# Treating Tobacco Dependence in Smokers with Severe Mental Illness

## Consent Form

**Key Information about this research:**
There has been a large decrease in the number of people in Minnesota and the US who smoke. Unfortunately, there are still some groups of people that have high rates of smoking compared to the general population, including people with serious mental illness (SMI). Using tobacco increases the risk for illness and early death, yet many doctors don't talk to their SMI patients about quitting. There is evidence that smokers with SMI want to quit.

You are being invited to participate in a research study to test methods of helping people with severe mental illness to quit smoking (or to cut back on the number of cigarettes smoked). People often find quitting smoking to be very difficult. Help and support can make quitting easier and can increase the likelihood of success.

The Principal Investigator of this study is Harry Lando, PhD in the Division of Epidemiology and Community Health of the School of Public Health at the University of Minnesota. The Co-Investigator is Andrew Busch, PhD at the Hennepin Healthcare Research Institute.

We are inviting patients from the clinics at Hennepin Healthcare and from the University of Minnesota Psychiatry Clinics who have a history of SMI and a desire to cut back on or quit smoking to participate. We will enroll patients with documented SMI including those with schizophrenia, any other psychotic disorder, bipolar I and II disorder, and/or recurrent/chronic major depressive disorder.

**What should I know about the research study?**
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

**How long will the research last and how many people will participate?**
We expect that you will be in this research study for approximately six months. We plan to enroll 60 people in the study.

**What will I need to do to participate?**
If you decide to participate, you will complete an assessment in person today. This assessment will consist of self-report and interview questions. Following this assessment you will then be randomly assigned (like by flipping a coin) to active treatment or to a comparison condition.

**Active treatment** will include a counseling session today plus follow up counseling calls over the course of six months. You will be able to have up to 6 calls over the first eight weeks. After the first eight weeks, you can receive a minimum of 3 additional phone calls plus encouraging text messages (if you choose) to help you quit or to cut back on the number of cigarettes that

you smoke . You and the counselor will decide the exact number and scheduling of calls. The counseling sessions will be audio-recorded.

In addition, you may be provided with nicotine patch or nicotine lozenge, or a combination of both at no charge if you qualify. You will be given a four-week supply of nicotine replacement during your first in-person visit. If you are using and want to continue using the nicotine replacement, another four-week supply will be mailed to you.

The **comparison condition** will include information about smoking and mental illness and referral to the QUITPLAN helpline.

Follow-up assessments will occur in person at 8 weeks and 6 months after you enroll. These will be similar to the baseline assessment except that we may also ask you to give us a carbon monoxide sample by blowing into a tube to confirm self-report of not smoking.

**Risks and Benefits:**
The risks of being in the study include possible discomfort from quitting smoking, side effects from nicotine lozenge or patch, and possible loss of confidentiality. We will check your use of lozenge or patch and will ask that you stop using these if you experience significant side effects such as continued nausea and vomiting or major skin irritation. We will keep your information confidential. The benefits of participating may include assistance in quitting smoking.

We exclude women who are pregnant or trying to become pregnant from this study because nicotine from a nicotine patch or nicotine lozenge has potentially greater risks during pregnancy. If you become pregnant during the study please call or email Dr. Harry Lando (612-624-1877 or lando001@umn.edu) and your healthcare provider immediately to help you determine next steps.

**What happens if I do not want to be in this research?**
This study is voluntary. You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you do not want to participate and your decision will not affect your medical care or your relationship with either the University of Minnesota or Hennepin Healthcare.

**What happens if I say "Yes," but I change my mind later?**
You can leave the research study at any time and no one will be upset by your decision. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care. If you stop being in the research, information about you that has already been collected may not be removed from the study database.

**Compensation:**
Taking part in this research study will not cost you anything. We will pay you $30 for completing the first questionnaire, $50 for completing the second questionnaire at 8-week follow-up, and $50 for completing the final questionnaire at 6 month follow up. We also will give you up to $30 for your costs in coming to the clinic (to cover bus fare, taxi, parking, gas money).

**Whom do I contact if I have questions, concerns or feedback about my experience?**
If you have questions or concerns about the study, you may contact Dr. Harry Lando at 612-624-1877 or lando001@umn.edu.This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**Optional Elements:**

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| **Yes, I agree** | **No, I disagree** | |
|---|---|---|
| ☐ | ☐ | It is okay for the study team to contact me through text to remind me of scheduled appointments and to give encouragement periodically throughout the study. |
| ☐ | ☐ | It is okay for the study team to contact me through email to remind me of scheduled appointments and to give encouragement periodically throughout the study. |
| ☐ | ☐ | It is okay for the study to contact my additional contact person in case of an emergency and/or if they are unable to reach me for study visits. |

Your signature documents your permission to take part in this research. By signing this form, you are saying that:

- You have read this form and that you understand what you are being asked to do
- You have had the chance to ask questions and have had any questions answered
- You agree to be in this research study
- You have received a copy of this form
- You understand that you are not giving up any legal rights by signing this form

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent