Participant Informed Consent for Clinical Research

Study title for participants: A Study to Develop a Strategy to Increase Lung Cancer Screening in Women Who May Be at Risk for Lung Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: Leveraging Mammography to Identify and Engage Women at Risk for Lung Cancer in Lung Cancer Screening

Lead Researcher: Tali Amir, MD (201-755-7153)

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you recently had a mammogram at Memorial Sloan Kettering Cancer Center (MSK) and Hartford Healthcare Alliance, and during your visit you informed us that you currently smoke or you have smoked in the past.

Researchers have found that lung cancer screening with an imaging procedure called low-dose computed tomography (LDCT) can help identify tumors early enough that they are treatable. During an LDCT scan, you lie on a table and an X-ray machine uses a low dose of radiation to make detailed images of your lungs. However, many people who are eligible for this cancer screening do not receive it because they are unaware of it.

We are doing this study to develop a digital strategy to increase awareness about lung cancer screening among women who are eligible to receive it. The digital strategy involves email communications and LungTalk, a web-based (accessed through the Internet) health communication tool that uses text, audio, video, and animation to increase awareness and knowledge about lung cancer screening. For this study, we will focus on women who have recently received a screening mammogram. Researchers have found that many more women schedule a mammogram to screen for breast cancer than they do an LDCT to screen for lung cancer. We think that the period of time right after the mammogram may be the ideal time to increase awareness and knowledge about lung cancer screening.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach for screening for lung cancer?

People who are not in a research study usually learn about screening for lung cancer through their regular healthcare provider(s). People who decide to have a screening for lung cancer will have an LDCT scan, which can help identify tumors.

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

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

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

If you decide to take part in this study, you will complete questionnaires online three times over 6 months. The questionnaires will ask for your demographic information (for example, your age, race, education, etc.), and they will ask about your health, smoking status (information about your current and past smoking), and knowledge of lung cancer and lung cancer screening.

You will complete the first questionnaire after you agree to participate in the study. You will also be provided with a website link to LungTalk, a health communication tool that uses text, audio, video, and animation to increase awareness and knowledge about lung cancer screening. You must use the tool within 7 days after you complete your first questionnaire.

You will complete another questionnaire 1 week and 6 months after you use LungTalk. After you fill out the 6-month questionnaire, your participation in the study will be complete.

Note that you will not receive a lung cancer screening as part of this study. You will need to contact your healthcare provider if you are interested in scheduling this screening.

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 to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

There is no physical risk involved in participating in this study but filling out the questionnaires may make you feel uncomfortable, stressed, or upset. Please note that you are not required to answer any questions that cause you to feel uncomfortable, stressed, or upset.

There is also a possible risk of loss of confidentiality (someone who shouldn't see your information will get access to it). Every effort will be made to keep your information confidential. However, this cannot be guaranteed.

Benefits

Participating in this study may increase your knowledge and awareness about lung cancer screening. However, participating in this study may not have any positive effect on your future health. What we learn from this study may help other people in the future.

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

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), US Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

We are doing this study to develop a digital strategy to increase lung cancer screening in women who are eligible to receive it. The digital strategy involves email communications and LungTalk, a web-based (accessed through the Internet) health communication tool that uses text, audio, video, and animation to increase awareness and knowledge about lung cancer screening. For this study, we will focus on women who have received a mammogram. Researchers have found that many more women schedule a mammogram to screen for breast cancer than they do a low-dose computed tomography (LDCT) scan to screen for lung cancer. We think that the period of time right after the mammogram may be the ideal time to increase awareness and knowledge about lung cancer screening.

