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Implementation of Smoking Cessation Services within NCI NCORP Community Sites with Organized Lung Cancer Screening Program

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Study Title for Study Participants: Implementation of Smoking Cessation Services (OaSiS)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: **Implementation of Smoking Cessation Services within NCI NCORP Community Sites with Organized Lung Cancer Screening Program**

Informed Consent Form to Participate in Research for Patient Participant

Site Principal Investigator

Introduction

You are being invited to participate in a research study. The clinic you are visiting is part of a randomized trial designed to test whether or not training lung cancer screening staff improves their ability to help patients quit smoking. We are working with 26 clinics across the United States; half of the clinics receive training and half of the clinics do not receive training. We are inviting you to participate in this study to help us evaluate the effectiveness of our training.

Please take your time to make your decision about volunteering. You may discuss your decision with your friends and family. You can also discuss this study with your health care team. If you have any questions, you can ask your study coordinator for more information. You should only agree to participate in this study when you are comfortable enough with the information so that you can make an informed decision about joining.

Why is this study being done?

The study is intended to help lung cancer screening clinics do a better job of supporting patients who want to quit smoking. The purpose of this study is to determine the best ways to deliver smoking cessation services during lung cancer screening. Today, we will ask you to complete a short questionnaire, less than 15 minutes. We also request your permission to obtain the results of your lung cancer screening exam and combine these results with the questionnaire results. We expect to enroll 1,114 participants.

What is the usual approach to my care?

You are being asked to participate in this study because you have smoked at least once in the past 30 days. You will be provided with the usual smoking cessation services offered by the clinic for patients who smoke and are being screened for lung cancer. Additional smoking cessation services may also be offered and will vary from clinic-to-clinic. Services may include providing you with brochures, sharing a Quitline telephone number with you, counseling, or nicotine replacement. You are under no obligation to accept any of these services and your decision to accept or reject these services does not impact your ability to be screened for lung cancer.

What are my other choices if I do not take part in this study?

Your care does not depend on your participation in this research study. You may choose to participate or not without any impact on your screening visit today. If you decide to participate, you can decide to stop at any time. There is no penalty for choosing not to participate, and your doctor will not change your care in any way.

What are the study groups?

In this study, clinics are randomly assigned into two groups (similar to flipping a coin). One group of clinics will provide patients with their usual smoking cessation services that are already routinely offered for all smokers who are screened for lung cancer. Health care team members of the other group of clinics will receive special training on how best to implement smoking cessation services for patients undergoing lung cancer screening.

How long will I be in this study?

Today you will complete a brief 15 minute questionnaire. We will contact you again by telephone within two weeks of today's visit to conduct a 5-minute questionnaire about your experience during today's visit. We will also contact you in 3 months and in 6 months and conduct a 5-10 minute telephone survey. Thus, you will be in this study for a total of 6 months. You can stop participating at any time. This clinic is committed to providing you with high quality of care regardless of whether or not you choose to participate.

You will receive a $10 gift card after completion of each survey as a thank you for your time.
If you have not smoked any cigarettes within the last 7 days when we call you in six months, we will send you, by mail, a saliva collection kit. The saliva kit includes a plastic vial that contains a small cotton roll, like those used by dentists and written instructions on how to use it. The purpose of the saliva kit is to verify your smoking status by measuring cotinine in your saliva. Cotinine is routinely used to verify if individuals have nicotine in their body. After we receive your saliva specimen, determine the cotinine level, and record the information, we will properly dispose of the saliva kit—it will not be saved. You will be provided with a postage paid return envelope to mail back your kit. After your saliva collection kit has been received by the lab, you will receive a $20 gift card in the mail as a thank you.

What extra tests and procedures will I have if I take part in this study?

Aside from interviews and saliva collection, there are no additional tests or procedures involved if you take part in this study.

What possible risks can I expect from taking part in this study?

Risks of this study include that some individuals may find discussing their smoking status or other personal information with others to be uncomfortable, embarrassing, and/or stressful. Every effort will be made, however, to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study. Although unlikely, there also may be other side effects that we cannot predict.

What possible benefits can I expect from taking part in this study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, we ask that you let the study staff person know as soon as possible.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____(insert name of center) *Institutional Review Board at* _____(insert telephone number). (Note to Local Investigator: Contact information for participant representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)

What are the costs of taking part in this study?

There are no costs to you for taking part in this study. All study costs, including any study treatment or materials, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

What happens if I am injured or hurt because I took part in this study?

If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study coordinator immediately. You will get medical treatment if you are injured or hurt as a result of taking part in this study. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be responsible for any costs. Even though you are in a study, you keep all of your legal rights to receive payment for injury caused by medical errors.

Who will see my medical information?

Your privacy is very important to us and we will make every effort to protect it. Your information may be given out if required by law. Your study information will be kept in a central database for research purposes only. Your name or contact information will not be put in this database. You will be given a study identifier that will be used for all research data. Data obtained as part of this study will be sent to a coordinating center, organized by the National Cancer Institute, and combined with data from other similar research studies. The data will be de-identified, such that your identity will not be known and cannot be linked to the study data.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board (IRB) is a group of people who review the research with the goal of protecting the people who take part in the study.
- The National Cancer Institute in the U.S.
- The Wake Forest NCORP Research Base

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: [redacted].

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.

Who can answer my questions about this study?

You can talk to study staff about any questions or concerns you have about this study or to report side effects or injuries to _____Site Principal Investigator at telephone number _____ if you have any questions or concerns.

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

Participant's signature_____

Date of signature_____ Time of signature: _____ AM/PM

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____ Time of signature: _____ AM/PM