Title of Project: Automated Mobile Contingency Management for Smoking Cessation: A pilot RCT (SCC PrevailGo)

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A. Specific Aims

Although smoking prevalence has declined to 15.5% among U.S. adults, 25.3% of those living below the poverty threshold continue to smoke.[1] Further, socioeconomic disadvantage is associated with a reduced likelihood of smoking cessation.[2-7] Although socioeconomically disadvantaged individuals are just as likely to initiate quit attempts, they are less likely to succeed.[8] There is mounting evidence that contingency management (CM), or the tangible reinforcement of abstinence and other related outcomes, is an effective approach to promoting smoking cessation in a variety of populations.[9-25] CM interventions are based on behavioral principles and operant conditioning, which originated with the work of Thorndike[26] and Skinner.[27] Specifically, outcomes associated with desirable consequences (i.e., positive reinforcement) are more likely to recur. Recent research suggests that financial incentives for smoking cessation may be particularly appealing among individuals of low socioeconomic status.[28,29] The findings of two recent meta-analyses have indicated that financial incentives are associated with greater odds of behavior change for a variety of behaviors particularly among socioeconomically disadvantaged individuals.[30,31] The preliminary work of the investigators has indicated that offering small escalating financial incentives for smoking abstinence (i.e., CM) dramatically increases short-term cessation rates among socioeconomically disadvantaged smokers when incentives are included as an adjunct to clinic-based smoking cessation treatment.[32,33] Preliminary findings from the investigators' full-scale randomized trial indicate that the effect of CM remains at 26 Weeks after the initial cessation attempt and continues months after incentives have been discontinued (R01CA197314; PI: Kendzor). However, approaches to smoking cessation are needed for those who are unable to attend office visits due to transportation difficulties, distance, or incompatible schedules.

To date, financial incentives interventions for smoking cessation have primarily relied on in-person visits to verify smoking abstinence. Internet[34-37] and mobile phone-based[38-40] CM approaches have been developed to reduce or eliminate the need for in-person visits. Several studies have evaluated an internet-based approach,[34-37] 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 and a credit is applied to their study accounts when abstinence and their identity are verified. This process requires the provision of expensive carbon monoxide monitoring equipment to participants (e.g., Vitalograph ≈ $1200 per device), and staff evaluation of CO values, verification of participant identity, and delivery of incentives. Studies have also employed a similar approach using mobile

phones.[38-40] Over the past two years, the investigators have *automated* the mobile CM approach, thereby simplifying financial incentives interventions for smoking cessation and making them more accessible to individuals who are unable or unwilling to attend in-person abstinence confirmation visits. Mobile, automated, CM may offer a *scalable* approach to cessation that could be combined with telephone counseling and pharmacological interventions.

The purpose of the proposed project is to pilot test this automated mobile phone-based CM approach. With the assistance of the Mobile Health (mHealth) shared resource[41] at the University of Oklahoma Health Sciences Center (OUHSC) and Stephenson Cancer Center (SCC), the investigators have combined technologies including 1) low-cost carbon monoxide monitors that connect with mobile phones[42] to remotely verify smoking abstinence, 2) facial recognition software[43] to confirm the identity of participants while they provide a breath sample, and 3) remote delivery of incentives[44] automatically triggered by biochemical confirmation of self-reported smoking abstinence. This automated, mobile CM approach will be evaluated in a randomized controlled pilot trial of 40 socioeconomically disadvantaged males and females seeking smoking cessation treatment. Participants will be randomly assigned to telephone counseling plus nicotine replacement therapy (standard care [SC]) *or* SC plus a 12 Week mobile financial incentives intervention (CM) for biochemically-confirmed abstinence. Participants will be followed for 12 Weeks after a scheduled quit attempt to assess smoking status.

