RESEARCH PROTOCOL OUTLINE

Title of Project: Empowering sexual and/or gender minority tobacco cessation: A pilot study

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Abstract

Sexual and/or gender minority (SGM) people have disproportionately high rates of tobacco use – the number one cause of preventable death. Reasons for this include using tobacco to cope with social minority stressors, pro-tobacco use norms in SGM social spaces and networks, and targeted tobacco industry marketing. Empowerment Theory explains how positive behavior change, like quitting smoking, can be promoted through skills development with greater participation in the public affairs of one's community. An empowerment approach may enhance tobacco cessation treatment for SGM people and other stigmatized groups because it links individual well-being with the larger social and political context. This pilot study will assess the acceptability, feasibility, and preliminary impact of empowerment-enhanced tobacco smoking cessation assistance for SGM adults. We will enroll N=20 SGM adults in Oklahoma who smoke and are willing to quit. Participants will receive standard tobacco cessation assistance through the Stephenson Cancer Center Tobacco Treatment Research Program (TTRP). Concurrently, they will also engage in 'empowerment activities', meaning SGM organizing and community-building activities, like conducting follow up phone calls to participants of a gender marker and name change clinic. This will be facilitated by an Oklahoman SGM-serving community partner. Participants will complete 12 surveys during the intervention period and 12 weeks post-quit-date, a 60-minute, in-depth exit interview, and biochemically-verified smoking status before the intervention and 12 weeks post-quit-date. This pilot study will establish collaborative relationships between the PI's team and local SGM-serving organizations, and will produce preliminary findings to support future R01-level funding to conduct a fully powered randomized control trial of a multi-level empowerment-enhanced SGM tobacco cessation intervention.

A. Specific Aims

State the hypothesis and specific aims. List the long-term objectives and what the proposed research will accomplish.

Aim 1: Assess the feasibility and acceptability of empowerment-enhanced tobacco cessation assistance for sexual and/or gender minority (SGM) adults. We will use baseline and exit surveys and in-depth interviews to assess retention, empowerment activity participation (e.g., number, duration, intensity, roles), and participants' perceptions of the intervention.

Aim 2: Compare individual empowerment and cessation predictors pre- and postintervention. *Hypothesis:* Post intervention, participants will have (i) increased adaptive coping strategies, social support, and smoking abstinence self-efficacy; and (ii) decreased internalized SGM stigma.
Aim 3: Assess tobacco cessation outcomes post-intervention. *Hypothesis:* The proportion of participants with biochemically-verified smoking abstinence at 12 weeks post-quit-date will be equal to or greater than the general Stephenson Cancer Center Tobacco Treatment Research Program (TTRP) intervention (i.e., 18% biochemically-verified abstinence at 12 weeks[1]); medication and counseling adherence will be moderate/optimal for >50% of treatment weeks.

We will produce preliminary data on a novel SGM tobacco cessation approach and establish collaborative relationships with SGM-serving organizations. Our findings will support a future NIH R01 to conduct a fully-powered randomized control trial of a multi-level empowerment-enhanced SGM tobacco cessation intervention. A longer-term research program will refine tobacco treatment strategies tailored to SGM individuals.

B. Background and Significance

Tobacco use – the number one cause of preventable death[2] – disproportionately impacts sexual and/or gender minority (SGM) groups.[3-6] In the U.S., 30% of sexual minority people use tobacco versus 20% non-sexual minority,[7] and gender minority people are 2–3 times more likely than cisgender people to use tobacco.[8] Tobacco interventions that are tailored to priority groups, like SGM, aim to address unique drivers of use and barriers to cessation. Our work and others' shows that SGM tobacco use is linked to how SGM people interact with and negotiate everyday environments as a social minority person.[9-17] Drivers of SGM tobacco use include social minority stressors,[9,16,18-21] pro-tobacco norms in SGM social networks and spaces,[22-26] and targeted tobacco industry marketing.[27-30] This is particularly true in states with high levels of structural SGM stigma, like Oklahoma (OK).[31] SGM Oklahomans experience disproportionate mental health and material hardship[32] and our preliminary data show that sexual minority adult Oklahomans are at greater risk for past 30-day tobacco use (51.6%) than non-SGM (40.4%). Yet, tobacco cessation assistance tailored for SGM Oklahomans is unavailable.

The past decade has seen increasing interest in tailoring tobacco control interventions to SGM people.[33-35] While a minority of interventions engage with SGM social networks and spaces,[36,37] most focus on individual-level factors (e.g., readiness to quit) and may not be equipped to address the unique person-environment drivers of SGM tobacco use.[38] An Empowerment Theory (ET)[39-41] approach to tobacco cessation may enhance efficacy for SGM Oklahomans because it links individual well-being with the larger social and political context.[39-41] ET asserts that positive behavior change can be promoted through skills development with greater participation in the public affairs of one's community.[42] Individual

empowerment outcomes may include perceptions of personal control and a proactive approach to life.[40] Efforts to exert control are central to ET approaches; empowering processes often involve participation with others to achieve goals, efforts to gain access to resources, and opportunities to more critically understand one's sociopolitical environment.[39,41]

