Title of Project: Mobile Contingency Management for Smoking Cessation among Socioeconomically Disadvantaged Adults (PREVAILgo)

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Abstract
Smoking prevalence rates are disproportionately high among individuals living below the poverty threshold, those living in rural areas, and Oklahomans. Nearly 1.3 million Oklahomans live in rural areas and the prevalence of poverty is elevated relative to the U.S. Our preliminary work has indicated that offering small escalating financial incentives for smoking abstinence (i.e., Contingency Management [CM]) dramatically increases short-term cessation rates among socioeconomically disadvantaged smokers when incentives are included as an adjunct to clinic-based smoking cessation treatment. However, other approaches are needed for socioeconomically disadvantaged individuals who are unable to attend clinic visits due to rural residence or other limitations. Internet and mobile phone-based CM approaches have been developed to reduce or eliminate the need for in-person visits. The goal of the current project is to improve upon existing mobile CM approaches by fully automating the process to make financial incentives interventions for smoking cessation feasible and accessible to individuals across the state. The aims of the proposed project are to 1) develop a fully automated, mobile phone-based CM approach to remotely verify smoking abstinence, confirm participant identity, and deliver financial incentives for smoking cessation, and 2) evaluate the feasibility and preliminary effectiveness of using fully automated mobile CM as an adjunct to telephone counseling and nicotine replacement therapy among 20 socioeconomically disadvantaged adults. The current project extends the scope of the parent study by increasing the reach of the CM approach to socioeconomically disadvantaged individuals who may be unable to attend in-person visits.

A. Specific Aims

The purpose of the proposed project is to develop a fully automated mobile phone-based CM approach that allows disadvantaged populations to remotely benefit from smoking cessation treatments that offer financial incentives for smoking cessation. With the assistance of the Mobile Health (mHealth) shared resource at the University of Oklahoma Health Sciences Center, the investigators will combine technologies including 1) low-cost carbon monoxide monitors that connect with mobile phones\(^1,2\) to remotely verify smoking abstinence, 2) facial recognition or similar software to confirm the identity of participants providing a breath sample, and 3) the delivery of automatic credits triggered by biochemical evidence of smoking abstinence. After the procedures are developed, the
feasibility of using the fully-automated CM approach will be evaluated with 20 socioeconomically disadvantaged males and females seeking smoking cessation treatment as an adjunct to telephone-based counseling and nicotine replacement therapy. Participants will be followed for 12 weeks after a scheduled quit attempt to assess feasibility. The development of a fully automated CM approach to smoking cessation will facilitate the delivery of interventions to socioeconomically disadvantaged and rural populations in Oklahoma and beyond. The aims of the proposed project are to:

**Aim 1.** Develop a fully automated, mobile phone-based CM approach that can remotely verify smoking abstinence, confirm participant identity, and deliver financial incentives for smoking cessation. **Mobile phone-based carbon monoxide monitoring, facial recognition software, and automatically triggered payments for biochemical evidence of smoking abstinence will be combined to accomplish the study aim.**

**Aim 2.** Evaluate the feasibility and preliminary effectiveness of using a fully automated mobile CM approach as an adjunct to telephone counseling and nicotine replacement therapy among socioeconomically disadvantaged adults. **It is hypothesized that treatment uptake, smoking cessation, and follow-up rates will be comparable to the traditional in-person CM approach evaluated in the pilot work** and parent study.  

**B. Background and Significance**

Smoking prevalence rates are disproportionately high among individuals living below the poverty threshold, those living in rural areas, and Oklahomans. Nearly 1.3 million Oklahoma (33.8%) live in rural areas and the prevalence of poverty in the state is elevated relative to the U.S. overall. Smoking cessation approaches are needed to reach rural, socioeconomically disadvantaged populations who may have reduced access to treatment due to lack of insurance and low physician supply. There is mounting evidence that contingency management (CM), or the tangible reinforcement of abstinence and other related outcomes, may be an effective approach to promoting smoking cessation in a variety of populations. The findings of two recent meta-analyses have indicated that financial incentives are associated with greater odds of behavior change particularly among socioeconomically disadvantaged individuals. Our own work has demonstrated the short-term efficacy of a low-cost CM intervention among homeless shelter residents and socioeconomically disadvantaged safety net hospital patients. To date, financial incentives interventions for smoking cessation have primarily relied on in-person visits to verify smoking abstinence. However, several recent studies have evaluated an internet-based approach, where participants access the study website and record themselves via webcam as they provide breath samples using a loaned carbon monoxide (CO) monitor. Participants upload the recordings for staff review (twice daily, at least 8 hours apart), and reinforcement is applied to their study accounts on the website when abstinence and their identity are verified. Studies have also employed a similar approach using mobile phones equipped with video cameras, where participants record themselves as they provide a CO breath sample and then upload the videos for staff review via a study website. The goal of the current project is to build upon the mobile CM approach by fully automating the process of biochemical verification and the
delivery of incentives. Low-cost, portable CO monitors that attach to a smartphone are now available,2 and this technology may be used to remotely verify smoking abstinence following random mobile phone prompts during waking hours. Facial recognition systems or other identification approaches may be used to verify the identity of participants, and an automatic gift card credit can be triggered based on CO values and identity verification. Thus, the contribution of the proposed project will be to develop and feasibility-test a completely automated approach to CM that may be combined with quitline or clinic-based telemedicine approaches for those who live in rural areas and/or who are unable to travel to in-person appointments.

C. Preliminary Studies/Progress Report

Darla Kendzor earned her Ph.D. in Clinical Psychology from Louisiana State University in 2007. She is currently an Associate Professor in the Department of Family and Preventive Medicine, and a member of the Cancer Prevention and Control Program of the Stephenson Cancer Center Cancer. She has a history of published research directly relevant to tobacco cessation interventions, and especially socioeconomically disadvantaged populations.28,35-44 She has also received external funding from the American Cancer Society (ACS) and the National Cancer Institute (NCI). Notably, Dr. Kendzor recently completed a randomized controlled trial (RCT) to evaluate the feasibility and short-term effectiveness of offering small financial incentives (gift cards) for biochemically verified abstinence as an adjunct to the tobacco cessation program offered at the Dallas County safety net hospital (the PREVAIL Study).3 Dr. Kendzor also used this identical incentives schedule successfully with a small sample of homeless smokers in a shelter setting.28 Dr. Kendzor is currently conducting an NCI-funded follow-up RCT to evaluate the longer-term impact of an adjunctive, low-cost intervention offering small financial incentives (relative to standard care) on smoking abstinence rates among socioeconomically disadvantaged individuals participating in a clinic-based tobacco cessation program (PREVAIL II).4 The study described in this protocol (PREVAIL go) is an NCI-funded supplement to the PREVAIL II study.

D. Research Design and Methods

Tobacco Cessation Treatment. Participants referred to the TTRP and who are interested and eligible for the current study will be offered weekly telephone counseling/support sessions led by a staff counselor. Five unique sessions covering the following topics will be offered: 1) the impact of tobacco on health/benefits of quitting, 2) stress management strategies, 3) making positive lifestyle changes, 4) developing coping skills, and 5) relapse prevention. The counselor will check in with participants each week about the difficulties and successes they have experienced, and plan for any challenging situations that are anticipated. Advice and support will be provided as needed. A two-week supply of nicotine replacement therapy (patches and gum) will be offered during the first session for medically eligible participants. Additional patches and gum will be mailed out for participants who wish to continue using pharmacotherapy (for up to 12 weeks).
**Financial Incentives.** Participants will be provided with a smartphone that has the PREVAILgo EMA app preloaded, as well as a Smokerlyzer iCO monitor. Participants will be randomly prompted 4 times daily during waking hours to complete smartphone-based EMAs. During random prompts, participants who self-report abstinence will be asked to provide a CO breath sample on 5 randomly selected days out of the week. Participants will be prompted to provide a CO breath sample at the first random assessment of the day, and at each random assessment afterwards until the sample is provided. A gift card credit may be earned following a self-report of abstinence during the past 24 hours combined with a breath CO sample of ≤ 6 ppm. Participants who are abstinent on the quit day will receive a $20 gift card credit. For each abstinent day during the first week post-quit, the mobile phone app will indicate that a $4 credit was earned. The incentive amount per abstinent day will increase by $1 per week with each week of consecutive abstinence until 4 weeks post-quit, when continuously abstinent participants will earn a $7 gift card credit per abstinent day. Participants who provide 5 negative breath samples within a week will additionally receive a $5 bonus through 4 weeks post-quit. Participants who are non-abstinent (or who do not provide a sample) will not earn incentives that day, but may begin earning incentives for abstinence again on their 2nd consecutively abstinent day. However, the amount will reset to the starting level of $4 per abstinent day. Participants may earn $8 per abstinent day during weeks 8 and 12 post-quit, with a $10 bonus for 5 negative samples each week.

<table>
<thead>
<tr>
<th>WEEKS POST-QUIT</th>
<th>CONTINGENT INCENTIVES</th>
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<tbody>
<tr>
<td>Quit Day</td>
<td>$20 for negative CO sample</td>
</tr>
<tr>
<td>Quit Day-1 Week</td>
<td>$4 per negative CO sample (up to $20 + $5 bonus)</td>
</tr>
<tr>
<td>1-2 Weeks</td>
<td>$5 per negative CO sample (up to $25 + $5 bonus)</td>
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<tr>
<td>2-3 Weeks</td>
<td>$6 per negative CO sample (up to $30 + $5 bonus)</td>
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<td>3-4 Weeks</td>
<td>$7 per negative CO sample (up to $35 + $5 bonus)</td>
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<tr>
<td>7-8 Weeks</td>
<td>$8 per negative CO sample (up to $40 + $10 bonus)</td>
</tr>
<tr>
<td>11-12 Weeks</td>
<td>$8 per negative CO sample (up to $40 + $10 bonus)</td>
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**Recruitment/Screening (Visit 1, Part 1; Screening).** Individuals who are referred to the TTRP for smoking cessation treatment and report that they are uninsured or receiving Medicaid benefits will be sent an informational handout with their TTRP information packet (prior to their first visit). Participants will be reminded of all future in-person appointments via telephone, mail, email, and/or text (texts will be sent using encrypted smartphones that belong to the TTRP; see scripts for each method of contact). Additionally, research staff may attempt to collect smoking cessation status with each reminder. Participants with transportation difficulties living in the Oklahoma City metro area may be scheduled for pick-up and drop-off for key visits with Sendaride (https://sendaride.com) through their secure dashboard. At the first visit, study staff will inquire about their interest in finding out more about the study. Study staff will review the consent form with interested participants, and they will be screened for eligibility on-site in a private room in the clinic. Participant eligibility for the current study will not influence eligibility for the TTRP. The Rapid Estimate of Adult Literacy in Medicine (REALM; see Appendix A) will be administered to ensure that all participants are able to read at ≥ sixth grade level (i.e., required to complete EMA and self-report questionnaires). Expired carbon monoxide (CO) will be measured and participants will be
questioned about their 1) insurance status 2) age, 3) current level of smoking, 4) willingness to quit smoking, 5) willingness/ability to complete 6 weekly counseling sessions (including the first visit), 6) pregnancy/breastfeeding status, 7) computer/internet access, and 8) contraindications for nicotine replacement therapy. Expired CO will be measured. Eligible participants may complete the assessment portion of the visit.

**Pre-Quit (Visit 1, Part 2; Assessment).** Participants will complete self-report questionnaires on a laptop computer; weight and height will be measured in a private room to ensure confidentiality. Visit 1 will be the only in-person visit. Participants will be provided with an Android smartphone and a Smokerlyzer iCO breathe monitor. They will be instructed regarding the use of the phone (participants may make personal calls), the EMA procedures, and use of the portable CO monitor. Participants will receive 4 random prompts and 1 daily diary prompt (in the morning) during the normal waking hours each day for five consecutive weeks. Participants will be instructed to quit smoking at bedtime or 10:00 pm (whichever occurs first) 7 days after enrollment. Participants will receive a $30 gift card credit for completion of the in-person assessment at visit 1 which takes approximately 1 hour.

**Quit Day.** Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $30 gift card for the completion of the web-based assessment, which takes approximately 40 minutes. Participants will receive an additional $20 payment if they self-report abstinence from smoking since 10 p.m. the prior evening, and their expired is CO level is < 10 ppm (please note that a less stringent cut-off of 10 ppm will be used to verify abstinence at the first visit only, due to the recency of quitting; see Table 1).

**1 Week Post-Quit.** Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $30 gift card for the completion of the assessment, which takes approximately 30 minutes. Participants will also had the opportunity to earn up to $25 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

**2 Weeks Post-Quit.** Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $30 gift card for the completion of the assessment, which will take approximately 5 minutes. Participants will have had the opportunity to earn up to $30 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

**3 Weeks Post-Quit.** Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $30 gift card for the completion of the assessment, which will take approximately 5 minutes. Participants will have had the opportunity to earn up to $35 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

**4 Weeks Post-Quit.** Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $30 gift card for the completion of the assessment, which will take approximately 50 minutes. Participants will be compensated based on the percentage of completed smartphone random assessments and daily diaries. Specifically, those who
complete 50%-74% of assessments will receive $75 in gift cards, those who complete 75%-89% of assessments will receive $100 in gift cards, and those who complete 90% or more of their assessments will receive $150 in gift cards. Finally, participants will have had the opportunity to earn up to $40 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

8 Weeks Post-Quit. Participants will remotely complete web-based self-report questionnaires and provide a smartphone-based CO measurement. Participants will receive a $40 gift card for completion of the assessment, which will take approximately 30 minutes. Finally, participants will have had the opportunity to earn up to $50 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

12 Weeks Post-Quit. Participants will return to the TTRP and complete self-report questionnaires on a tablet or laptop computer and provide a CO measurement. Participants will receive a $40 gift card for completion of the assessment, which will take approximately 30 minutes. This final payment will be contingent on the return of the study phone. Finally, participants will have had the opportunity to earn up to $50 in gift cards for biochemically verified smoking cessation (self-reported abstinence and CO level of ≤ 6 ppm) during the previous week (see Table 1).

MEASURES

Biological/Anthropometric Measures.

Expired Carbon Monoxide (CO) levels will be measured with a portable iCO smokerlyzer breath CO monitor that attaches to a smartphone. Abstinence from smoking will be verified with a CO level of < 10 on the quit day, and ≤ 6 ppm at all subsequent post-quit visits.

Body Mass Index (BMI) will be calculated (kg/m²) based on height and weight measurements collected at visit 1. Self-reported weight measurements will be collected at each subsequent assessment.

Traditional Questionnaire Measures.

Questionnaire data will be collected via web-based questionnaire using REDcap. The amount of time needed to complete the computer-administered questionnaires varies by study visit. It is estimated that the longest visit (baseline) will require 1 hour to complete. See Appendix A for assessment schedule and questionnaire measures.

Ecological Momentary Assessment.

Participants will be trained in the EMA procedures at the baseline (1 week pre-quit) visit. Assessment items were selected based on their hypothesized relations to smoking behavior, temptation and lapse episodes, and/or their potential importance in understanding the influence of socioeconomic disadvantage. The items will assess smoking urges, affect, expectancies, self-efficacy, and related constructs. EMA items are detailed in the Appendix B.

Hardware. An android smartphone will be loaned to each participant for the duration of the study so that they may complete EMAs and provide CO measurements. Participants navigate through the EMA program and enter data simply by touching the screen. Participants will have the ability to call (e.g., if they have problems completing EMAs) and receive calls from research staff through the smart phone free of charge. The smart phones are equipped with a Secure Digital card to store data as they are collected.
**Programming.** The EMA program will be developed by and accessed through the mHealth core led by Michael Businelle (co-investigator). The core is located in the Oklahoma Tobacco Research Center and is part of the Stephenson Cancer Center. The EMA program that was developed for the PREVAIL II study will be modified for the purposes of the proposed study.

**EMA Assessment Types.** Three types of assessments will be used: daily diary, random sampling, and event sampling (i.e., pre-cessation smoking, urge, post-cessation lapse). Daily diary assessments will be completed once every day (30 minutes after waking), and all questions will refer to the previous 24 hours. Random sampling and daily diary assessments will be initiated by the smart phone. The phone will audibly and visually cue each random assessment for 30 seconds. If the participant has not responded after three prompts, the assessment will be recorded as missed. Random sampling will include four smart phone initiated assessments per day, scheduled to occur during each participant’s normal waking hours. Event sampling is initiated by participants. Participants are instructed to complete “smoking assessments” when they smoke prior to the quit date, “urge assessments” when they have an urge to smoke or they feel like they almost smoked, and “lapse assessments” if they smoke after the quit date. GPS coordinates (i.e., latitude and longitude) will be collected via the smartphone during each assessment. On average, random and event sampling assessments will take 2.5 minutes to complete, while daily diary assessments will take approximately 5 minutes to complete. All assessments will be date and time stamped for future analyses.

**Daily Diary.** Daily Diary Assessments will be completed daily from 1 week prior to the quit date through 3 weeks post-quit (4 weeks total) and all questions will query about the previous day.

**Random Sampling.** Participants will be prompted to complete random assessments 4 times each day from 1 week pre-quit date through 3 weeks post-quit (i.e., 4 weeks total).

**Event Sampling.** Smoking Assessments. During the first week of assessment (i.e., the pre-quit week), participants will be instructed to click the “record cigarette” button immediately prior to smoking each cigarette. Because the assessment burden would be excessive for heavy smokers if each smoking occasion were assessed, two of these smoking occasions each day will be randomly sampled for pre- and post-cigarette assessments. Ten minutes after completing the pre-cigarette assessment, the smartphone will automatically prompt the post-cigarette assessment which includes unique items and the core EMA items. Urge Assessments. Following their quit date, participants will be instructed to initiate an urge assessment each time they “experience an urge to smoke” and answers should be focused on their immediate thoughts/feelings. Lapse Assessments. Participants will be instructed to complete lapse assessments each time they smoke after the quit date. Questions asked during lapse assessments are nearly identical to those presented in random and urge assessments. However, questions are worded to separately assess the participant’s responses immediately prior to AND following the lapse. Post lapse assessments also query about recent discrimination, the reinforcing value of the lapse cigarette(s), and lapse causes.

**E. Statistical Methods**

**Sample Size/Analysis Plan.** We will recruit a sample of 20 participants to test the feasibility of offering a completely remote and fully automated CM intervention.
Analyses will be descriptive, and provide information about the rates of treatment participation, smoking cessation, and follow-up. A conservative intention-to-treat approach will be employed, such that participants with missing data will be considered non-abstinent. Future studies may build upon the information and lessons learned from this preliminary study.

**Expected Outcomes.** Treatment participation, cessation, and follow-up rates are expected to be comparable to those to those in the standard care + financial incentives (CM) group in both the parent study⁴ and our pilot work.³ In the pilot study, 49% and 33% of participants achieved 7-day point prevalence abstinence at 4 and 12 weeks post-quit respectively. Participants attended 57% of weekly treatment sessions during the first 4 weeks post-quit, and follow-up rates for smoking status were 86% and 74% at 8 and 12 weeks post-quit respectively. Participants completed 83% of random mobile phone assessments, and only 2 devices were lost/broken. Thus, each of the following will be considered indicators of intervention feasibility: 1) ≥80% of phone-based smoking status assessments completed (i.e., 4 completed out of 5 per week, or 24 completed out of 30 total), 2) 7-day point prevalence cessation rates that are similar or even slightly lower than our clinic-based CM given the potential for greater reach (i.e., 40-50% at 4 weeks post-quit; 25-35% at 12 weeks post quit), 3) ≥2-3 telephone counseling sessions completed on average per participant, 5) follow-up rates ≥80% at 4 weeks and ≥70% at 12 weeks, and 5) device loss of no more than 1-2 phones and 1-2 portable CO monitors (≤10% loss).

**F. Gender/Minority/Pediatric Inclusion for Research**
The study has no inclusion/exclusion criteria based on gender or race/ethnicity. However, note that counseling is offered in English only. The TTRP is available to patients who are ≥ 18 years of age. Children < 18 years of age will be excluded from the study.

**G. Human Participants**
1. **Subject Population.** Participants will be up to 30 individuals (20 required) recruited during their first visit to the OUHSC Tobacco Treatment Research Program (TTRP). Interested participants may be included in the study if they: 1) are currently uninsured or receiving Medicaid benefits, 2) earn a score ≥ 4 on the REALM indicating > 6th grade English literacy level, 3) are willing to quit smoking 7 days from their first visit, 4) are 18-65 years of age, 5) have an expired CO level ≥ 8 ppm suggestive of current smoking, 6) are currently smoking ≥ 5 cigarettes per day, and 7) own or have access to a computer (to remotely complete study questionnaires). Participants will be excluded from the study if they report that they 1) are pregnant or breastfeeding, 2) have uncontrolled hypertension (or average of 2 blood pressure readings is > 140/90), 3) had a myocardial infarction within the past two weeks, 4) have an allergy to adhesive tape, or 5) are unwilling to use nicotine replacement therapy.

2. **Sources of Research Material.** Demographic, psychosocial, environmental and behavioral data will be collected via 1) traditional web-based self-report questionnaires, and 2) EMA completed daily via smartphone (4 random assessments daily, 1 daily dairy, pre-quit smoking assessments, and post-quit urge and lapse assessments). GPS coordinates (i.e., latitude and longitude) will be captured at the time of each EMA assessment. Smoking status will be evaluated via expired carbon
monoxide and self-report. Height and weight will be measured at the first visit, last visit, and self-reported weight will be collected with each web-based assessment afterwards.

3. **Recruitment and Informed Consent.** Individuals attending their first visit to the TTRP will be provided a 1-page information handout via mail or email prior to their first scheduled visit. At their first visit, individuals will be provided with detailed information about the study and given the opportunity to have their questions answered within a private room to ensure confidentiality. Written informed consent will be obtained from those who are interested in participating.

4. **Risks.** Participation in this study poses minimal risk to participants. However, one potential, although unlikely, risk to participants is loss of confidentiality. The severity of harm in the case of loss of confidentiality 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 tobacco cessation treatment, as loss of confidentiality may be experienced in either case.

**Medication Risks.** Nicotine replacement therapy (i.e., patch and gum) offered as part of this research protocol is FDA-approved for tobacco cessation. 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.

5. **Protections against Risk.**

**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. All print information including informed consent will be stored in locked filing cabinets at the Oklahoma Tobacco Research Center. Electronic data (with names omitted) will be maintained on the investigators’ computers, and all computers and electronic files will be password protected. Participants will complete smartphone assessments through an encrypted mobile application, and all data is automatically saved and sent to institutional servers in real-time. All project staff will receive 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 portable carbon monoxide ecolyzer. Study staff will attempt to follow-up with participants every 1-2 weeks via phone to monitor the use of NRTs during the 12-weeks of pharmacotherapy.

**EMA Confidentiality Procedures.** The following features are designed to address smartphone/EMA/GPS data security issues: 1) the data stored on the smartphone device is in a SQLite database in a sandbox environment where read/write operations are only available through the programming application. No file or output is readable to end users, 2) a password (only known to researchers) is required to authenticate the current user before data can be downloaded from the smartphone device to the server,
3) the web browser application linking the principal investigator’s computer to the database is on HTTPS protocol (SSL certificate with encryption) which will guarantee the data transfer from web browser to the backend database is well protected, and 5) the backend database is hosted by the University of Oklahoma Data Center in a secure setup.

6. **Potential Benefits.** Potential benefits to participants include the possibility that the adjunctive CM intervention will have a beneficial impact on smoking cessation outcomes. In addition, the knowledge gained from this study may be utilized to improve our understanding of the barriers to quitting and predictors of relapse among socioeconomically disadvantaged individuals. Such information may facilitate the development of more effective smoking cessation interventions that may be utilized within safety net hospitals and clinics.

7. **Risks in relation to Benefits.** The current study involves very minimal risk to participants, and the risks of study participation are similar to that of participation in any intensive smoking cessation intervention (e.g., loss of confidentiality). All participants will be already seeking treatment before they are provided with any information about the research study. Participants receiving the financial incentives intervention may benefit from increased odds of smoking cessation, and participants will be compensated for their time and effort. In addition, the knowledge gained from this study may be utilized to improve our understanding of the barriers to quitting and predictors of relapse among socioeconomically disadvantaged individuals.

H. **Data and Safety Monitoring Plan**

The study poses minimal risk to participants, therefore continuous monitoring and reporting of events will be undertaken by the principal investigator (Dr. Kendzor) and co-investigators (Drs. Businelle and Vidrine). Unanticipated problems/adverse events will be promptly reported to the IRB by the research coordinator or study staff. Possible (though unlikely) adverse events might include compromised data security. Procedures to minimize the risk of loss of confidentiality are described in section G under the heading *Protections against Risk.*

I. **Literature Cited**

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