Protocol title: Implementation of Cessation Treatment in Community Based Mental Health Centers

Version Date: 6/14/21

Consent to Participate in a Research Study

Title of Research Study: Proactive Outreach for Smoking Treatment (POST)

Investigator Team Contact Information:
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Sandra Japuntich, Ph.D.
Investigator Departmental Affiliation:
Hennepin Healthcare
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Email Address: Sandra.Japuntich@hcmed.org

Supported By: This research is supported by The National Institute on Drug Abuse.

KEY INFORMATION ABOUT THIS RESEARCH STUDY

The following is a short summary to help you decide whether to be a part of this research study. More detailed information is listed later in this form.

- The purpose of this study is to develop a stop smoking program for community mental health centers.
- You are being asked to participate because you are a patient at Central Minnesota Mental Health Center who smokes cigarettes.
- If you participate in this study, you will be asked to complete five surveys, and to receive three phone calls or text messages offering you help to stop or reduce smoking. You may be asked to participate in an interview or to take a carbon monoxide breath test.
- Your participation will last 15 months.
- Your participation is voluntary. Your choice to participate (or not) will not affect your healthcare.
- This study has very few risks. You may stop smoking as part of the study.
- If you do not want to be in the study, you can ask your providers about stop smoking treatment or call 1-800-QUIT-NOW.

DETAILED INFORMATION ABOUT THIS RESEARCH STUDY

The following is more detailed information about this study in addition to the information listed above.

1. **SITE OF THE RESEARCH STUDY**
   Where will this study be done?

   This study will be done at Central Minnesota Mental Health Center by Hennepin Healthcare Research Institute.

2. **PURPOSE OF THIS RESEARCH STUDY**
   Why is this research study being done?

   People with mental illness are more likely to smoke cigarettes than people without mental illness. Mental health providers often do not provide treatment to help their patients stop smoking. The goal of this research is to create a stop smoking program in your community mental health center. Your participation will last about 15 months. Fifty patients will participate in the study.

   ELIGIBILITY
   Who is being asked to be part of this research study?

   You are being asked to be part of the study because you are a patient in a community mental health center and because you smoke cigarettes.

3. **PROCEDURES**
   What procedures will be done for this research study?

   This study will take about 15 months. You will be asked to complete five surveys. You will complete the first survey at the beginning of the study. You will complete a second survey three months later. You will complete the other surveys three, six, and twelve months later. The surveys will be sent over email or text. If you do not complete the survey, you will be called and given the opportunity to complete the survey by phone and mailed a copy of the survey.

   Following your second survey, you will get a call or text from a staff member at Central Minnesota Mental Health Center offering to connect you to treatment to stop or reduce smoking. Treatment options could include helping you to get stop smoking medicine,

signing you up for up to 7 sessions of telephone counseling to help you stop smoking, or connecting you to community stop smoking resources.

At the end of the study, you may be asked to take a breath carbon monoxide test. This test may be done in person or using a testing kit that is mailed to you. You also may be invited to participate in an interview about your experiences in the study.

4. RISKS, DISCOMFORTS, AND INCONVENIENCES

What are the possible risks, side effects, discomforts, or inconveniences of this research study?

We do not expect the stop smoking counseling to cause you discomfort. It is possible, but unlikely, that filling out surveys about your smoking and psychiatric symptoms or talking to a counselor would make you feel uncomfortable. All research staff are professionals and all information will be kept confidential. If you experience distress at any point in the study, you may skip any study activities that are causing you distress, ask to speak to the study principal investigator, or connect with your Central Minnesota Mental Health Center providers.

If you choose to stop or reduce smoking, you may experience discomfort. The discomforts of quitting or reducing smoking include withdrawal symptoms such as mood swings, anxiety, irritability, decreased concentration, restlessness, excessive hunger, and trouble sleeping. These symptoms are not dangerous and usually only last about one to two weeks after quitting/reducing.

It is possible that if you stop smoking, the doses of your psychiatric medicine will need to be adjusted. To participate in this study, you must agree to allow study staff to inform your primary care provider and your psychiatric providers about your participation in the study.

It may be inconvenient to accept study phone calls, complete surveys, or arrange to take a carbon monoxide test.

5. REPRODUCTIVE AND PREGNANCY ISSUES

What is important to know about being a part of this study and pregnancy?

There are no known reproductive issues with being part of the study.

6. **HEALTH BENEFITS**

What are the possible health benefits to you or to others from your being part of this research study?

Quitting smoking reduces the risk of smoking related diseases such as cancer, heart disease, and COPD.

7. ALTERNATIVE TREATMENTS

What treatments or procedures are there for you if you decide not to be part of this research study?

If you decide not to be in the study, you can still get help to stop smoking. You can buy stop smoking medicines over the counter or get a prescription from your doctor. You can work with a counselor at your community mental health center or call Quit Partner at 1-800-QUIT-NOW.

8. CONFIDENTIALITY

Who will know that you are part of this research study?

Any information that could be used to identify you will be treated in strict confidence to the extent allowed by law. Nevertheless, some uses and disclosures of your information are necessary to conduct the study. If you agree to be part of this study, you will also be allowing the uses and disclosures of your private health information as needed for the purposes of this study as described in this consent.