ET approaches have not been used in SGM-tailored tobacco interventions, but have been shown to be efficacious, feasible, and acceptable for use in SGM HIV/STI prevention[43,44] and youth-tailored tobacco interventions.[45-47] For SGM people, SGM-related social change mobilization and community-building participation are linked to empowering outcomes, including more adaptive coping with minority stress, experiencing more meaning in life, greater community connection, and overall positive psychological functioning.[48] Minority Stressguided[49] research on SGM people shows that as levels of coping and social support increase, so does engagement in health-promoting lifestyles.[50] For SGM smokers, adaptive coping strategies,[51] [52] social support,[52] smoking abstinence selfefficacy,[53] and internalized SGM stigma[54] may influence tobacco use and cessation behaviors, suggesting that empowerment activities may indirectly support tobacco cessation among SGM. We will pilot a novel tobacco cessation intervention that uses an empowerment approach focused on SGM community building to enhance smoking cessation outcomes for SGM Oklahomans.

This project is innovative because it is:

- A novel application of a theoretical framework, Empowerment Theory, from parallel health behavior change fields to advance tobacco cessation assistance for a social group with persistent tobacco-related disparities.
- The first SGM-tailored tobacco cessation intervention to integrate SGM empowerment activities with tobacco cessation assistance best practices to address person-environment drivers of SGM tobacco use.
- The first SCC partnership with an SGM-serving organization to reduce SGM Oklahoman tobacco use.

C. Preliminary Studies/Progress Report

1. Provide an account of previous studies and/or information that establishes the experience and competence of the investigator to pursue the protocol.

Team Expertise and Preliminary Data. Our team brings the requisite expertise in SGM tobacco disparities, tobacco cessation assistance for priority groups, community-engaged interventions, and SGM empowerment. PI McQuoid, Co-I Ehlke, and Drs. Heffner and Tan's work[55] shows the person-environment relationship drivers of SGM tobacco use, including using tobacco to cope with social minority stressors like fear of rejection and harassment.[14-17,55-59] Co-I Kendzor is PI of the SCC Tobacco Treatment and Research Program (TTRP),[60] which will assist with study recruitment and enrollment and provide standard tobacco cessation treatment. Co-I Frank-Pearce has expertise in biostatistical analysis of TTRP data. Drs. Heffner, Tan, Durazo and Co-I Kendzor have expertise

in tobacco and other health interventions for priority groups, including SGM,[61] Latinx,[62] and socioeconomically disadvantaged.[63-68] PI McQuoid's evaluation of a bar-based tobacco intervention for high-risk young adults found that immersive experiences that encourage a sense of collective purpose may enhance endorsement of anti-tobacco messaging.[69,70] Ms. Horn has over 15 years of experience developing social change and community-building programming for priority communities, including SGM groups in Oklahoma.

D. Research Design and Methods (What, When, How, Where)

Study overview. This study will assess the feasibility and acceptability of empowerment-enhanced tobacco cessation assistance for SGM adults. We will use a single-arm pilot design given funding, time, and sampling pool limits. Participants (N=20) will receive standard TTRP tobacco cessation assistance and concurrently participate in SGM empowerment activities. We will assess outcomes quantitatively and qualitatively. Primary outcome variables will be retention, perceptions of the intervention, adaptive coping strategies, biochemically-verified smoking abstinence at 12 weeks post-quit-date, and treatment adherence.

Recruitment. We will enroll participants over a 4-month period and recruit through the TTRP, which serves an average of 30 SGM individuals per year without SGM-targeted recruitment. We will supplement this by recruiting via local SGM-serving organizations, SGM targeted social media ads (e.g., Facebook), and snowball recruitment.

Eligibility criteria: Self-identify as SGM, 18+ years of age, report past 30-day combustible tobacco use (i.e., current smokers), willing to quit in the next two weeks, no contraindications for nicotine replacement therapy (NRT), reside in OK (verified with valid ID), willing to refrain from smoking any substance (e.g., cannabis) within 48 hours of expired carbon monoxide collection as this may impact biochemically-verified smoking abstinence.

Demographic sampling. Our racial and ethnic identity sampling targets roughly reflect the general Oklahoma population. The largest racial and ethnic groups in Oklahoma are Non-Hispanic White (65%), Hispanic (11.1%), American Indian (9.4%) Black/African American (7.8%), and two or more races (6.3%).[71] For gender targets, we aim to recruit for an approximately even number of cisgender female, cisgender male, and 'other gender' identifying participants (e.g., transgender, gender non-conforming, gender queer, refuse to answer). Approximately 3% of the general TTRP participant pool identify within this 'other gender' identity group. We will aim to over-recruit for 'other gender' identifying participants given the SGM focus of this pilot study. For sexual identity, our recruitment aims will reflect the non-heterosexual identity groups in the TTRP participant pool; the largest of these is gay/lesbian (4.9%), followed by 'unsure or refused to answer' (2.5%) and bisexual (2%).

Intervention. Participants will receive standard TTRP tobacco cessation assistance either remotely or in-person: 6 weekly counseling sessions and 12 weeks of

combination NRT (nicotine patches + nicotine gum or lozenges). During the 6 weeks of counseling, participants will also engage in 4 'empowerment activities' (i.e., SGM social change mobilization and community building activities[48]) lasting approximately 1.5 hours each, with the option to do more if desired. Activities will be tailored to each participant's comfort level and scheduling restraints.

