Washington University in St. Louis

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INFORMED CONSENT DOCUMENT- In Person

Project Title: Implementation Science to reduce the disparity in tobacco treatment among individuals with serious mental illness (IS-RAISE)

Principal Investigator: Li-Shiun Chen, MD
Research Team Contact: Jimmy Reddy, Research Assistant
Phone Number: 314-362-1030

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you may find important.

This is a research study conducted by Li-Shiun Chen, MD to better understand how to reduce smoking. You were invited because you are a patient who smokes at Washington University. Taking part in this research study is completely voluntary. You may choose not to take part at all. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could decide not to be in the study at all or ask your doctor about information about your tobacco use.

If you agree and sign this consent, you will be volunteering to participant in a research study. As a voluntary participant, your involvement will last approximately 6 months and you will be asked to complete three surveys. As part of this study you will be randomly assigned to receive information on smoking cessation and a brief coaching session either at the beginning of the study (at the end of visit 1) or approximately 3 months later (at visit 2). You may choose to complete these surveys in-person at Washington University, over the phone, or via secure video conference. You will at no time be required to answer any survey questions that you do not feel comfortable answering.

One risk of participating in this study is that confidential information about you may be accidentally disc losed or you may experience some questions that make you feel uncomfortable. You may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because it will help us advance the delivery of smoking cessation treatment. You do not need to participate in this study to discuss or receive smoking cessation treatment from your clinician. You may contact your clinician at any time to discuss these options without participating. By volunteering, you may help someone else, in the future. There is no cost to you and you will be paid up to $150 for being a volunteer participant.

All of the information below will be explained and is listed in more detail in the consent document below.

WHAT WILL HAPPEN DURING THIS STUDY?

As part of this study you will be randomly assigned (50/50 chance of being in either group) to receive information on smoking cessation and a brief coaching session either at the beginning of the study (at the end of visit 1) or approximately 3 months later (at visit 2). The coaching session will take about 5 minutes. A message will be sent to you (mail and email) and your provider (secure email or inbasket message) with information on your medication and smoking cessation program interest and brief advice about how smoking cessation medication and evidence-based programs may help improve your chances of quitting. Additionally, this message will encourage you to consider talking to your doctor about these options.

All visits can take place either in person or remotely.

- Visit 1: The study team will ask you questions about your demographics, health, social history (i.e. alcohol, marijuana, tobacco use, vaping), and treatment information. During this time, you will also receive a hand out about tobacco use.
    - Your smoking information and other information you tell us may be shared with your care team.
- Visit 2: Three months later, the study team will ask similar survey questions. We may also ask you to complete a carbon monoxide breath test if you report that you quit smoking cigarettes. This is a non-invasive breath test that measures the amount of carbon monoxide on a person's breath. The test takes one minute to complete and involves exhaling into a carbon monoxide monitor for a maximum of 4 times during the visit. The results of the test are then recorded by a study team member.
- Visit 3: Six months later, the study team will contact you for the final survey.

If you tell us that you are thinking about hurting yourself or others, the research staff may give you referrals for treatment or work with you to contact your personal doctor or therapist to discuss your thoughts of harming yourself. We may need to work with you on a plan that might include getting you to a medical facility for safety. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) or St. Louis Behavioral Health Response at 1-800-811-4760 (https://bhrstl.org/crisis-hotline/).

Medical record information:
We will also ask you to allow a research member to look at the information in your medical record regarding smoking-related information such as smoking status, cost of care, and treatments, and safety-monitoring information such as serious injury or hospitalization.

Reminders and Prompts:
We plan to send you reminders, directions, and study-related information for your visits through email, mail, and/or telephone. If we are unable to reach you for your visit, we will call you and your contacts you provide approximately 2-3 times a week until we can get in touch with you.

Identifying information may be removed from your information, so that the data cannot be connected it to you. If this occurs, we may share your data with other researchers without asking you for additional consent.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio and video recordings of you. Audio and video recordings are being made to help ensure data quality and as a backup in cases of technical difficulty that might risk loss of data. Only the research team will have access to the audio and video recording, and the electronic audio and video file will be labeled with an ID number only and stored securely in a password-protected, encrypted server along with your other data files. While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

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HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 60 people will take part in this study conducted by investigators at Washington University.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks from the Interviews: It is possible that some of the interview questions may make you uncomfortable. You can refuse to answer any questions you do not want to answer or you may take a break at any time during the interview.

Risks from the Breath Test: There are no foreseeable risks associated with the breath test; however, failure to follow directions on how to use this monitor during a breath test, may cause incorrect readings.

Breach of Confidentiality: One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because more will be understood about how to connect patients at with evidence based tobacco cessation treatment.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid with a gift card for being in this research study. You will be asked to provide your social security number (SSN), date of birth, and address for us to send your payment. You may choose not to be paid if you do not want to provide this information. Your payment may take approximately 4 weeks for you to receive and under extreme circumstances even longer.

You will receive a total of $150 if you complete all study activities:
Visit 1: $50 Visit 2: $50 Visit 3: $50

WHO IS FUNDING THIS STUDY?

The National Cancer Institute (NCI) is funding this research study. This means that Washington University is receiving payments from NCI to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NCI for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- National Cancer Institute (NCI)
- Your clinician, to provide information about your smoking or if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Siteman Cancer Center

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will store all data collected including audio/videos on secure servers that are password protected that only the study team or others listed above have access. It is possible that your provider can document information provided to them such as your smoking status and interest in smoking cessation treatments in the medical record, although this is not a requirement.

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.

The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these messages may contain health information that identifies you.

- Smoking Cessation Education
- Reminders and directions of upcoming study activities (e.g., study visits)
- Trying to locate you if we cannot do so through phone
- Sending Zoom invite links and instructions
- Links to online surveys and study-related information
- Appointment scheduling

Only the research team will have access to your email communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or phone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.

- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

If you have a MyChart account we may use this as a way to communicate with you about appointment reminders, try to get in contact with you, and also to send you smoking cessation education.

What if I decide to withdraw from the study?
If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

If you decide to leave the study early, we will ask you to let the study staff know so we will no longer contact you or your contacts.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason, because funding for the research study has ended, you became ineligible to participate, or we are not able to contact you for study visits.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact Jimmy Reddy at (314) 362-1030 or Dr. Li-Shiun Chen. If you experience a research-related injury, please contact: Dr. Li-Shiun Chen at 314-362-1030.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)