY WTC Chest CT program (CT), previously consented to WTC-related research, and indicated on your most recent monitoring exam that you currently smoke cigarettes. As part of your enrollment, we are testing the effectiveness of treatment interventions specifically designed to help individuals *stop* or *reduce their smoking* with minimal discomfort.

You have the access to the following *free* tobacco cessation program services:

- A prescription of Varenicline, a medication approved by the US FDA in 2006 to help people quit smoking **by reducing cravings**.
- 7 free counseling telehealth sessions provided through the FDNY WTC Health Program tobacco cessation program.
- Nicotine Replacement Therapies, as needed.

Your pension status cannot be affected by participation in this program

Your results will NOT be shared with FDNY, the Pension Board, or any insurance company. This program will be conducted over the course of 28 weeks (7 brief telehealth visits). We strongly encourage and appreciate your participation. We will provide a $30 reimbursement for each visit (for up to a total of $210).

Should you choose to access these free clinical services, please call **Tyrone Moline at 718-403-4422 or email tyrone.moline@fdny.nyc.gov.**

We strongly encourage and appreciate your participation.

Thank you and stay safe,



Dr. David Prezant

Appendix 6: Clinic Behavioral checklist for enhanced care:

Strengthen ex-smoker identity
Elicit patient views
Measure Nicotine Metabolites
Give options for additional and later support
Provide rewards contingent on successfully stopping smoking
Advice on changing routine
Facilitate relapse prevention and coping
Ask about previous experiences with stop smoking medications
Advice on stop smoking medication(s)
Advise on/facilitate use of social support
Summarize information/confirm patient decisions
Provide reassurance
Boost motivation and self-efficacy
Provide information on withdrawal symptoms
Explain the purpose of CO/ Nicotine monitoring
Use reflective listening
Help patients to obtain medication
Advice on avoidance of social cues for smoking
Advice on environmental restructuring
Assess current and past smoking behavior
Assess current readiness and ability to quit
Assess past history of quit attempts
Assess withdrawal symptoms
Build general rapport
Elicit and answer questions
Emphasize choice
Explain expectations regarding treatment program
Explain the importance of abrupt cessation
Facilitate action planning/help identify lapse triggers
Facilitate barrier identification and problem solving
Facilitate goal setting
Identify reasons for wanting and not wanting to stop smoking
Offer/direct toward appropriate written materials
Prompt commitment from the patient
Prompt review of goals
Prompt self-recording of tobacco use
Provide feedback on current behaviors
Provide information on consequences of tobacco and tobacco abstinence
Provide normative information about others' behavior and experiences
Rewards contingent on effort or progress
Set tasks / homework
Tailor interaction appropriately

Adapted from The Manual of Smoking Cessation: A Guide for Counsellors and Practitioners By Andy McEwen, Peter Hajek, Hayden McRobbie and Robert West (2006) Blackwell Publishing, ISBN 1405133376, paperback. *Journal of Smoking Cessation,* 2(2), 77-77. doi:10.1375/jsc.2.2.77