Below is a list of empowerment activities that may be offered to participants:

- Compile publicly available, online information about school board meetings (locations, times, board contact information) into a spreadsheet. This spreadsheet will be made available to the public online to make it easier for people to be involved in their local schools.
- Conduct online research regarding HIV resources and services (for example, testing sites) in Oklahoma and compile into a word document. This will be made available to the public online to make it easier for people to access HIV resources in Oklahoma.
- Conduct phone calls using a script to gender marker and name change clinic[72] participants to assess their needs and report those needs back to the clinic.
- Conduct online research on the process to change gender markers and names in Oklahoma to be compiled into a resource document that will be made available to the public online.
- Support preparation for public webinars to raise community awareness about local LGBTQ2S+ resources by conducting phone calls to community members who are part of Freedom Oklahoma's network to assess what they would like to learn about in the webinars.
- Support in-person community engagement events, like the community gala skate night, by helping with event registration, event set-up, and event take down.

Participants will complete the following assessments: (i) 12 surveys (baseline, exit, quit-day, 1-4 and 12 weeks post-quit-date, and immediately following 'empowerment activity' participation for up to 4 sessions; (ii) biochemically-verified smoking status at baseline and 12 weeks post-quit-date via expired carbon monoxide monitors; and (iii) a 60-minute in-depth interview over Zoom video chat within weeks 6-8 post-quit-date. Participants will be incentivized a total of $300 for the baseline survey ($25), 6 subsequent short surveys ($70), 4 empowerment activity feedback surveys ($100), 2 expired carbon monoxide tests ($20), , exit survey ($25), and 60-minute interview ($60). Participants are also eligible to receive up to two additional incentive bonuses for assisting in snowball recruitment of eligible participants who enroll in this study ($25 per referral, maximum of $50). Participants will be eligible for up to a $350 incentivized total. Freedom Oklahoma staff will participate in interviews and reflect on the intervention and Freedom OK's role in it. Freedom Oklahoma will adopt a tobacco-free policy and provide feedback on the cultural competence of TTRP materials.

Partnerships. TTRP will provide the standard tobacco cessation assistance. Freedom Oklahoma will design the empowerment activities. Freedom Oklahoma is a community-based organization in Oklahoma City that has worked to secure lived equality and legal protection for SGM Oklahomans for over 15 years. PI McQuoid and Freedom OK have held more than 4 project planning meetings over the past year.

Measurement of Feasibility and Acceptability (Aim 1). We will use exit surveys and empowerment activity feedback surveys administered via REDCap to assess retention and self-reported empowerment activity participation (i.e., total hours, types of events/activities, roles played).[73] We will cross-reference with research project records of empowerment activity participation. We will also qualitatively assess perceptions of the intervention by interviewing participants over Zoom video chat at 12 weeks post-quit-date. PI McQuoid, a qualitative methods expert, will train a team to conduct semi-structured, in-depth interviews lasting approximately 60 minutes. We will elicit rich content regarding experiences of empowerment activity participation and tobacco cessation as an SGM person in Oklahoma. Interview guide domains will include: (i) best intervention aspects (e.g. highlights, peak experiences); (ii) biggest challenges or negative experiences; (iii) empowerment activity experiences; (iv) interactions of empowerment activity participation with tobacco cessation experiences; (v) outcomes and personal growth (vi) suggestions for intervention improvements. Interviews will be audio-recorded and professionally transcribed verbatim.

Qualitative Analysis: We will use Dedoose qualitative data analysis software to conduct an inductive-deductive thematic transcript analysis with a priori themes derived from ET[39-42,45-47,73] and SGM tobacco cessation literature.[33-35] We will use an iterative codebook development process involving weekly team discussions, independent coding, and member checking of findings[74] to enhance rigor and trustworthiness.[75,76] We will also interview Freedom Oklahoma staff about their perceptions of the intervention and their organization's role in it.

Measurement of Individual Empowerment and Cessation Predictors (Aim 2). We will compare individual empowerment and cessation predictors pre- and postintervention with baseline and exit surveys. We will assess predictors of smoking cessation[51-54,77,78] and individual empowerment outcome measures adapted from a youth empowerment tobacco control model[42,73] and SGM social change mobilization participation research.[48] These will include: (i) adaptive coping strategies (Cognitive Emotion Regulation Questionnaire[79]), (ii) (v) social support (Relational Health Indices[80]), (iii) abstinence self-efficacy (Confidence Inventory[81]), and (iv) internalized SGM stigma (Internalized Transphobia and Pride[82] and Internalized Homophobia items[83]).

Measurement of Tobacco Cessation Outcomes (Aim 3). We will use benchmarks to assess participants' tobacco cessation outcomes. Tobacco abstinence will be measured via self-report and biochemically-verified via expired carbon monoxide at baseline and 12 weeks post-quit-date. Treatment adherence will be assessed with

the 4-item Medication Adherence Questionnaire (MAQ)[84] and counseling session attendance tracking.

