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Fred Hutchinson Cancer Center

Consent to take part in a research study:

Tailoring Screening and Smoking Cessation for the LGBTQ Community

Aim 3 Navigation Intervention & Shared Decision Making

Project Leader: Matthew Triplette, MD, MPH. University of Washington; Fred Hutchinson Cancer Center. Telephone: 206-667-6335

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to evaluate an intervention used to improve lung cancer screening and smoking cessation for members of the lesbian, gay, bisexual, trans and queer (LGBTQ) community.

People who agree to join the study will be asked to attend 2 study visits and participate in a "navigation intervention". The initial study visit will be with a patient navigator to discuss the process of lung cancer screening (LCS) and tobacco cessation services. The "navigation intervention" involves a series of predominantly phone contact with the patient navigator through the LCS care process. A second study visit will occur at three months. During both study visits you will be asked to exhale into a carbon monoxide monitor. Carbon monoxide gives us an indication of recent exposure to tobacco smoke.

You do not have to join this study. Participation in this study may benefit you personally, as you will have access to a patient navigator during the study. We also hope the information we learn will help people undergoing lung cancer screening and smoking cessation programs in the future. Participating in the study should not be associated with any significant harms to you, but we will outline these further below.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to understand how to provide more effective smoking cessation and lung cancer screening (LCS) services for LGBTQ persons. In this portion of the study, we want to evaluate a "navigation intervention", a tailored approach to lung cancer screening and smoking cessation for members of the LGBTQ community.

Since you are a member of the LGBTQ community who is eligible for lung cancer screening, we are interested in you joining our study.

If you agree to be in this study:

- During a scheduled study visit, you will meet with a patient navigator to discuss the process of lung cancer screening and tobacco cessation services.
- You will complete a pre-intervention survey.
- You will exhale into a personal disposable adaptor which measures your carbon monoxide levels at two time points.
- You will receive the following "navigation intervention":
    - You will periodically communicate with a patient navigator/tobacco treatment specialist by phone.
    - The patient navigator will provide information surrounding the LCS process, deliver a smoking cessation intervention and if interested, link you to alternative treatment options.
    - You will have the opportunity to discuss your experiences and opinions surrounding smoking cessation and lung cancer screening with the patient navigator.
    - You will allow a research coordinator to selectively listen in on your navigation visit.
- You will have the opportunity to discuss lung cancer screening with a nurse practitioner and decide whether lung cancer screening is right for you in a shared decision-making visit.
- During a scheduled study visit 3 months after enrollment, you will complete a post-intervention survey.
- You will have the opportunity to discuss your experience and opinions of the "navigation intervention" in a post-intervention interview. This will be recorded and transcribed.
- We will follow your lung cancer screening results through review of the medical records.
- You will have the opportunity to participate in a referral recruitment program with cash incentive. Participation is not required and will not otherwise influence services you receive as part of this study.

If you agree to join this study, your participation will last for approx. 3 months.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

If you leave this study, you study records and transcripts will be destroyed and you will not be included in the study results.

What are the risks?

- The questions we ask about your medical history in the survey may be sensitive and may make you feel uncomfortable.
- There is minimal risk to using the carbon monoxide monitor with a very small risk of feeling light-headed after exhaling.
- There is a slight risk of loss of confidentiality.

What are the benefits?

The study may benefit you directly as a person who may have lung cancer screening or use smoking cessation resources. However, we cannot guarantee this. We hope the information we learn will help people undergoing lung cancer screening and/or smoking cessation programs in the future.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

If you join this study, some people and organizations might need to look at your self-reported data from the surveys you complete or data from your medical records. They include:

- Researchers involved with this study.
- LUNGevity (the study sponsor) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Office for Human Research Protections (OHRP)
- Fred Hutchinson Cancer Center, and University of Washington.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

Will you pay me to be in this study?

If you complete this study, you will receive $40 for completing the initial study visit and pre-survey, an additional $40 for following the "navigation intervention" and completing the post-survey 3 months after enrollment, $20 for completing the post-intervention interview, and travel reimbursement as needed.

Individuals who refer eligible individuals to join the study will receive a $10 incentive by mail following enrollment of eligible persons (max $20, or 2x incentive payments).

How much will this study cost me?

There are no costs for being in this study. All the costs associated with usual clinical care are the responsibility of the participant.

What if you get sick or hurt after you join this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact your primary care provider. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for?

Your information will be used for the purposes of this study.

During this study, if the researchers learn new information that may be important to your general health or to your disease or condition they will share that information with you. We will share results of this study with patients undergoing lung cancer screening in our program and the faculty of the Madison Clinic.

In addition to the planned uses described above, we might remove all identifiers and codes from your information. We could then use or share them with other researchers for future research. If you do not want your anonymous information used for other projects, you should not participate in this study.

If we do share your information with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information back to you. We will not contact you or otherwise inform you before we share your information for future research.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

For more information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. Other people you can talk to are listed below.

If you have questions about:	Call:
This study (including complaints and requests for information)	206-667-6335 (Dr. Matthew Triplette) 206-667-4589 (Madison Snidarich, research coordinator)
If you get sick or hurt in this study	206-667-6335 (Dr. Matthew Triplette)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to participate in this study? (circle one)			
YES	**NO**	Initials:	Date:

Is it OK if someone contacts you in the future to ask you about future research studies on lung cancer screening? (circle one)			
YES	**NO**	Initials:	Date:

Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant :

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol:
Current version date:
Previous version date:
Copies to: