Research Study Informed Consent Document

Study Title for Participants: Smoke Free Support Study 2.0

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: EAQ171CD Implementing a Virtual Tobacco Treatment in Community Oncology Practices NCT03808818

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Overview and Key Information

What am I being asked to do?

We are asking you to take part in this research study because you routinely assist in the care or study of patients diagnosed with cancer. This study will enroll approximately 10 oncology care providers, oncology-research and oncology-care-support staff per NCORP site, across multiple NCORP sites in the United States.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time.

This document has important information to help you make your choice. Take time to read it. Talk to your colleagues about taking part in the study. It is important that you have as much information as you need and that all your questions are answered.

Why is This Study Being Done?

The purpose of this study is to compare the effectiveness of two smoking cessation treatment strategies for tobacco dependent cancer patients and to examine barriers that might facilitate or impede implementation of tobacco treatment delivery in community oncology practices.

What will happen if I decide to take part in this study?

Rev. Add4

If you decide to participate in this study, you will be asked to complete three surveys: one at the start of the study and again at about 12 months and 36 months after starting the study. You will also be asked to participate in one focus group about tobacco treatment delivery in

your community oncology setting.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

There is minimal risk associated with participating in this study. There are no physical risks. There is some potential risk that you may feel uncomfortable answering survey questions about the challenges of assessing and treating tobacco dependence at your NCORP worksite. However, survey questions are brief and have been used in other similar health care delivery studies without untoward effects. Nonetheless, you are entitled to decline to answer any questions that you may find sensitive. There will be no penalty or loss of employee benefits to you if you decline to answer a question.

Benefits

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about delivery of tobacco treatment in cancer care settings.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time. If you decide to stop, let the study researchers know as soon as possible. The researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to compare the effectiveness of two smoking cessation treatment strategies for tobacco dependent cancer patient. The study will compare a virtual telehealth intervention and a referral to a national quitline in producing abstinence at 3 and 6 months. At the organizational level, this study will also examine potential barriers that might impede implementation of tobacco treatment delivery in community oncology practices. The goal of this study is to establish the effectiveness and cost of delivering a virtual tobacco cessation intervention in community oncology settings and provide initial implementation data to inform broader national dissemination.

What is involved in this study?

If you decide to participate in this research study, you will be asked to complete three online

surveys and participate in one focus group interview focusing on possible barriers and facilitators of tobacco treatment delivery in your community oncology setting. The three surveys will each require approximately 15 minutes of your time and will be administered at
Rev. Add4 baseline and at 12 and 36 months follow-up. The content of the survey and focus group interview questions will examine your beliefs, attitudes and current practices regarding tobacco treatment in the context of cancer care. The focus group interview will be conducted using WebEx conference call software, will require about 60 minutes of your time and the audio portion will be recorded.

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

General Risks

There is some potential risk that your study information could become known to someone who is not involved in performing or monitoring this study. It is also possible that you may feel anxious from knowing that your conversations with the study staff and other colleagues at your NCORP site are being audio-recorded. If you feel uncomfortable about being audio-recorded after the recording has begun, you may request that the study team stop the audio recorder at any time. Please be advised that although the study staff will take every precaution to maintain confidentiality of the focus group interview data, the nature of focus group discussion prevents the study staff from guaranteeing confidentiality. The study staff have extensive experience collecting focus group data and will remind participants to respect the privacy of fellow group members and not repeat what is said in the focus group to others. To further protect your confidentiality, we will ask participants to avoid using their full name or the full names of their NCORP site colleagues during the discussion. We will also remind participants to respect different perspectives and opinions of focus group participants so as to allow for open discussion of the perceived challenges of assessing and treating tobacco dependence within NCORP sites.

What are the costs of taking part in this study?

There are no costs involved with participation in this study. Depending on your institution's regulations, you may receive small financial remuneration as a token of appreciation for your participation in the study. This may include up to $100 in gift card incentive, in total, for completion of the baseline, 12 month, and 36 month surveys, ($20 per survey) and the focus group interview ($40).

Who will see my information?

Your privacy is very important to us. The study researchers will make every effort to protect it. The study researchers have a privacy permit to help protect your records if there is a court case. However, some of your information may be given out if required by law. If this should happen, the study researchers will do their best to make sure that any information that goes out to others will not identify who you are.

Conversations that are recorded throughout your participation will be transcribed and coded

with a study ID number. Only study staff and trained transcriptionists will have access to the audio files. All identifying information will be redacted in the written transcript. The audio files will be destroyed once the study is complete. Retained data (transcripts and surveys) will be de-identified once data collection is complete.

While there will likely be publications as a result of this study, your name will not be used. Only group characteristics will be published. If you participate in this study, we would like to be able to quote the words you have used without using your name. If you agree to allow us to quote you in publications, please initial the statement at the bottom of this form.

There are organizations that may look at your study records. Your information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Memorial Sloan Kettering Cancer Center
- Massachusetts General Hospital
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.

In the future, other researchers may find it valuable to use the transcripts of the audio recorded conversation obtained from this study. While we are primarily interested in the conversation to analyze your feedback on tobacco treatment implementation, because the transcripts of the audiotapes have possible value to other researchers, we would like your permission to let other researchers use these transcripts for future research studies. These researchers would not have any information about who you are.

I give my permission for the use of the de-identified transcripts for future research:

_____YES

_____NO

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: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study coordinator about any questions or concerns you have about this study. Contact the study coordinator (*insert name of study coordinator[s]*) at (*insert

telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

^Note to Local Investigator: Contact information for patient 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. ^

My signature agreeing to take part in the study

I have read this consent form and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature _____

Date of signature _____

Signature of person(s) conducting the informed consent discussion _____

Date of signature _____