Other purposes of this study include looking at the following:

- Whether it's practical (feasible) to approach women who have received a mammogram about lung cancer screening awareness
- The impact of the digital strategy on people's knowledge and awareness about lung cancer screening and their participation in lung cancer screening

Lung cancer screening with the imaging procedure LDCT can help identify tumors early enough that they are treatable. It's important for people who are at high risk of developing lung cancer to receive a lung cancer screening. However, many people who would benefit from this screening do not receive it because they are unaware of it. This study will provide us with information about how to increase

awareness and knowledge about lung cancer screening. The study may also help us find ways to approach screening for other types of cancer or diseases.

About 150 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK) and Hartford Healthcare Alliance.

What are the study groups?

All study participants will complete the same questionnaires and use the LungTalk tool.

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

You will not have to come to the clinic for any extra study visits or procedures.

After you sign this consent form, you will complete your first questionnaire (baseline questionnaire), which will ask for your demographic information (for example, your age, race, education, etc.) and ask about your health, smoking history, and knowledge of lung cancer and screening for lung cancer. The questionnaire will take about 25 minutes to complete.

We encourage you to complete this study's questionnaires electronically. You will receive an email with a link to the survey for you to complete at your convenience. However, if you prefer, you may complete the questionnaires over the phone with a member of the study team, or you may complete them on paper and mail them to the study team.

After you complete your first questionnaire, you will receive an email with a website link to the LungTalk tool. To use LungTalk, you must click the link you receive in your email since it will contain a specific code for you to access the tool. LungTalk uses text, audio, video, and animation to increase awareness and knowledge about lung cancer screening. It will take about 15 minutes for you to use the tool. You may use the tool in one sitting or multiple sittings, depending on how much time you have. However, you must use the tool within 7 days after you complete your first questionnaire.

You will complete questionnaires 1 week and 6 months after you use LungTalk. These questionnaires will ask about your knowledge of lung cancer and screening for lung cancer. They will also ask about whether you've talked to family members or people in your social network about lung cancer screening. The second questionnaire will take about 17 minutes to complete, and the third will take about 5 minutes to complete.

After you fill out the 6-month questionnaire, your participation in the study will be complete.

Note that you will not receive a lung cancer screening as part of this study. You will need to contact your healthcare provider if you are interested in scheduling this screening.

Will I receive the results of my research tests?

You will not receive the results of any evaluations done for research purposes during this study.

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

If you choose to take part in this study, there is a risk that:

- You may be asked sensitive or private questions that you do not usually discuss

There are no physical risks involved in participating in this study. You may feel uncomfortable, stressed, or upset when you are filling out the questionnaires. You do not have to answer any questions that cause you to feel uncomfortable, stressed, or upset. If you become very upset while you are taking part in this study, we can give you a list of counseling resources that might be helpful.

MSK will protect your personal information (data), so that your name and any other identifying information will be kept private. The chance that your information will be given to anyone other than the people or organizations named in the Research Authorization form (below) is very small.

Let the study doctor know about any questions you may have about possible risks of taking part in this study.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Let the study doctor know if you skipped or chose not to answer any of the questions in the questionnaire/survey.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK). There are no known investigator and/or institutional conflicts of interest for this study.

What are the costs of taking part in this study?

There is no additional cost to you for taking part in this study.

You and/or your health plan/insurance company will have to pay the costs of preventing/treating cancer while you are participating in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will receive a $20.00 electronic gift card for each set of questionnaires you complete (baseline, 1 week after LungTalk, 6 months after LungTalk), for up to a total of $60 in electronic gift cards. After you complete each questionnaire, you will receive an electronic gift card by email.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for 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 doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

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

A Study to Develop a Strategy to Increase Lung Cancer Screening in Women Who May Be at Risk for Lung Cancer

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Tali Amir, MD and Jamie Ostroff, PhD.
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSKCC, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant. In my judgment, and in that of the participant, sufficient information, including risks and benefits, was provided for the participant to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my protected health information (data about myself); and (3) to state that I have received a signed and dated copy of this consent form.

Participant must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's language, and I confirm that the consent discussion was appropriately interpreted for the participant.
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant must be provided with a **signed copy** of this form.