Sample Size/Analysis Plan. Primary outcome variables will be: retention, perceptions of the intervention, adaptive coping strategies, biochemical verification of tobacco abstinence at 12 weeks post-quit-date, and treatment adherence. We will evaluate retention by calculating the proportion of participants who complete the final study visit at 12-weeks post-quit, with the goal of retaining >80% of participants. We will qualitatively evaluate perceptions of the intervention (as described above). We will use a two-sided paired samples t-test to examine the mean differences in adaptive coping strategies pre- and postintervention (α=0.05). Assuming 20% attrition and a standard deviation of differences of 4.0[85], n=20 participants will provide 80% power to detect a mean difference of 2.6 in adaptive coping strategies. Tobacco cessation outcomes will be considered successful if the proportion of participants with biochemically-verified smoking abstinence (expired carbon monoxide) at 12 weeks post-quit date is equal to or greater than the general TTRP sample (i.e., 18% at 12 weeks[1]). Treatment adherence will be considered successful with all participants having >50% of treatment weeks with an MAQ score indicating moderate/high adherence and counseling session attendance.

Expected outcomes: Empowerment-enhanced tobacco cessation assistance will be acceptable and feasible (Aim 1), will increase within-subject empowerment and improve cessation predictors (Aim 2), and will meet benchmarks for tobacco cessation outcomes (Aim 3).

Identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

Potential problems and alternative strategies. COVID-19: All intervention activities can be conducted remotely, including cessation counseling, empowerment activities (e.g., remote phone banking), and mailing iCOquit devices (expired carbon monoxide) to participants. Retention: We budgeted for 25 participants to allow for a 20% drop out rate. Some participants may not find certain empowerment activities acceptable and will be encouraged to continue TTRP tobacco cessation assistance. Recruitment: We have budgeted for contingency recruitment efforts, including contracting a specialized recruitment service (e.g., TrialFacts) and distributing press releases to regional media outlets.

Timeline. Month 1 Study preparation; Months 2-6 Recruitment and enrollment; Month 10 All 12-week follow-up visits will have concluded; Month 10-12 Data analysis and manuscript preparation.

E. Chart Review

N/A. This study is not conducting a chart review or electronic medical records.

F. Biospecimens

N/A. There will be no biospecimen collection in this study.

G. Banking/Repository/Database

All data collected during the study will be retained for future use in tobacco and nicotine research. Data will be stored electronically on a secure password server that can only be accessed by approved study personnel. No biospecimens will be collected or stored.

H. Inclusion / Exclusion Criteria

1. List the criteria that will define who will be **included** in the study

   - ≥18 years old
   - Self-identify as sexual and/or gender minority
   - Reside in the State of Oklahoma
   - Report past 30 day use of combustible tobacco
   - Willing to quit using combustible tobacco within the next 2 weeks
   - English-speaking
   - Willing to refrain from smoking any substance, such as cannabis, within 48 hours of expired carbon monoxide collection
   - Willing to complete all intervention components and data collection activities

2. List the criteria that will define who will be **excluded** in the study.

   - Have contraindications for nicotine replacement therapy (NRT)

3. Provide early termination criteria.

   - Participants will be terminated at any point during their study participation if they have stopped participating study activities and are non-responsive to 3 or more consecutive contact attempts from research staff.

I. Gender/Minority/Pediatric Inclusion for Research

The study has no inclusion/exclusion criteria based on race/ethnicity. We are specifically recruiting for cisgender women (target 35% of the sample) and gender minority identified people (i.e., transgender, gender non-conforming, other gender; target 30% of the sample) given the sexual and/or gender minority focus of this pilot intervention. We do not anticipate difficulty achieving this gender composition given that cisgender women have been easier to recruit than cisgender men in our past studies on tobacco and/or cannabis use and our recruitment efforts will specifically target the gender and sexual minority

community in Oklahoma. The PI has developed a strong working relationship with local SGM-serving organizations in Oklahoma, including our community partner on this proposal (Freedom Oklahoma), and has successfully targeted sexual and/or gender minority participants through targeted social media campaigns and community partner recruitment in past studies. All materials will be tailored to low-literacy populations to enhance inclusion of under-represented populations and minority groups.

J. Recruitment and Enrollment

1. Describe the plans for recruitment.
    a. Methods to identify and recruit potential participants

We will enroll participants (N=20) over a 4-month period and recruit through the Tobacco Treatment Research Program (TTRP), which serves an average of 30 sexual and/or gender minority (SGM) individuals per year without SGM-targeted recruitment efforts. We will supplement this pool of SGM participants by recruiting for SGM participants through local SGM-serving organizations, SGM targeted social media ads (e.g., Facebook), and snowball recruitment.

- Tobacco Treatment Research Program (TTRP) enrollments. The Stephenson Cancer Center's TTRP follows an Institutional Review Board (IRB)-approved research protocol where participants are referred by a health care provider through the University of Oklahoma Health Sciences Center (OUHSC) electronic medical record. Community participants may contact the clinic via the web, email, phone, fax, walk-in and tablet connection (in certain circumstances). The TTRP responds to referrals by providing information about treatment options, screening participants, and scheduling them for standard TTRP treatment or for an ongoing trial (if eligible and interested).
- Local sexual and/or gender minority (SGM)-serving organizations. Freedom Oklahoma, a SGM-serving organization in Oklahoma City and the community partner on this proposal (See Letter of Support) will distribute recruitment materials to their extensive professional networks and channels of communication and will connect the research team to additional SGM-serving community organizations as needed to diversify the sample. Physical materials with study information will be printed as needed for distribution by SGM serving community organizations in Oklahoma and posted in public spaces (e.g., palm cards, flyers).
- Targeted social media campaign. Participants will be recruited through paid advertisements on Facebook and Instagram that target SGM people who use tobacco and live in Oklahoma using a well-established campaign program managed by the University of Oklahoma Marketing team. Additional recruitment advertisements will be posted on Craigslist or other local advertising services and online forums as needed.
- Snowball recruitment. Participants will be invited and incentivized ($25 per referral of an eligible individual who enrolls in the study for a maximum of two

referrals and $50 additional at the end of their participation in the study)to share the study information and/or Dr. McQuoid's contact information with anyone they think may be eligible and interested in participating in the study.

2. Describe the consent procedures to be followed

Informed consent. All study advertisements will provide a link to the study's REDCap website with a short eligibility questionnaire. If respondents are eligible, they will be taken to the informed consent webpage, where will have the opportunity to consent. Dr. McQuoid's contact information will be made available to participants to answer any questions about the study and to provide a way to inform the researchers at any point should they wish to withdraw from the study or have changed their minds about the use of their data. All materials will be tailored to low-literacy populations (i.e., a 4th grade reading level).

Participants will be reminded that their participation is voluntary. Additionally, they will be reminded that they are allowed to discontinue participation in the study at any time, without any loss of benefits or other negative consequences. Individuals will be given as much time as they need to make a decision about participation; they will initiate their own consent on the informed consent at any time that they wish. The participant will be given a copy of the consent form to keep for his or her records. All research team members will complete an approved course on the protection of human subjects and be trained on how to clearly describe study procedures and the obtain informed consent process.

3. Describe the location where consent is most likely to take place. Consent will most likely take place in the participants' own home or any other location where they are accessing the consent webpage on their own device without the presence of a researcher.

4. Describe provisions for recruiting non-English speaking participants. This study will not recruit non-English speaking participants.

5. Describe measures to decrease participant coercion.
Several recommended approaches will be used to reduce coercion, including allowing participants ample time to review the consent, and using only qualified trained research staff to engage in the consent form process. Further, participants will be told in writing at the screening and at the time of consent that their participant is completely voluntary. They will be reminded during phone calls/video chat interactions with research staff and before and during the in-depth interview that they can decline to answer any question and they can withdraw their participation at any time without penalty.

K. Risks and Benefits

1. Describe risks and assess their likelihood and severity.

The primary risks to participants are discomfort, loss of confidentiality, and medical side effects from FDA-approved Nicotine Replacement Therapy (NRT).
Discomfort may be experienced during participation in empowerment activities or the in-depth interview discussion, or due to some of the questionnaire items administered over the study period.

A potential, although unlikely, risk to participants is loss of confidentiality. The severity of harm in the case of loss of confidentially may range from mild to severe depending upon the individual and the specific circumstances. However, the risks of participation in the study are similar to that of participation in standard care, as loss of confidentially may be experienced in either case. In addition, participant data residing on laptop/tablet computers and smart phones will be encrypted and password protected.

There is a risk of side effects associated with FDA-approved tobacco cessation medications; Nicotine Replacement Therapy (NRT):

- Possible risks of the nicotine patch include: increased blood pressure; skin redness, swelling, or rash; irregular heartbeat or palpitations; or symptoms of nicotine overdose including nausea, dizziness, weakness, and rapid heartbeat; and vivid dreams or sleep disturbance.
- Possible risks of nicotine gum include: increased heart rate and blood pressure; mouth, teeth, and jaw problems; irregular heartbeat or palpitations; symptoms of nicotine overdose including nausea, vomiting, dizziness, weakness, and rapid heartbeat; or allergic reaction such as difficulty breathing or rash.
- Possible risks of nicotine lozenges include: increased heart rate and blood pressure; mouth, teeth, and jaw problems; indigestion or sore throat; irregular heartbeat or palpitations; symptoms of nicotine overdose including nausea, vomiting, dizziness, weakness, and rapid heartbeat; or allergic reaction such as difficulty breathing or rash. Nicotine replacement medications may have enough medication to make children and pets sick.

2. Describe procedures for protecting against or minimizing potential risks.
    a. Address measures instituted to protect the privacy and/or confidentiality of participant PHI

Detailed protocols are in place to assess participant safety and respond effectively throughout participant engagement in this empowerment-enhanced tobacco cessation intervention pilot study, and to minimize risk of loss of participant confidentiality and data storage procedures.

General Procedures: Each participant will be assigned an identification number that will be utilized in place of names in all electronic and print data

files. The file containing the links between participant names and identifiers will be kept in a separate password-protected file, which will be destroyed 12 months after the completion of the study. Any print information will be stored in a locked filing cabinet in the Principal Investigator's locked office. Electronic data (with names omitted) will be maintained on the investigator's computers, and all computers and electronic files will be password protected. Biochemical verification of smoking status will be collected in a private room in the TTRP. All project staff will complete extensive training focused on each of the following topics: 1) project rationale and objectives, 2) the informed consent process, 3) general data collection procedures (e.g., computer data collection, privacy), and 4) use of the carbon monoxide monitor.

Minimizing risk of participant discomfort and side effects from FDA approved Nicotine Replacement Therapy (NRT):

Participant safety and level of distress will be assessed through research team members' and TTRP counselors' direct interactions with participants over video chat or in-person (including during interviews), on the phone, and during email correspondences. Specific protocols for participants who request substance use dependence treatment support, appear heavily intoxicated, and/or appear suicidal are provided below.

The Tobacco Treatment Research Program (TTRP) tobacco cessation assistance activities – including tobacco cessation counseling, biochemical verification of smoking status, nicotine replacement therapy, and administration of follow up surveys - follows a University of Oklahoma Health Sciences Center Institutional Review Board (IRB)-approved research protocol (PI: Darla Kendzor).

This study will not enroll individuals with contraindications for Nicotine Replacement Therapy (NRT).

Participants will be told prior to starting the study that their participation in research is voluntary and they may stop at any time. Prior to beginning each empowerment activity participation session and the interview they will be reminded that they may choose to stop or pause the activity/interview at any time and may decline to answer any questions or engage in any activity that causes them discomfort. If a participant becomes distressed during the empowerment activity or interview they will be offered the option to stop or pause.

Empowerment activity debriefing sessions. Following each empowerment activity participation session, the empowerment activity facilitator (a member of the McQuoid research team) will engage participants in a debriefing session to reflect on their experiences participating in the activity and any emotions or topics that arose for them. During this debriefing session, and during any other point of contact with participants, the activity

facilitator and research team will follow the protocol for 'Vulnerable Subjects' as needed (described below).

Minimizing risk of loss of participant confidentiality and data storage procedures:

All information obtained from participants will be kept completely confidential. Data will be stored as follows:

- **All data will be stored in secure locations to minimize the risk of breach of confidentiality**, including locked file cabinets and password-protected computers and databases. Adverse events will be reported to the University of Oklahoma Health Sciences Center IRB, as appropriate, to ensure the safety of subjects' information.
- **All study questionnaires** will be administered online with participants' own devices or a study device using an electronic data capture system (REDCap) to maintain 21 CFR Part 11 compliance and Good Clinical Practice (GCP) standards.
- **All transcripts from interviews will be stored on encrypted hard drives** disconnected from the Internet and kept in locked file cabinets.
- **Human subjects will be assigned coded participant ID numbers.**
- **Files with identifying information will be stored separately** from files with other forms of data (e.g., substance use status, mobility data, transcripts).
- **Access to individually identifiable private information about human subjects will be had only by the individuals listed in this proposal.**
- **Study investigators have completed required University of Oklahoma Health Science Center training and certification** in the conduct of research with human subjects.

Vulnerable Subjects:

This study focuses on tobacco cessation and empowerment for sexual and/or gender minority people in Oklahoma. Specific protocols will be in place to protect participant safety. **See protocol in Data and Safety Monitoring Plan, below.**

Clinical Resource to the Research Team: Dr. Jon Hart will serve as the clinical resource to the research team for this pilot study (PhD in Counseling Psychology, University of Oklahoma; NPI 1508236787; OK 1239). Dr. Hart is the Director of the Oklahoma Tobacco Helpline and Assistant Professor at the University of Oklahoma Health Sciences Center. He is a Licensed Psychologist whose expertise includes suicide prevention. Dr. Hart will train Dr. McQuoid and the rest of the research team in the study protocols designed to minimize risk to participants (described below) and will be available to the study team to discuss the protocols as needed throughout the duration of the study.

3. Describe potential benefits and importance to the participants and others. Potential benefits to participants include individual empowerment outcomes (e.g., more active coping strategies for minority stressors) and the possibility that the empowerment-enhanced tobacco cessation intervention will have a beneficial impact on smoking cessation outcomes.

4. Discuss why risks are reasonable in relation to benefits.

The knowledge gained from this study may be utilized to enhance efficacy of tobacco cessation assistance for sexual and/or gender minority (SGM) people, improve smoking abstinence rates in SGM populations, and thereby reduce tobacco-related disease and health disparities.

L. Multiple Sites

N/A. This study does not involve multiple sites.

M. Statistical Methods

Provide biostatistical design, power calculations determining the number of participants, and the proposed analysis.

Dr. Summer Frank-Pearce, biostatistician, is a Co-Investigator on this project and informed the design of the statistical methods for this study.

This is a pilot study to assess feasibility and acceptability of an intervention.

Sample Size/Analysis Plan. Primary outcome variables will be: retention, perceptions of the intervention, adaptive coping strategies, biochemical verification of tobacco abstinence at 12 weeks post-quit-date, and treatment adherence. We will evaluate retention by calculating the proportion of participants who complete the final study visit at 12-weeks post-quit, with the goal of retaining >80% of participants. We will qualitatively evaluate perceptions of the intervention (as described above). We will use a two-sided paired samples t-test to examine the mean differences in adaptive coping strategies pre- and postintervention (α=0.05). Assuming 20% attrition and a standard deviation of differences of 4.0[85], n=20 participants will provide 80% power to detect a mean difference of 2.6 in adaptive coping strategies. Tobacco cessation outcomes will be considered successful if the proportion of participants with biochemicallyverified smoking abstinence (expired carbon monoxide) at 12 weeks post-quitedate is equal to or greater than the general TTRP sample (i.e., 18% at 12 weeks[1]). Treatment adherence will be considered successful with all participants having >50% of treatment weeks with an MAQ score indicating moderate/high adherence and counseling session attendance.
Expected outcomes: Empowerment-enhanced tobacco cessation assistance will be acceptable and feasible (Aim 1), will increase within-subject empowerment and

improve cessation predictors (Aim 2), and will meet benchmarks for tobacco cessation outcomes (Aim 3).

N. Data and Safety Monitoring Plan

Continuous monitoring and reporting of events will be undertaken by the Principal investigator (Dr. Julia McQuoid) and unanticipated problems will be promptly reported to the IRB. Since the standard smoking cessation treatment is offered by the Stephenson Cancer Center independent of this research proposal, adverse event monitoring will focus on events related to empowerment activity participation and study assessments. Possible adverse events might include compromised data security, and severe emotional reactions by participants due to participation in SGM social change mobilization and community building activities and/or questionnaire items.

Participant Safety Monitoring Plan:

This study focuses on tobacco cessation and empowerment for sexual and/or gender minority people in Oklahoma. Specific protocols will be in place to protect participant safety. See below.

Clinical Resource to the Research Team: Dr. Jon Hart will serve as the clinical resource to the research team for this pilot study (PhD in Counseling Psychology, University of Oklahoma; NPI 1508236787; OK 1239). Dr. Hart is the Director of the Oklahoma Tobacco Helpline and Assistant Professor at the University of Oklahoma Health Sciences Center. He is a Licensed Psychologist whose expertise includes suicide prevention. Dr. Hart will train Dr. McQuoid and the rest of the research team in the study protocols designed to minimize risk to participants (described below) and will be available to the study team to discuss the protocols as needed throughout the duration of the study.

PROTOCOL FOR REQUESTS FOR SUBSTANCE USE DEPENDENCE TREATMENT AND/OR CRISIS SERVICES:

Upon request, participants will be given the contact information for resources from the Substance Abuse and Mental Health Services Administration:

- FindTreatment.gov - Millions of Americans have a substance use disorder. Find a treatment facility near you.
- Suicide prevention lifeline 1-800-273-TALK (8255) Free and confidential support for people in distress, 24/7.
- National Helpline 1-800-662-HELP (4357) Treatment referral and information, 24/7.
- Oklahoma-specific Google map that allows users to select which type of resource they need, and then see which facilities in OK are licensed by ODMHSAS:https://www.google.com/maps/d/u/0/viewer?mid=137cjQWot11ah4uYf2vIE7hjRGU&ll=35.62854113370643%2C98.30299192656254&z=7

PROTOCOLS FOR HEAVILY INTOXICATED PARTICIPANTS:

During any point of contact with the research team or TTRP staff, participants may be heavily intoxicated and/or express thoughts of suicide or related ideation or thoughts of harming self-suggestive of suicidal risk. Participant safety will be monitored by researchers during in-person, phone, or email contact with participants.

Below are protocols to be followed for heavily intoxicated and/or suicidal participants:

Warning Signs for Intoxication

- Unsteady gait
- Breath that smells of alcohol

If a participant is heavily intoxicated or high at the time of participation, there are two issues that must be considered. First there is the issue of whether the participant should complete the study activity or return/reengage at a later date. The researcher/staff will need to make a judgment as to whether the participant can continue based on such factors as their ability to understand and complete activities, forms or interviews. The second issue to consider in the case of inperson data collection is whether the individual is safe to travel home at the end of the activity or assessment (if occurring in person).
If the participant traveled from their home to another location for the study activity (e.g., our offices, the TTRP clinic) and there is any concern about the participant's ability to get home safely or if the participant discloses that they are too "high" or intoxicated to continue with the assessments, the researcher/staff should secure safe transportation home for the participant and reschedule the assessment process.

"I am concerned that you may be intoxicated right now. Is that true?"

If true, then you may say:

"*If you are intoxicated, I don't think this is a good time for us to continue with the interview/activity. But I am concerned about how you are going to get home safely. It is the study's policy for you to stay here until you are okay to drive home. We are going to help arrange transportation."*

1. Notify Dr. McQuoid by calling her at (cell) 510-672-0394.
2. Give Dr. McQuoid the participant's name, and any other relevant information you have. Ask for assistance in arranging for transportation.
3. Have the participant talk with Dr. McQuoid over the phone, via video chat, or in person.
4. Stay with participant (in person or virtually) until transportation arrives.

Note: If the participant refuses this transportation assistance and insists on driving in an intoxicated state, they should be informed that the police will be called and a description of their car given and the direction it is heading.

PROTOCOLS FOR SUICIDAL PARTICIPANTS:

Acute Suicidal Warning Signs

- The participant expresses hopelessness (e.g., "I'll never get better").
- The participant makes direct or indirect statements about killing themselves, being better off dead, or things being better for others if participant wasn't alive

If any participant makes a direct or indirect statement about suicide, hopelessness or death, even when said in a joking or off hand manner, this is a cause for concern. Sometimes suicidal people leave hints. It is not true that a person who talks frequently about committing suicide will not do it. Some keep their suicidal thoughts to themselves, while others do not. If a participant shows a desire or intent to kill her/him/their self, s/he/they should be evaluated by a qualified clinician to determine her/his/their level of risk and be connected to treatment setting that can ensure their safety. If you suspect that a person is in danger of killing her/him/their self, the interview should be stopped and specific focus should be made on the participant's safety, and the protocol below should be followed:
To start, you should say:
"I am concerned about what you just said to me about your feelings/thoughts right now (e.g., "feeling so bad that you wish you were dead" or "thinking things are hopeless or would be better if you weren't around"). I think this is really important. I need to connect you with someone to talk to who can help. I can give you the National Suicide Prevention Lifeline number for you to call privately, or we can do it together if that would be helpful."

Step-by-step process

1. Stop the interview/activity
2. Express concern for participant's safety and well-being and the importance of getting participant the help they need to get through this difficult time (see script above)
3. Encourage the participant to call the hotline and/or offer to call together:

- Toll-free, 24-hour hotline of the **National Suicide Prevention Lifeline** 1-800273-TALK (**1-800-273-8255**)

Your call will be connected to a trained counselor at a suicide crisis center nearest you.https://suicidepreventionlifeline.org/?utm_source=google&utm_medium=web&utm_campaign=onebox

4. If the participant won't call and/or disconnects the call and won't reconnect, and you are concerned they are in imminent danger of hurting themselves or others, stay on the phone with them and ask them to "hold while you make a call to get some help to them."
5. Call 9-1-1 and request a CIT officer make a welfare check on an individual expressing an imminent desire to kill themselves. Cooperate with the 91-1 operator to provide details about participant's location and specific

statements that caused you to believe the individual was at imminent risk of suicide.

6. If the participant is still on the phone, reassure them that you will stay on the phone until the help arrives. Wait with the participant on the line until they confirm the CIT officer has arrived at their location.

7. Immediately following a referral to the suicide prevention lifeline or a 9-11 welfare check call:

- If in TTRP, inform TTRP supervisor on-call and inform them of the situation
- If not in TTRP, call Dr. McQuoid at 510-672-0394 (cell) and inform her of the situation

8. After you provide participant support and have informed either the TTRP supervisor or Dr. McQuoid, document the incident in RedCap in the participant's file.

9. The day following the incident, attempt to call the participant to follow up and schedule next study visit and/or leave a message requesting participant reach out when able.

The following statement has been included in the Informed Consent form so that participants are aware of this protocol:

What will happen if the research team thinks I am suicidal?

If, while we are interacting with you, any member of our research team or smoking cessation staff is concerned that you are in danger of killing yourself, you will be encouraged to call the National Suicide Prevention Lifeline or 9-1-1. If you do not agree to voluntarily call the Suicide Prevention Lifeline or 9-1-1, the study protocol requires the research team and/or staff member to call 9-1-1 and request a CIT officer provide a welfare check to ensure your safety.

O. Data Sharing

De-identified data will be made available to outside investigators upon request. However, it is noteworthy that data collected as part of the current proposal will be from a small sample, and will not provide sufficient information from which to draw conclusions. Rather these data will support a larger, adequately powered trial, from which data may be more complete and useful to other investigators.

P. Confidentiality

General Procedures: Each participant will be assigned an identification number that will be utilized in place of names in all electronic and print data files. The file containing the links between participant names and identifiers will be kept in a separate password-protected file, which will be destroyed 12 months after the completion of the study. Any print information will be stored in a locked filing cabinet in the Principal Investigator's locked office. Electronic data (with names omitted) will be maintained on the investigator's computers, and all computers and electronic files will be password protected. Biochemical verification of smoking

status will be collected in a private room in the TTRP. All project staff will complete extensive training focused on each of the following topics: 1) project rationale and objectives, 2) the informed consent process, 3) general data collection procedures (e.g., computer data collection, privacy), and 4) use of the carbon monoxide monitor.

Minimizing risk of loss of participant confidentiality and data storage procedures:

All information obtained from participants will be kept completely confidential. Data will be stored as follows:

- All data will be stored in secure locations to minimize the risk of breach of confidentiality, including locked file cabinets and password-protected computers and databases. Adverse events will be reported to the University of Oklahoma Health Sciences Center IRB, as appropriate, to ensure the safety of subjects' information.
- All study questionnaires will be administered online with participants' own devices or a study device using an electronic data capture system (REDCap) to maintain 21 CFR Part 11 compliance and Good Clinical Practice (GCP) standards.
- All transcripts from interviews will be stored on encrypted hard drives disconnected from the Internet and kept in locked file cabinets.
- Human subjects will be assigned coded participant ID numbers.
- Files with identifying information will be stored separately from files with other forms of data (e.g., substance use status, mobility data, transcripts).
- Access to individually identifiable private information about human subjects will be had only by the individuals listed in this proposal.
- Study investigators have completed required University of Oklahoma Health Science Center training and certification in the conduct of research with human subjects.

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