Primary Aim. To evaluate the preliminary efficacy of an *automated*, mobile phone-based CM approach relative to SC on smoking cessation among socioeconomically disadvantaged adults. Hypothesis: *Individuals randomly assigned to the CM intervention will have significantly higher rates of biochemically-verified abstinence at the 12 Week post-quit follow-up visit than those assigned to SC.*

The proposed project responds to the Stephenson Cancer Center (SCC) pilot grant funding opportunity which encourages collaborative research among SCC members and the translation of a novel idea into clinical or community practice. Findings will extend an ongoing, collaborative program of research focused on using CM to increase cessation rates among socioeconomically disadvantaged adults, and will provide preliminary data supporting an application to the National Institutes of Health for a full-scale randomized controlled trial. This fully automated CM approach to smoking cessation is highly *scalable* and will facilitate intervention delivery to socioeconomically disadvantaged individuals in Oklahoma and beyond.

B. Research Strategy

I. Significance. The current proposal is significant because the project will evaluate the preliminary efficacy of an *automated* process of identity verification, biochemical verification of self-reported abstinence, and delivery of abstinence-contingent incentives. This is different than past mobile CM approaches because this approach *does not require intensive staff attention and oversight*. The automated mobile CM approach described in this application was developed by the investigators (Kendzor, Businelle) through the SCC mHealth Shared Resource and an NCI R01 supplement awarded to Dr. Kendzor (R01CA197314). The proposed project will contribute evidence of the efficacy of an *automated and scalable* approach to CM for smoking cessation, which will provide preliminary data for a full-scale randomized controlled trial.

II. Innovation. The investigators have built upon existing internet[34-37] and mobile phone-based[38-40] CM approaches by *automating* the process, which eliminates the need for staff to review recordings, verify identity, and award financial incentives, thus reducing staff burden.

Specifically, the investigators have combined technologies including 1) portable breath CO monitors that connect with mobile phones[42] for remote biochemical verification of abstinence, 2) mobile phone-based facial recognition software[43] to verify the identity of the individual providing the breath sample, and 3) automated delivery of incentives to a credit card[44] following biochemical verification of self-reported abstinence. Thus, the current proposal is highly innovative in the following ways: 1) the investigators will be the first to completely automate the mobile CM approach by combining existing technologies to offer researchers and clinicians a tool to remotely verify and incentivize smoking abstinence that requires little staff involvement, 2) frequent mobile phone assessments will be used to prompt breath CO samples, which will increase the possibility of detecting smoking between assessments, and 3) this automated mobile CM approach will increase the reach of an effective smoking cessation treatment (CM) to individuals who are unable or unwilling to attend regular office visits to verify smoking abstinence.

Preliminary Studies. *PREVAIL Pilot.* The PREVAIL pilot study was designed to evaluate the feasibility and short-term efficacy (4 and 12 Weeks post-quit) of offering small financial incentives (gift cards) for biochemically-verified abstinence as an adjunct to the smoking cessation program offered at the Dallas County safety net hospital (i.e., counseling and pharmacological treatment). **Findings were published in the *American Journal of Public Health*.[32]** Interested and eligible individuals newly enrolled in the Parkland smoking cessation program ($N = 146$) were randomized to either Usual Care (UC; $n = 71$) or 4 Weeks of CM (UC + adjunctive financial incentives; $n = 75$). All participants were followed weekly from 1 Week pre-quit through 4 Weeks post-quit; and a sub-sample ($N = 128$) was additionally asked to complete an in-person follow-up visit at 12 Weeks post-quit. Individuals randomized to the CM intervention earned gift cards for self-reported and biochemically-verified abstinence at each visit, such that participants could earn $20 in gift cards for quitting on the specified quit day, and this amount increased by $5 with each successive abstinent visit (i.e., up to $40 in gift cards at 4 Weeks post-quit; up to $150 total). Participants who were non-abstinent at any visit were able to earn gift cards at the next visit if abstinence criteria were met, though the gift card payment was reset to the starting level of $20. **This incentive schedule was also used with a sample of sheltered homeless adults.**[33] CM participants were significantly more likely to achieve 7-day point prevalence abstinence than UC participants at all visits after the quit date (all p's < .05; see Figure 1). CM participants also had higher rates of continuous abstinence than UC participants at 4 Weeks (i.e., 25.3% vs. 12.7%, $p<.05$) and 12 Weeks post-quit (20.3% vs. 7.8%, $p<.05$). Findings suggest that this CM intervention approach continues to have a significant impact on cessation outcomes even after the incentives are discontinued.

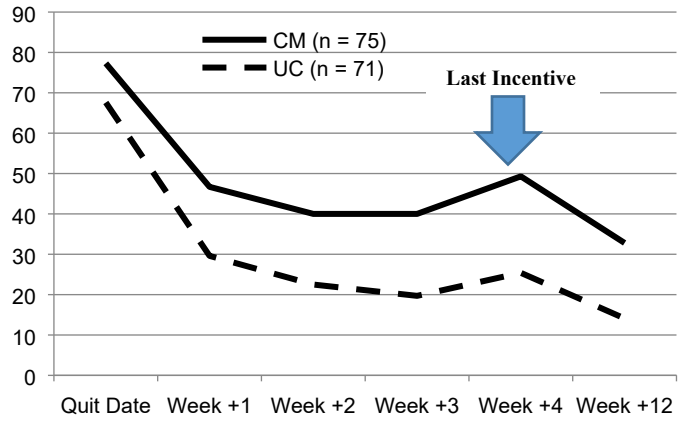

Figure 1. **PREVAIL Pilot, % abstinent by treatment group (N = 146)**

PREVAIL II. Based on promising findings from the PREVAIL Pilot study, Dr. Kendzor was awarded an NCI R01 (R01CA197314) to evaluate the longer term effectiveness (26 weeks post-quit) of providing small financial incentives (gift cards) for biochemically verified abstinence as an adjunct to the smoking cessation program offered through the Tobacco Treatment Research

Program (TTRP). A total of 320 socioeconomically disadvantaged men and women will be enrolled in the study. The TTRP offers 6 weekly counseling sessions delivered by a Tobacco Treatment Specialist, and 12 Weeks of pharmacological treatment. To date, 74 interested and eligible individuals have been randomized to either Usual Care (UC; $n = 39$) or UC + adjunctive financial incentives (CM; $n = 35$). The incentives schedule was the same as described above for the PREVAIL pilot study, with the addition of $50 incentives for biochemically-verified abstinence at 8 and 12 Weeks post-quit date. To date, CM participants have higher rates of 7-day point prevalence abstinence than UC participants at all visits after the quit date (see Figure 2). These preliminary findings suggest that the CM intervention continues to have an impact on cessation outcomes months after the incentives are discontinued.

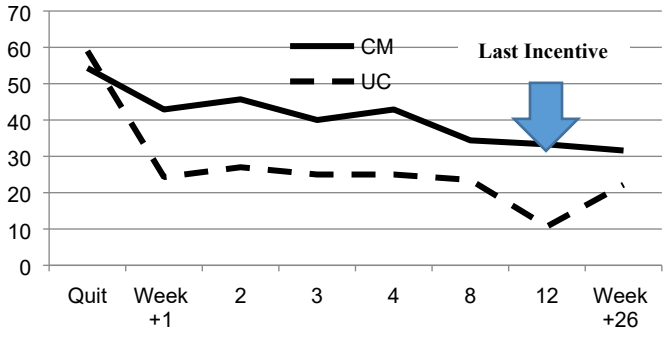

Figure 2. **PREVAIL II, % abstinent by treatment group (N = 74)**

PrevailGO. This is an ongoing administrative supplement to R01CA197314 to develop and assess the feasibility of an *automated*, mobile CM approach to smoking cessation for socioeconomically disadvantaged adults that can be delivered remotely. The investigators have combined technologies including: 1) low-cost portable breath CO monitors that connect with mobile phones for remote biochemical verification of abstinence, 2) mobile phone-based facial recognition software to verify the identity of the individual while they provide breath samples, and 3) automatically delivered incentives to a credit card following biochemical verification of abstinence. These features are now integrated into the existing Insight platform developed by the SCC mHealth Shared Resource. Internal testing of all PrevailGO features has been completed by the study team, and the app has undergone refinements to correct "bugs" and improve usability.

III. Approach

Study Overview. The purpose of the study is to evaluate the preliminary efficacy of an automated, mobile phone-based CM approach (relative to SC) on smoking cessation among socioeconomically disadvantaged adults. Eligible adults referred to the TTRP for tobacco cessation treatment or recruited via social media ($N = 40$) will be randomized to: 1) Standard Care (SC), which includes 5 Weeks of telephone counseling and 12 Weeks of combination nicotine replacement therapy (patches + gum or lozenges) through the TTRP ($n = 20$), or 2) SC + automated, mobile phone-based CM (CM; $n = 20$). Biochemically-verified 7-day point prevalence abstinence at 12 Weeks post-quit will serve as the primary outcome variable.
Recruitment. Participants ($N = 40$) will be recruited through the TTRP[45] or social media (Facebook, etc.). Over the past 12 months, the TTRP has enrolled nearly 300 adults into the standard treatment program or ongoing trials. We expect to enroll 6-7 participants per month in the proposed study over a 6 month period.

Eligibility Criteria. Eligibility criteria: 1) annual household income of < 200% of the federal poverty guideline given household size,[46] 2) > 6th grade English literacy level[47] (i.e., a 7th grade reading level is necessary to complete assessments), 3) willingness to quit smoking 7 days after enrollment, 4) ≥ 18 years of age, 5) currently smoking ≥ 5 cigarettes per day, 6) no

contraindications for NRT, and 7) willingness to complete an identity check (i.e., video conference call or provide a photo ID). The federal poverty guidelines are used as an eligibility criterion by Medicaid and a number of other Federal programs.[46] Some federal programs use a percentage multiple of the poverty guidelines to determine eligibility. For example, the percentage of the poverty threshold required for Medicaid and CHIP eligibility varies widely by state, age, pregnancy status, and other factors, and is commonly (though not always) below 200 percent of the federal poverty guidelines (e.g., see https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-eligibility-levels/index.html). The Principal Investigator has previously used <200% of the federal poverty guidelines as an indicator of "low-income" status in her peer-reviewed, published research (e.g., Kendzor, Caughy, & Owen, 2012, BMC Public Health), as have other investigators (e.g., Kim-Mozeleski & Tsoh, 2018, American Journal of Health Promotion; Kalkhoran et al., 2018, American Journal of Preventive Medicine). In sum, an annual household income of <200% of the federal poverty guidelines is a reasonable proxy for indicating socioeconomic disadvantage as evidenced by similar thresholds used as eligibility criteria for federal need-based programs, in addition to the common use of this threshold to indicate low-income status in research studies.

Screening/Enrollment. Enrollment may take place in-person at the TTRP or remotely. For details on in-person enrollment TTRP refer to protocol IRB# 6951. Remote enrollment may take place in 2 phases. In phase 1, participant eligibility will be assessed. Eligibility criteria includes: 1) annual household income of < 200% of the federal poverty guideline given household size[46], 2) > 6th grade English literacy (i.e., a 7th grade reading level is necessary to complete assessments) 3) willingness to quit smoking 7 days after enrollment, 4) ≥ 18 years of age, 5) currently smoking ≥ 5 cigarettes per day, 6) no contraindications for NRT, and 7) willingness to complete an identity check (i.e., video conference call or provide a photo ID). Participants who meet the criteria will be sent a REDCap link and will have a chance to review the consent form and HIPAA electronically. Eligible participants will be given a chance to ask questions about the research study and be asked to electronically sign both forms. Participants will also be asked to complete the baseline questionnaires and meet with their Tobacco Treatment Counselor (refer to TTRP protocol IRB# 6951 procedure). Participants will also have their smartphone assessed to determine if the INSIGHT smartphone app is compatible with their phone (currently the INSIGHT smartphone app is only compatible with Android phones). Participants who have a smartphone that is not compatible with the INSIGHT smartphone app may be mailed a study smartphone. Participants who complete phase 1 will be scheduled for a phase 2 visit and be mailed a Bedfont iCO smokerlyzer, a Greenphire clinicard, and if applicable a study smartphone. At the phase 2 appointment, the participant will be be oriented to the INSIGHT smartphone app. The participant will be paid the $30 baseline payment after completing the phase 2 appointment. Participants will have 7-10 days to complete the phase 2 appointment. Participants who do meet the eligibility criteria or complete phase 2 in time will have the option to enroll in the TTRP for (see TTRP protocol IRB #6951) or be connected with the Oklahoma Tobacco Helpline.

Randomization. Participants will be assigned to the two treatment conditions using a form of adaptive randomization called minimization.[48] Sex (male vs. female), race/ethnicity (white vs. non-white), and CPD (≤10 vs. >10) will be balanced between the treatment groups.

Intervention Groups. Standard Care (SC). All recommended components of an intensive tobacco treatment intervention[49] will be provided. Participants will be offered an in-person counseling session to create a quit plan (during the baseline/enrollment visit), and then 5 weekly telephone counseling sessions with a Certified Tobacco Treatment Specialist. All participants will receive 12 weeks of nicotine patches, and nicotine gum or lozenges.
Contingency Management (CM). CM participants will receive SC in addition to small financial incentives for biochemically-verified abstinence. The proposed incentive amounts are similar to the schedule used in our past work[32,33] with $143 in possible earnings by 4 Weeks post-quit, and an additional $105 by 6 Weeks post-quit. More specifically, CM participants may earn $20 for quitting on the scheduled quit day (with 2 breath samples submitted and identify verification to corroborate), and may earn daily payments for quitting each day they are smoke free thereafter. Payments will start at $3 per day and increase each week by $1 if they remain abstinent. The daily incentive increases weekly with continued abstinence until they reach $8 per day during week 6. Participants who smoke at any time, will not earn the incentive that day. However, they may begin earning incentives on the next full day of abstinence, though the daily incentive amount will reset to $3 per day. Incentives may be earned daily, but they will be credited to the study credit card every Friday. (See Table 1. Compensation Schedule).

Yoking/Compensation for Samples. Participants will be asked to provide a breath sample to assess their level of smoking using the Bedfont iCO smokerlyzer from 1 week pre-quit through 12 weeks post-quit date. Participants will be asked to provide 2 breath samples per day (8 hours apart) through 6 weeks post-quit, and 1 breath sample per day through 12 weeks post-quit. Participants in the CM group will receive abstinent-contingent incentives as described above. Participants assigned to the SC group will be yoked to participants in the CM group. SC participants will receive the same payments as their CM counterparts, regardless of their abstinence status. This strategy (yoking) will be employed to equate sample submissions and payments between the groups, thereby isolating the impact of abstinence-contingent incentives on cessation.

Table 1. Compensation Schedule

Time	**Abstinence-Contingent Incentives/Yoking Payments Day**							**Questionnaires**	**EMAs**	**Incentive/ Yoking**	**Breath Samples**	**Weekly Totals**
	1	**2**	**3**	**4**	**5**	**6**	**7**					
Pre-Quit	$0	$0	$0	$0	$0	$0	$0	**$30**	**$10**	**$0**	**$12**	**$52**
Week 1	$20	$3	$3	$3	$3	$3	$3		**$10**	**$38**	**$14**	**$62**
Week 2	$4	$4	$4	$4	$4	$4	$4		**$10**	**$28**	**$14**	**$52**
Week 3	$5	$5	$5	$5	$5	$5	$5		**$10**	**$35**	**$14**	**$59**
Week 4	$6	$6	$6	$6	$6	$6	$6		**$10**	**$42**	**$14**	**$66**
Week 5	$7	$7	$7	$7	$7	$7	$7		**$10**	**$49**	**$14**	**$73**
Week 6	$8	$8	$8	$8	$8	$8	$8		**$10**	**$56**	**$14**	**$80**
Week 7	-	-	-	-	-	-	-		**$10**	**-**	**$7**	**$17**
Week 8	-	-	-	-	-	-	-		**$10**	**-**	**$7**	**$17**
Week 9	-	-	-	-	-	-	-		**$10**	**-**	**$7**	**$17**
Week 10	-	-	-	-	-	-	-		**$10**	**-**	**$7**	**$17**
Week 11	-	-	-	-	-	-	-		**$10**	**-**	**$7**	**$17**
Week 12	-	-	-	-	-	-	-	**$30**	**$10**	**-**	**$1**	**$41**
TOTAL POSSIBLE $:								**$60**	**$130**	**$248**	**$132**	**$570**

Programming. The mHealth Shared Resource at OUHSC and Stephenson Cancer Center (SCC) will provide the programming services for the proposed project. Over the past two years, the investigators have worked with programmers at the mHealth Shared Resource to guide the development of the automated mobile CM approach to smoking cessation (see preliminary studies, PrevailGO). Future programming will focus on refinements to the app to address problems and increase usability.

Intervention Hardware. The investigators have combined technologies including 1) portable breath CO monitors that connect with mobile phones[42] for remote biochemical verification of abstinence, 2) mobile phone-based facial recognition software[43] to verify the identity of the individual providing the breath sample, and 3) automated delivery of incentives to a credit card[44] following biochemical verification of self-reported abstinence. The Bedfont iCO smokerlyzer is a personal, portable carbon monoxide (CO) monitor that interfaces with the Insight platform/app on an electronic device (smartphone or tablet). Participants in this study may either use their own electronic device or maybe provided an Android smartphone. All participants will be provided a Bedfont iCO smokerlyzer, and the Insight platform/app will be installed on the participant's chosen electronic device. The Bedfont iCO smokerlyzer is used by participants in this study to collect CO levels (in ppm) in exhaled breath, a biochemical indication of smoking abstinence. Data collected via the Bedfont iCO smokerlyzer is saved to the electronic device via the Insight platform/app and then uploaded to the secure Microsoft Azure content management system (CMS) when the electronic device is synced. The Insight platform/app will also be installed on each participant's chosen electronic device. The camera feature on the electronic device is also necessary for coincidental facial recognition of a participant as he/she exhales into the Bedfont iCO smokerlyzer. The mHealth Shared Resource at OUHSC and the Stephenson Cancer Center empowers researchers to build, test, and launch technology-based assessment and intervention tools. The Insight platform/app, and facial recognition app are products of the SCC mHealth Shared Resource directed by Michael Businelle, co-investigator of this study. The Insight platform/app enables the automated mobile contingency management (CM) approach investigated by this study, as threshold facial recognition and CO data prompt automated delivery of financial incentives to participants. The Insight platform works cooperatively in this study to achieve the desired automation, thus eliminating intensive staff attention or oversight.

Measurement of Abstinence. Smoking abstinence will be measured via self-report and expired carbon monoxide (Bedfont iCO smokerlyzer) twice per day from the scheduled quit date through 12 weeks post-quit. Quit Day abstinence (self-report being smoke free, 2 breath samples submitted <10 and identify verification), 1 Week Post-Quit through 6 Weeks Post-Quit (self-report being smoke free, 2 breath samples submitted ≤ 6 and identify verification), and 7 Weeks Post-Quit through 12 Weeks Post-Quit (self-report being smoke free, 1 breath samples submitted ≤ 6 and identify verification).

