THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Optimizing Effectiveness of Smoking Cessation Intervention during Low Dose CT Screening for Lung Cancer
2016-0626
Subtitle: Luna

Study Chair: Paul Cinciripini

Participant's Name

Medical Record Number or Study ID

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study.

1. DESCRIPTION OF STUDY

The goal of this clinical research study is to offer lung cancer screenings to smokers who want to change their smoking behaviors. All eligible participants will receive smoking cessation counseling and may be offered at least one form of smoking cessation drug. Different forms of counseling (the delivery of counseling and access to counseling) will be compared.

This is an investigational study. Participants on this study will not be prescribed smoking drugs directly by the study staff. However, participants in this study may or may not receive smoking cessation drugs, depending on what the provider thinks is in the participants best interest. All smoking cessation drugs being used are FDA approved and commercially available. It is investigational to compare the different forms of counseling participants receive.

Counseling and smoking cessation drugs (if applicable) will be provided at no cost to you.

Up to 1260 participants will be enrolled in this study. All will take part at MD Anderson.

2. STUDY PROCEDURES

Screening Tests

Signing the informed consent document does not mean that you will be able to take part in this study. The following screening tests will be completed to determine if you are eligible:

- You will be asked about your history of smoking and tobacco use, as well as alcohol use.
- You will complete questionnaires about depression, emotions, motivation, negative events, suicide, and your dependence on smoking. These questionnaires should take about 30 to 45 minutes total to complete.
- Your carbon monoxide (CO) level will be measured. CO is a gas that is found in higher levels among cigarette smokers. For this test, you will be asked to blow air through a CO-measuring device.
- If you can become pregnant, you will have a urine pregnancy test. To take part in this study, you must not be pregnant.

The study staff will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will have a CT scan of your chest to look for signs of lung cancer. You will receive the results 0-4 days after the scan. If there are any abnormal areas, you will be referred to your regular doctor for follow-up. No matter what the results are, you will be advised to quit smoking.

You will have a decision-making conversation with the CT scan provider or a study staff member before you have the CT scan about the risks and benefits of a CT scan. This discussion may include watching a short video (about 9 minutes), reviewing a smart phone application ("app"), a power-point presentation, or a face-to-face conversation about lung cancer, CT scans, and smoking cessation. You will also receive a referral for counseling to help you reduce/quit smoking. You may also discuss medications you can take to reduce smoking.

As part of your counseling treatment, you may be prescribed an FDA-approved and commercially available anti-smoking drug. This may be either nicotine replacement therapy (such as a patch, gum, or lozenge) or an oral drug (such as varenicline or

buproprion). The provider will tell you when and how much of your anti-smoking drug you should take each time, based on a discussion between you and your provider. Receiving anti-smoking medication will be done through your counseling treatment and not as part of your participation in this study.

You will have at least 5, but no more than 8, smoking cessation counseling sessions over the next 12 weeks. Each session will last between 30 - 60 minutes, in which you will set a quit date, prepare for your quit date, and discuss coping skills for dealing with smoking "triggers" after your quit date. You will also discuss challenges you may have with quitting.

Study Visits

You will have 3 additional study visits, at around 6 weeks, 12 weeks, and 6 months after the screening visit,-as well as 1 follow-up phone call. At all study visits:

- You will complete questionnaires about several topics, including depression, suicide, and your smoking behavior. These questionnaires should take about 30-45 minutes in total to complete.
- Your CO level will be measured.
- Urine and/or saliva will be collected (at 12 weeks and 6 months only) for a routine test to check your cotinine and nicotine. Cotinine is a chemical released in your body when it breaks down nicotine and will show whether and how much you have recently smoked.

Follow-Up

About 5 months after you start receiving counseling sessions, you will be called by a member of the study staff and asked about your recent smoking behaviors and habits. This call should last about 5-10 minutes.

3. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person and will be discussed with your provider before receiving any smoking cessation medications. In addition to a discussion with your provider, you will be given standard patient package inserts for any medication you are prescribed.

Tell your provider of any side effects you may have, even if you do not think they are related to the tobacco cessation medications/procedures.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel "closed in" while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with

doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaires, you are encouraged to contact your doctor or the study chair.

You may experience **nicotine abstinence/withdrawal effects** if you quit smoking. These effects may include irritability, difficulty concentrating, difficulty sleeping, anxiety, voice changes, and increased hunger. None of these effects result in serious adverse health effects.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: You will be allowed to choose your preferred method (text messaging, emails, phone calls, or in-person discussions) to receive study-related communications such as visit reminders, study letters, lab reports, and so on. You will be told which methods are secured and which are not. If you choose to receive communications by an unsecured method (text messaging or unencrypted [unsecured] emails), you will mark your preference on the Optional Procedures signature page below. If you do not wish to receive your communications by an unsecured manner, you will receive your communications in a secure manner (phone calls, encrypted emails, or in-person discussions). For encrypted emailing, you will need to log in to the MD Anderson secured system.

There are no benefits to you for taking part in the optional procedure. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

Optional Procedure Risks:
Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to receive study communications by an

unsecured method (text messaging or unencrypted emails) because that is your preference?

YES NO

4. POTENTIAL BENEFITS

CT scans may cause lung cancer to be detected and cared for earlier than normal. Taking part in this study may help you quit smoking and reduce your risk of cancer. Future patients may benefit from what is learned There may be no benefits for you in this study.

5. OTHER PROCEDURES OR TREATMENT OPTIONS

You may choose to receive smoking cessation therapy without taking part in this study.

6. STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or National Cancer Institute for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

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

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

You may be compensated by way of a reloadable, prepaid Bank of America card up to $200 for participation in this study. You will receive $50 ($40 for time; $10 for completing questionnaires prior to each visit) for each in-person visit (Baseline, Week 6; Week 12 and 6 month after starting treatment).

ADDITIONAL INFORMATION

7. You may ask the study chair (Dr. Paul Cinciripini, at 713-792-0919) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

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

9. This study or your participation in it may be changed or stopped at any time by the study chair, National Cancer Institute, or the IRB of MD Anderson.

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

11. MD Anderson may benefit from your participation and/or what is learned in this study.
12. This study is sponsored and/or supported by: National Cancer Institute.

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

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:

- The OHRP
- The IRB and officials of MD Anderson
- National Cancer Institute, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Alere Wellbeing, Inc. (Quitline), MD Anderson's Tobacco Treatment Program (TTP), Arrowhead Promotion and Fulfillment and Salimetrics
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

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

Information you provide on questionnaires regarding anxiety, depression, alcohol use, sleeping difficulties, smoking withdrawal symptoms, nicotine dependence and smoking may be used by your counseling provider, so that you do not have to fill out these questionnaires twice. Some of the data you provide to your counseling provider regarding mood, nicotine withdrawal, and smoking may be provided to this study so that

it does not have to be collected twice, however some questions may overlap between some of the questionnaires.

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

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

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

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

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

CONSENT/AUTHORIZATION

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

SIGNATURE OF PARTICIPANT DATE

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR DATE

RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2016-0626**.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT

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

SIGNATURE OF STUDY CHAIR
OR PERSON AUTHORIZED TO OBTAIN CONSENT

DATE

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE