PROTOCOL TITLE:

Treating Tobacco Dependence in Smokers with Severe Mental Illness

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Protocol Title	Treating tobacco dependence in smokers with severe mental illness
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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	October 11, 2018	Response to IRB letter	Yes
2	January 2, 2019	Adding exclusionary criteria and changes to NRT distribution	No
3	February 18, 2019	Fixing a discrepancy – replacing "gum" in a few places with "lozenge". Also deleting "additional community resources" from the control group information.	Yes
4	May 1, 2019	Adding contact letters to mail to participants between assessments	no
5	July 16, 2019	Adding 1) that we will pay non-eligible candidates $10 for coming in, 2) end of study satisfaction questions, 3) asking participants for an additional contact person.	yes

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ABBREVIATIONS/DEFINITIONS

- SMI - Severe mental illness
- NRT – Nicotine Replacement Therapy
- ECRC – Epidemiology Clinical Research Center
- SOP – Standard operating procedures

1.0 Objectives

1.1 Purpose:

This is a pilot study to assess the following research aims:

1) **Is our approach is feasible?** Can we recruit smokers with SMI, deliver counseling and NRT, and keep participants engaged over the six months of intervention? Can we minimize attrition and loss to follow up?
2) **Are our proposed treatments acceptable?** How much counseling will we be able to deliver? How many participants will adhere to recommended NRT? Will participants utilize options for re-treatment after relapse or failing to initiate a quit/reduction attempt?
3) **How do 7-day abstinence outcomes** (and continuous abstinence, quit attempts, and reduced smoking) **compare between intervention and control conditions at 1- and 6-month follow-ups?**

2.0 Background

2.1 Significance of Research Question/Purpose:

There have been dramatic drops in overall smoking prevalence both in Minnesota and in the US as a whole (Cook et al. 2014; Steinberg et al. 2015). However, there are a number of subpopulations with a high continuing prevalence of tobacco use including those with serious mental illness (Gfroerer et al 2013). For those with severe mental illness (SMI) tobacco use is perhaps the leading factor implicated in their dramatically increased risk for morbidity and early mortality (Cook et al 2014; Kelly et al 2011; Lawn & Lucas, 2016; NIMH, Prochaska 2011). People with SMI die sooner than adults without SMI from illnesses such as heart disease, cancer, diabetes, and stroke (Kelly et al 2011; McGinty et al. 2012.) Clinical practitioners often fail to prioritize tobacco cessation because they are more focused on psychiatric issues (Lawn & Lucas, 2016; Prochaska 2011).

There is evidence that smokers with SMI want to quit, are receptive to offers of cessation treatment, and can quit successfully. We are seeking to deliver an intensive but low cost and widely disseminable intervention to smokers with SMI that addresses tobacco dependence as a chronic disease.

2.2 Preliminary Data:

This is a pilot study with the intent of gathering preliminary data on this subject.

2.3 Existing Literature:

The 2008 US Clinical Practice Guideline Treating Tobacco Use and Dependence (on which Dr. Lando was a panel member) states that all

smokers with psychiatric disorders should be offered tobacco dependence treatment (AHRQ 2018; Fiore et al 2008). The American Psychiatric Association recommends that psychiatrists assess the smoking status of all patients, including readiness to quit, level of nicotine dependence and previous quitting history. Clinicians are encouraged to use this information to provide explicit advice to motivate patients to stop smoking (Prochaska, Gill, & Hall 2004).

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

The primary outcome of our study is to determine the proportion of patients in the intervention and control conditions who achieve 7-day point prevalence abstinence at 8 weeks and 6 months after enrollment

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

The secondary outcome of our study is to determine the proportion of patients in the intervention and control condition who achieve continuous abstinence, reduced number of cigarettes per day, and self-reported minimum 24 hour quit attempts.

4.0 Study Intervention(s)/Investigational Agent(s)

4.1 Description:

This randomized trial will include in-person meetings and phone counseling sessions with participants. We will seek to deliver treatment that optimally follows current guidelines, provides for substantial counseling support, includes an option for NRT, and keeps patients engaged in quitting.

Drug/Device Handling:

We will be using different types of NRT in this study including lozenge and patches. Only study staff who have been trained to follow standard operating procedures for handling and distributing the NRT drugs used in this study will have access to them. These NRT drugs are currently FDA approved, on the market, over-the-counter medicines that do not require a doctor or pharmacist for distribution. All NRT drugs will be kept in the locked Drug Supply Room at the ECRC. The study coordinator will maintain a Drug Accountability Record of the purchase and distribution of all NRT drugs.

Patients will be offered the nicotine patch (dose based on number of cigarettes per day) and/or the nicotine lozenge (2 or 4 mg if less or greater than 30 minutes to first cigarette in the morning respectively) depending on participant preference and how much they are smoking based on FDA guidelines for use. We will follow FDA guidelines for the length of time a participant should use their NRT, anywhere between 8 and 12 weeks, depending on cigarette use, addiction level, and type of NRT. Participants will receive a four-week supply of NRT during the baseline visit. If participants are using and want to continue using NRT,

the remainder of their supply will be distributed to them at 4 weeks. We will either mail subsequent NRT in puncture resistant packaging to the participants or participants come to the ECRC to pick up their remaining supply.

4.2 Biosafety: N/A
4.3 Stem Cells: N/A

5.0 Procedures Involved

5.1 Study Design:

This is a randomized clinical trial that will enroll patients with documented SMI (ICD-10 codes) including schizophrenia, any other psychotic disorder, bipolar I and II disorder, and/or recurrent/chronic major depressive disorder into either a counseling intensive smoking cessation program or the control group.

5.2 Study Procedures:

This intervention is tailored to the needs of SMI smokers including addressing barriers to quitting and the need for continued supportive contact. Following is an outline of the study procedures:

Baseline assessment

Trained study staff will:

- Conduct informed consent
- Collect demographic and smoking history information along with current interest in quitting, readiness to quit, confidence in ability to quit, and nicotine dependence. We also will include mood, general psychiatric health, and quality of life questionnaires. (SMI Smokers BL Interview V1.1, SMI Smokers BL Self Report V1.1)
- Collect the name and phone number of an additional contact. Study staff will call the contact in the case of an emergency with the participant or if staff are unable to reach the participant for study visits. Staff will explain the two reasons for needing the additional contact person to the participant during the baseline visit.
- Randomize participants: prior to the baseline visit, we will complete a 1 to 1 non-stratified randomization. The randomization results will be put in envelopes to be opened during the baseline visit, determining if a participant will be allocated to the intervention or the control group.
- Conduct or schedule session one with those in the intervention group
- Distribute materials/resources to all participants.

Follow up assessments:

- Conducted at 8 weeks and 6 months post baseline assessment. (SMI Smokers 8 Week Interview V1.0, SMI Smokers 6 Month Interview V1.0,

and SMI Smokers 8W 6M Self Report V1.0, Study Satisfaction Survey V1.0 will be administered only at the 6 month assessment and only to participants in the Intervention group).

- Conducted in person when possible, but a phone option will be available.
- Measures will include current smoking status, quit attempts, self-reported number of cigarettes per day for those who currently are smoking, and interest and confidence in quitting/continued abstinence.
- Reported 7-day abstinence at 8 weeks and 6 months will be validated by an expired carbon monoxide sample.

<u>The intervention group activities include the following:</u>

Session 1:

- 1 hour in person visit
- Will include population specific information about smoking and mental illness
- Counselor will provide a strong and personalized recommendation to quit
- The remainder of Session 1 will be guided by current clinical practice guidelines and the National Cancer Institute's Clearing the Air patient workbook
    - The counselor will cover: past attempts to quit (reframing these as learning opportunities), and education on the risks of smoking and benefits of quitting both in general and for SMI patients.
    - Emphasis will be placed upon personal reasons for quitting or reducing number of cigarettes, especially those that are intrinsic
    - The counselor will discuss coping strategies and will focus on identifying strategies that are appropriate for the individual patient.
    - The counselor will provide tips for how to elicit support and for managing cravings
    - The counselor will address planning for behavior change including preparation for a quit date when applicable and anticipating challenging situations
- For those patients who initially choose to reduce rather than quit, the focus will be on reduction strategies including substituting NRT lozenge for individual cigarettes
- Patients who want to quit will be offered a nicotine patch and/or the nicotine lozenge.
- The counselor will review correct placement and/or use.
- Counselor also will address the efficacy and safety of nicotine replacement

Follow up counseling calls:

- Counselors will make 6 calls over 8 weeks after initial in person session.
- There will be assessments of current smoking status, NRT use and side

effects, and motivation to continue/restart quitting/reduction plan. NRT use will be encouraged.

- For those who have discontinued use or who have encountered problems with NRT, the counselor will review the patient's experience and consider alternatives including advice to try a different form of NRT
- If the patient is abstinent, the counselor will reinforce their success, discuss any times since the previous session when the participant struggled with cravings, will review strategies for managing triggers and cravings, and problem solve upcoming challenges to continued abstinence.
- If the patient is smoking, the counselor will reinforce any efforts that the patient made including cutting down or attempting to quit and will apply brief motivational strategies to prompt further reduction or a subsequent quit attempt.
- The counselor will seek to keep all patients engaged in active behavior change.

Additional counseling phone calls:

- 3 calls (minimum) from 8 weeks to 6 months
- Telephone calls will be supplemented by supportive text messages when agreed to by participants during this phase.
- Those who choose to initiate a new quit/reduction attempt will be eligible for multiple telephone calls (up to six in one or more new rounds of intervention before the end of 6 months).

The control group activities include the following:

Participants in the control group will complete the baseline assessment interview and self-report and follow-up assessments at 8 weeks and 6 months. They will also receive information about smoking and mental illness and referrals to the QUITPLAN helpline.

Contact Letters

Participants in both the intervention and control groups will receive three letters by mail from the study. The first letter will be mailed approximately four weeks post baseline, the second approximately six weeks post 8-week assessment, and the last letter will be mailed approximately 12 weeks post 8-week assessment (Contact Letters V1.0)

5.3 Study Duration:

This study will enroll participants beginning fall of 2018 and continue enrollment until we recruit 60 participants or until time will no longer allow us to recruit based on the funding deadlines. As this is a two-year grant with no opportunity for a no-cost extension, all study related activities should be completed within two years.

5.4 Individually Identifiable Health Information:

As part of the recruitment process, study staff at UMN will call potential participants whose names are on a list they receive from the Clinical Research Advocate within the UMN Department of Psychiatry. The people on this list have given written consent and have agreed to be contacted for study recruitment purposes. UMN staff may also receive calls from patients who self-identify in response to flyers hung in the UMN Department of Psychiatry. If an individual self-identifies and diagnosis needs to be verified, Dr. Linda Skalski, an Assistant professor in the Department of Psychiatry, clinical psychologist, and Co I on this study, is authorized to review patient charts and can verify diagnosis for study purposes. Patients who are taking the medications Clozapine/Clozaril or Chantix/Varenicline will not be allowed in the study. Dr. Skalski will also be reviewing charts to ensure otherwise eligible patients are not currently taking these medications. HCMC screeners will be accessing individual medical charts of HCMC patients to verify a diagnosis of SMI, collect contact information, and perform screening.

5.5 Use of radiation*:* N/A

5.6 Use of Center for Magnetic Resonance Research: N/A

6.0 Data and Specimen Banking

N/A

7.0 Sharing of Results with Participants

7.1 No individual results will be shared. If a participant requests the results of the study, a summary of the study results will be provided at study conclusion.

8.0 Study Population

8.1 Inclusion Criteria:

Study participants will be between the ages of 18 and 65, have diagnosed SMI, and be current daily smokers willing to attempt to quit or reduce their daily smoking. They must exhibit current stable psychiatric illness. Patients must be willing to either plan for a quit attempt or for cigarette reduction with a long-term goal of quitting.

8.2 Exclusion Criteria:

8.3 Our exclusion criteria include anyone who has had an active psychotic episode or been hospitalized within the past six months due to suicidal ideation or suicidal behavior. Anyone judged unable to give valid informed consent and unable to tolerate NRT will also

be excluded. Anyone who has had a heart attack in the past two weeks will be excluded. Additional exclusion criteria include regular use of tobacco products other than cigarettes, terminal illness (life expectancy of less than 12 months), or lack of a local address and telephone. If patients are currently taking the medications Clozapine/Clozaril or Chantix/Varenicline, they will be excluded from the study. Screening:

Hennepin County Medical Center Screening:
Patients at HCMC will be recruited into the study through two routes. The first is to receive a letter from HCMC that includes a brief description of the study and an HCMC phone number to call with questions. This letter will also give patients information on opting out of the chart review and subsequent screening phone call. The second is to get a referral to the study from the patient's medical/psychiatric provider. For those who do not opt out and for those who have a provider referral, an HCMC employee will reach out to patients over the phone to discuss the study and complete an eligibility screening. (SMI Smokers Screening Form V1.1) If a patient is eligible to proceed and interested in participating, the HCMC screener will forward the patient's information on to the UMN study staff who will reach out to schedule the in person baseline visit.

University of Minnesota Clinics Screening:
The outpatient Psychiatry Clinic in the Department of Psychiatry at the University of Minnesota provides new patients the opportunity to indicate whether they are interested in being contacted to hear about research studies or whether they prefer to not be contacted. Patients have the opportunity to sign the Psychiatry Research Registry Authorization form to participate in the Psychiatry Recruitment Registry when they come to the outpatient clinic for a visit. This authorization form gives the Clinical Research Advocate (CRA) access to their contact and health information to be added to the Psychiatry Research Recruitment Registry so that researchers recruiting for a study may contact them and inform them about possible opportunities they might be eligible for. Access to this contact information is managed by the Department of Psychiatry CRA. The CRA will provide us with a list of patients who have given their written consent to be contacted for research study opportunities and who meet our study's minimum requirements to be screened. The CRA will also hang posters and hand out study cards containing contact information to patients in the Department of Psychiatry. (Recruitment Card SMI Smoking and UMN SMI Smoking Recruitment Poster) UMN study staff will contact people on the list received from the CRA and complete an eligibility screening (SMI Smokers Screening Form V1.1). This same screening form will be used by UMN study staff if they are contacted directly by an interested patient.

9.0 Vulnerable Populations

9.1 Vulnerable Populations:

☐ Children
☐ Pregnant women/Fetuses/Neonates
☐ Prisoners
☒ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
☐ Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
☐ Disadvantaged in the distribution of social goods and services such as income, housing, or healthcare
☐ Serious health condition for which there are no satisfactory standard treatments
☐ Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
☐ Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research
☐ Undervalued or disenfranchised social group
☐ Members of the military
☐ Non-English speakers
☐ Those unable to read (illiterate)
☐ Employees of the researcher
☐ Students of the researcher
☐ None of the above

9.2 Additional Safeguards:

The target population for this study is adults who have a diagnosis of a severe mental illness and who smoke. We will take all precautions necessary to ensure participants fully understand the purpose of the study, the requirements of participation, and what participation would entail. We will address any confusion about the study through a clear informed consent process that will include using the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research. As mentioned in our background section, this is a population that is often overlooked for smoking cessation programs and that has voiced an interest in quitting smoking. Patients with

SMI tend to die at earlier ages than those without and it is important to reduce health risks, especially smoking.

10.0 Local Number of Participants

10.1 Local Number of Participants to be Consented:

We plan to recruit 60 participants for the study. However, we are requesting permission to enroll up to 80 participants to allow for early dropouts and inability to reach participants following initial enrollment in the study.

11.0 Local Recruitment Methods

11.1 Recruitment Process:

Patients will be recruited from those attending smoking cessation and/or psychiatric clinics at Hennepin County Medical Center (HCMC) and the University of Minnesota (UMN). We may also be displaying flyers at both HCMC and UMN clinics with a brief study description and contact information so that interested patients have the option to contact us as well. (Recruitment Card SMI Smoking, UMN SMI Smoking Recruitment Poster, HCMC SMI Smoking Recruitment Poster)

Hennepin County Medical Center Recruitment:

Patients at HCMC will be recruited into the study through two routes. The first is to receive a letter from HCMC that includes a brief description of the study and an HCMC phone number to call with questions. This letter will also give patients information on opting out of the chart review and subsequent screening phone call. The second is to get a referral to the study from the patient's medical/psychiatric provider. For those who do not opt out and for those who had a provider referral, an HCMC employee will reach out to patients over the phone to discuss the study and complete an eligibility screening. (SMI Smokers Screening Form V1.1) If a patient is eligible to proceed and interested in participating, the HCMC screener will forward the patient's contact information on to UMN study staff who will reach out to schedule the in person baseline visit.

University of Minnesota Clinics Recruitment:

The outpatient Psychiatry Clinic in the Department of Psychiatry at the University of Minnesota provides new patients the opportunity to indicate whether they are interested in being contacted to hear about research studies or whether they prefer to not be contacted. Access to this contact information is managed by the Department of Psychiatry Clinical Research Advocate (CRA). The CRA will provide us with a list of patients who are interested in being contacted for research studies and who meet our study's minimum requirements to be screened. The CRA will also hang posters and hand out study cards containing contact information to patients in the

Department of Psychiatry. If study staff are contacted directly by a patient in response to a poster, we will have a two-step process for verifying their mental health diagnosis. Step one will be to look for their name on the list received from the CRA. If they are not on the list, Dr. Linda Skalski, an Assistant Professor and licensed clinical psychologist within the Department of Psychiatry who is Co-I on this study and has legitimate access to patients' medical records, will verify diagnosis.

<u>After the screening process is complete:</u>
Those who are interested and who meet initial eligibility criteria will be invited to the ECRC study site for further assessment and enrollment in the study. We plan to recruit a minimum of 60 participants with close to equal distribution from HCMC and UMN clinics. During the first in person visit, participants will be randomly allocated to the intervention or control group with approximately 30 in each.

11.2 Identification of Potential Participants:

We may be hanging flyers in the HCMC and UMN psychiatric clinics which contain study information. Patients who are interested in the study will then be able to reach out to study staff to get more information.

At HCMC, a chart review of patients attending smoking cessation or psychiatric clinics will be used to identify potential participants. Letters that include a brief description of the study, information about opting out of the recruitment phone call, and an HCMC study phone number will be sent to patients. HCMC medical and psychiatric providers may also refer their patients to the study.

UMN Department of Psychiatry maintains a database of patients who have agreed to be contacted about research studies. The Clinical Research Advocate will be using this database to find patients interested in being participants and will then run a query of the database to find patients who meet our minimum requirements to be screened.

11.3 Recruitment Materials:

In addition to the proactive methods described above, we may also place flyers describing the study and containing study contact information within the clinics so that patients may self-identify for the study. Study recruitment flyers are attached in the ETHOS recruitment section.

11.4 Payment:

Patients will receive a $30 incentive for completing the baseline survey, a $50 incentive for completing the 8-week survey, and a $50 incentive for completing the final survey at six months post baseline assessment. All counseling sessions and related materials, including NRT, will be given to the patients free of charge. Participants will also be given $30 to help cover the cost of transportation to the in-person sessions. If a candidate comes in

for the baseline visit and is deemed unable to give informed consent based on the results of the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research, they will be given $10 to help with travel expenses for the appointment.

12.0 Withdrawal of Participants

12.1 Withdrawal Circumstances:

Because we are using an intention-to-treat paradigm, subjects will be encouraged to continue their participation even if they are unsuccessful in quitting or making significant reductions in smoking. Participants may choose to withdraw from the study at any time without penalty. The PI and Co-PI may withdraw a patient from the study without their consent if that patient has an active psychotic episode or is hospitalized due to suicidal ideation or suicidal behavior. If this happens, trained study staff will have a conversation with the participant explaining the reasons for their withdrawal from the study.

12.2 Withdrawal Procedures:

If a participant withdraws from the study, no new data will be collected on that participant.

12.3 Termination Procedures:

If a participant in terminated from the study, no new data will be collected on that participant.

13.0 Risks to Participants

13.1 Foreseeable Risks:

Our study procedures involve minimal risk. Patients may experience discomfort from quitting or attempting to quit smoking. Use of NRT has led to skin irritation in the case of the patch and occasionally to nausea in the case of the lozenge or patch. We will provide instructions in correct use of NRT and will advise patients to discontinue use in the event of significant nausea or discomfort.

Patients will need to make in-person visits as well as be available for phone counseling sessions. Both of these could pose an inconvenience and we will do our best to accommodate patients' schedules and needs.

In addition to the above mentioned minimal risks, we will also store all study related data in secured locations separately from personal identifiers to ensure information remains strictly confidential.

14.0 Potential Benefits to Participants

14.1 Potential Benefits:

The potential benefits to participation in our study include all of the benefits related to a reduction in smoking or quitting smoking, including improving cardiovascular health.

15.0 Statistical Considerations

15.1 Data Analysis Plan:

Feasibility analyses (e.g. recruitment rate, retention rate) and acceptability analyses (e.g., satisfaction scores, sessions attended, uptake of NRT) will be primarily descriptive. Given the limited number of participants, primary and secondary outcome analyses will be exploratory and will be used for effect size estimates for a potential larger future trial.

15.2 Power Analysis:

Although we are not powered to detect differences in abstinence, the current study will provide a necessary demonstration of the feasibility of our approach.

15.3 Statistical Analysis:

All analyses will be conducted on the intent to treat sample, with all randomized participants included in the analysis. We will estimate the effect of the intervention on smoking cessation (biochemically verified 7-day point prevalence abstinence) over 6 months using a single repeated measures regression model implemented with generalized estimating equations (GEE) and robust standard errors. Specifically, we will regress smoking status on intervention group and potential covariates using binomial errors, a logit link function, and a working unstructured correlation to accommodate within-subject correlation. For continuous secondary outcomes we will use linear regression models.

15.4 Data Integrity:

All study staffed will be trained on how to collect and store data. Data quality will be evaluated by study staff through review and assessment of gathered data to ensure completeness. Data will be kept in locked files or on a secure server, to both of which only authorized study personnel will have access. All identifying data will be stored separately.

16.0 Confidentiality

16.1 Data Security:

All study personnel will be trained on and follow standard operating procedures for interacting with participants and managing data to ensure proper handling and security of data. All data will remain strictly confidential and will be stored in secured locations separately from personal identifiers. Only approved study personnel will have access to collected data. All paper documents will be stored in a locked file cabinet. We will be using either RedCap or Box (or both) to digitize and

share data. As described on the UMN RedCap website, Redcap uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by the University of Minnesota Academic Health Center's Information Systems group (AHC-IS).

The phone counseling sessions will be audio-recorded. The audio recording devices will be stored in a locked file cabinet that only study staff have access to. The recordings will be uploaded and stored in Box where only study personnel will have access to them. As described on the UMN Box Secure Storage website, Box is a secure environment delivered by the Center of Excellence for HIPAA Data intended for storing, sharing and accessing sensitive and private-highly restricted files. The security of Box includes encryption, activity logging, Duo Two-Factor Authentication, and access controls such as view-only access. After uploading the sessions, they will be deleted from the audio recording device.

17.0 Provisions to Monitor the Data to Ensure the Safety of Participants

17.1 Data Integrity Monitoring.

This study involves no more than minimal risk. The study team, including the PI, Co-PI, and study coordinator will all be involved in monitoring the data to ensure the safety of the participants. We will ensure participants are fully aware of the expectations of participating in the study during the enrollment and consent process. The minimal risks associated with the study will be clearly outlined. Data will be reviewed for completeness, counseling sessions will be reviewed for accuracy and competence. Any adverse reactions to the NRT or the counseling sessions will be monitored and recorded and adjustments made for individual participants when necessary.

17.2 Data Safety Monitoring. This purpose of this study is not to diagnose or evaluate psychiatric symptoms or behaviors. That being said, if study staff observe a participant acting in a way that causes concern for either the physical or mental health of the participant or others, the staff will report this to Dr. Skalski, whom we have added to the study team with the specific responsibility of monitoring for worsening symptoms. If warranted, Dr. Skalsi will contact the participant to determine if they should be referred for help. If there is an immediate medical emergency, study staff will call 911. All paper data will be stored in locked file cabinets and all digital data will be stored in UMN Secured BOX or REDCap to which only study team members who need to use the data will have access.

18.0 Provisions to Protect the Privacy Interests of Participants

18.1 Protecting Privacy:

Study personnel will meet with participants in the ECRC building in private rooms designated specifically to the study. Participants will be encouraged to schedule their counseling phone calls at times that allow them to have privacy.

18.2 Access to Participants*:*

The UMN Department of Psychiatry Clinical Research Advocate has a pre-determined list of patients who have given written consent to be contacted about studies for which they are potentially eligible to participate. This list will be shared with the study team through Secure Box for recruitment and screening purposes. If medical records need to be reviewed as part of the recruitment process, Dr. Skalski is able to do that.

19.0 Compensation for Research-Related Injury

19.1 Compensation for Research-Related Injury: N/A

19.2 Contract Language: N/A

20.0 Consent Process

20.1 Consent Process (when consent will be obtained):

All potential participants will give their written consent to participate in the study in a private study room in the ECRC building with a study staff member who has been trained on the enrollment and consenting SOP. There will be time between the initial contact with a potential participant and the consenting/enrollment/baseline session. All participants will have the opportunity to read the consent form and to ask any questions they may have. The study staff member will also review the form with all potential participants asking open-ended questions about the study to ensure understanding. As mentioned previously, we will also administer a brief quiz to potential participants during the consenting process to ensure they are able to give informed consent.

20.2 Waiver or Alteration of Consent Process (when consent will not be obtained): N/A.

20.3 Non-English Speaking Participants: N/A

20.4 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

20.5 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

The target population for this study is adults who have a diagnosis of a severe mental illness (and who smoke). We will take all precautions necessary to ensure participants fully understand the purpose of the study, the requirements of participation, and the demands that participation may

place on them. We will mitigate any confusion about the study through a clear informed consent process that will include using the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research. If a potential participant is deemed unable to provide informed consent, they will not be enrolled in the study.

20.6 Adults Unable to Consent: N/A

21.0 Setting

21.1 Research Sites:

Recruitment of potential participants will take place in HCMC and UMN clinics. Research procedures, including all in-person visits, will take place in the ECRC building.

21.2 International Research: N/A

22.0 Multi-Site Research: N/A

23.0 Resources Available

23.1 Resources Available:

Dr. Busch has experience in recruiting participants from the HCMC clinics and we have the support of the Clinical Research Advocate at the UMN clinics to assist in recruitment of patients. We have access to the patients attending UMN and HCMC smoking cessation and psychiatric clinics as our base for recruiting potential participants. We plan to recruit 60 into the study.

Study staff with be housed in the Division of Epidemiology and Community Health and ECRC. Within the Division, we have access to all needed office supplies, printers, and technical assistance. The division also offers administrative support for research projects. The study coordinator will also have space designated to the study at the ECRC building. This is where the all in-person visits will take place. The ECRC also has basic office support and resources available for study use. In addition, ECRC has an Emergency Response Team (ALERT) that responds to any emergency that may occur within the clinic. All study staff members have experience in conducting human subjects research and will be trained by the PI and/or the study coordinator on standard operating procedures that need be followed for every aspect of the study.

We will be following the UMN Psychiatry Department's "Unanticipated Problem/Crisis Communication Plan for Research Activity" flowchart for any psychiatric issues that arise while we are meeting or speaking with our study participants. We will also be employing a clinically licensed UMN employee (TBD) who will provide psychiatric safety information and guidance to study staff.

24.0 References

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