Questionnaire Measures. We will include measures of mobile CM treatment acceptance, stress/adversity,[50-52] psychosocial resources,[53-55] nicotine dependence/craving,[56,57] negative affect/distress,[58-60] and treatment adherence.[61,62] Participants will complete a baseline and 12 Weeks Post-Quit assessment. Participants will be compensated for completing the $30 for completing each assessment. Payments will be applied to participants' study credit cards. (See Table 1. Compensation Schedule). Please refer to the TTRP questionnaire appendix (IRB 6951).

Ecological Momentary Assessment. Participants will complete mobile phone-based EMAs from 1 Week pre-quit through 12 Weeks post-quit. Compensation is based on weekly completion percentages. Specifically, those who complete 50%-79% of prompted assessments will receive a $5 credit and those who complete 80%-100% of assessments will receive a $10 credit. EMA 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. Participants will self-report on smoking status and provide a breath CO sample twice per day. Participants will be prompted to complete a daily diary and 2 random assessments each day from 1-week pre-quit through 6 weeks post-quit. From 7 through 12 weeks post-quit, this will reduce to one daily diary prompt per day. *Daily diaries* are scheduled for each morning 30 minutes after the usual wake time. *Random assessments* are scheduled for twice per day during waking hours. GPS coordinates (i.e., latitude and longitude) may be collected via the smartphone during each assessment.

Sample Size/Analysis Plan. Forty participants will be enrolled during a 6-month period. The TTRP enrolls ≈24 participants per month, and PREVAIL II enrolls a subset of ≈7 participants per month. This sample size will allow for project completion within the funding period to provide effect size estimates for the full-scale trial.

Expected Outcomes. It is expected that those randomized to the mobile CM intervention will have higher rates of abstinence at 12 Weeks post-quit (and all other time points) than those randomized to SC.

Potential Problems. Some participants will have limited experience using smart phones, therefore all will receive hands-on training, including a brief step-by-step video tutorial that demonstrates use of the phone and app features (also loaded onto the phone). To overcome loss of data if participants lose or change phones, phones will be programmed to connect to our secure server daily to upload encrypted data. This will also allow the researchers to remotely monitor each participant's EMA completion rate and call the participant when this rate is low. Importantly, EMA data are password protected, encrypted within the Insight app, and only accessible by the research team. If a phone is lost, participant data will be remotely deleted.

IV. Relevance. The proposed project will evaluate the prelimary efficacy of an automated, mobile phone-based approach to offering financial incentives for smoking cessation in order to reach socioeconomically disadvantaged individuals and reduce tobacco-related health disparities without requiring in-person visits.

C. Bibliography and References Cited

D. Protection of Human Subjects

Human Subjects Involvement, Characteristics, and Design. Eligible adults ($N = 40$) will be randomized to: 1) Standard Care (SC), which includes 5 Weeks of telephone counseling and 12 Weeks of combination nicotine replacement therapy (patches + gum or lozenges) through the TTRP ($n = 20$), or 2) SC + automated, mobile phone-based CM through 12 Weeks post-quit (CM; $n = 20$). Biochemically-verified 7-day point prevalence abstinence at 12 Weeks post-quit will serve as the primary outcome variable. Participants will be followed weekly from 1 Week pre-quit through 4 Weeks post-quit, with a follow-up assessments at 12 Weeks post-quit. Participants will complete assessments on their phones or other preferred device for all assessments. Based on recruitment for an ongoing study in the TTRP (PREVAIL II), we expect more women than men to participate (73% women). Participants are expected to be primarily of non-Hispanic White/Caucasian (63%), Black/African American (27%), or American

Indian/Alaska Native (5%) race/ethnicity. Eligibility criteria are: 1) annual household income of < 200% of the federal poverty threshold given household size,[46] 2) > 6th grade English literacy level[47] (i.e., a 7th grade reading level is necessary to complete assessments), 3) willingness to quit smoking 7 days after enrollment, 4) ≥ 18 years of age, 5) currently smoking ≥ 5 cigarettes per day, 6) no contraindications for NRT, and 7) willingness to complete an identity check (i.e., video conference call or provide a photo ID).