"Private health information" means information that identifies you and is collected:

- during this study;
- from your past and current medical records maintained by your regular health care providers, to the extent the information is relevant to this study or to your eligibility for this study; or
- from any payment records relating to items or services furnished to you during this study.

By signing this consent, you are agreeing that your private health information may be used by and disclosed to:

- the research team involved in this study: Hennepin Healthcare providers, their staff, and others who may become involved in the study
- Your healthcare providers at Central Minnesota Mental Health Center
- Landmark Associates for transcription of interviews
- Hennepin Healthcare Research Institute and Hennepin Healthcare System, Inc.;
- the sponsor of this study and its agents; and
- representatives from the United States Government and/or Food and Drug Administration (FDA).

- The findings of this study may be used for scientific meetings, written reports, and publications, but no information that could be used to identify you will be disclosed for these purposes.

Private health identifiers might be removed and the de-identified information used for future research or distributed to another investigator without additional informed consent from you.

Once your private health information has been disclosed to a third party, federal privacy laws may no longer protect it from re-disclosure. However, anyone obtaining access to your private health information under this consent must agree to protect your information as required by this consent.

This consent to use your private health information as described above does not expire. However, if you later change your mind, you can revoke this consent by writing to Sandra Japuntich, Ph.D. saying that you no longer wish to allow your private health information to be used for this study. If you revoke your consent, you may no longer be able to participate in the study. Moreover, we cannot undo uses or disclosures of your private health information that have already taken place in reliance on your prior consent.

You will not be allowed to see your study data while the study is in progress. However, after the study is finished you may see this information upon written request.

9. CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institute on Drug Abuse. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should

understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

10. COSTS ASSOCIATED WITH THE RESEARCH STUDY

Will your insurance provider or you be billed for any costs of any treatments, medicines, or procedures done as part of this research study?

Neither you nor your insurance provider will be billed for the costs of any of the counseling provided by the research study. If you and the community mental health center staff determine you would like medicine to help you stop smoking, the staff member will help you learn how to get stop smoking medicine, but the study will not cover the cost of stop smoking medicine.

11. COMPENSATION AND MEDICAL TREATMENT FOR ANY STUDY RELATED INJURY

If you are injured from being part of this research study, what should you do and who will pay for it?

If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study doctor, Sandra Japuntich, 612-873-6856, day or night. Medical care for any study-related sickness or injury will be available to you at Hennepin Healthcare. Financial compensation for lost wages, disability, and discomfort is not routinely available.

12. COMPENSATION FOR PARTICIPATION

Will you be paid for being part of this research study?

You will be paid $20 per survey, for a total of $100. If you are selected to complete the CO test, you will be paid $20 to complete the test. If you are selected for an interview, you will be paid $20 to complete the interview.

13. NEW FINDINGS

Will you be told of any new information or new risks that may be found while this study is going on?

In every research study, there may be risks we do not expect. You will be told about any important new information that may cause you to change your mind about being part of this study. Individual research results will not be disclosed to subjects.

14. FREEDOM TO PARTICIPATE AND WITHDRAW

Is being part of this research study voluntary?

Can you decide to stop being in this research study at any time?

Being part of this research study is your choice. You do not have to be part of this study. You can agree to be in the study now and change your mind later. Your decision to stop being in the study will not affect your regular care. Your doctor's attitude toward you will not change.

If you decide to stop being in the study, the study doctor may discuss with you a more limited participation in this study such as still collecting information from your medical records after you stop your direct participation. If you agree at that time to such continued limited participation, that agreement will be noted in your records.

15. **PROCEDURES FOR ORDERLY WITHDRAWAL OR REMOVAL FROM THE STUDY**

What would happen if you decide to stop being part of this study or if you are removed from this study?

You may be taken out of the study by the researchers if:

- staying in the study would be harmful;
- you fail to follow instructions;
- the study is cancelled.

16. CONTACT INFORMATION FOR QUESTIONS

Who should you contact if you have questions?

If you have any problems, concerns, or questions about the study or your rights as a subject in this research study, want to obtain information, or want to offer input to someone other than the study doctor, please contact the Hennepin Healthcare Human Research Protection Office (HRPO) at HRPO@hhrinstitute.org or (612) 873-6881.

If you have any questions before signing this consent, please be sure to ask them now. During the study, if you have any questions, concerns, or complaints for the study doctor, please call Sandra Japuntich, Ph.D. at (612) 873-6856.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VOLUNTARY CONSENT FORM

- I have either read the attached consent or it has been read to me.
- By signing this form, I do not give up any of my legal rights or release anyone involved in this research study from their responsibility for negligence.
- By signing this form, I agree to be part of this research study and consent to the use of my private health information as described in Section 8 ("Confidentiality") of the attached consent.
- A signed copy of this consent will be given to me.

_____

Subject's Printed Name (or Legally Authorized Representative's)

_____

Subject's Signature (or Legally Authorized Representative's)

_____

Date

I certify that a copy of this form has been provided to the above-named subject.

_____ _____

Explained by Printed Name, Title Signature

_____

Date