Sources of Materials. Demographic, psychosocial, environmental and behavioral data will be collected via: 1) traditional self-report questionnaires completed in-person and via smartphone or other preferred device, and 2) EMA completed daily diary via smartphone (2 random assessments daily, 1 daily dairies). Smoking status will be evaluated up via expired carbon monoxide (iCO) and self-report. If the baseline visit is in-person then we will measure height and weight. Weight will also be measured if the 12 Week Post-Quit visit is in-person. If the baseline visit is taking place remotely then the participant may self-report height and weight. Counseling session completion will be noted by the staff each week.

Potential 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 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.

Adequacy of Protection against Risks

Recruitment and Informed Consent. Eligible individuals will be provided with detailed information about the study via a REDCap link or in person at the TTRP. The REDCap link will include information about the study, study staff contact information, and a signature field for the individual to sign. Participants will have an opportunity to speak with study staff and have their questions answered over the phone or in person at the TTRP. Written informed consent either remotely via REDCap or in person or in will be obtained from those who are interested in participating.

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, screening questionnaires, and smoking status questionnaires will be stored in a locked filing cabinet in the Principal Investigator's office. Electronic data (with names omitted) will be maintained on the investigators computers, and all computers and electronic files will be password protected. Anthropometric measures and CO 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), 4) measurement of anthropometric data, and 5) use of the carbon monoxide smokelyzer. The financial incentive amounts for abstinence (see Table 1. Compensation Schedule) were chosen because they are small (inexpensive) relative to those used in other research studies and could therefore conceivably be implemented into standard clinic practice. Gift card amounts through 4 Weeks post-quit are similar to the successful incentive strategy used in our pilot study. During two

additional payment Weeks, incentives of up to $105 (at 5 and 6 Weeks post-quit) will be provided to motivate and reinforce abstinence. The proposed intervention offers a maximum of $248 for smoking abstinence over a 6 Week post-quit period. Thus, the amount of incentives offered in the current study is low relative to the average weekly amounts offered in most other CM interventions for smoking cessation.

EMA Confidentiality Procedures. The following features are designed to address EMA 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.

Potential Benefits of the Proposed Research to Human Subjects and Others. Potential benefits to participants include the possibility that the automated mobile CM intervention will have a beneficial impact on smoking cessation outcomes.

Importance of the Knowledge to be Gained. The knowledge gained from this study may be utilized to expand the reach of effective smoking cessation interventions, improve smoking abstinence rates in socioeconomically disadvantaged populations, and thereby reduce tobacco-related disease and health disparities.

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. Darla Kendzor) and unanticipated problems will be promptly reported to the IRB. Since the standard smoking cessation treatment is offered by the TTRP independent of this research proposal, adverse event monitoring will focus on events related to study assessments and the administration of financial incentives. Possible adverse events might include compromised data security, and severe emotional reactions by participants due to non-payment of incentives following conflicting self-reports of abstinence and expired CO levels suggestive of non-abstinence.

E. Inclusion of Women and Minorities. The study has no inclusion/exclusion criteria based on gender or race/ethnicity. Based on the demographics of our PREVAIL II participants recruited through the TTRP, we expect more women than men to participate (73% women). Participants are expected to be primarily of non-Hispanic White/Caucasian (63%), Black/African American (27%), or American Indian/Alaska Native (5%) race/ethnicity.

F. Targeted/Planned Enrollment Table. See attached.

G. Inclusion of Children. The current study focuses only on individuals who are 18 years of age and older. Smoking cessation treatment through the TTRP is available to patients who are ≥ 18 years of age. Potential participants < 18 years of age (children) will be excluded from the study and connected with the Oklahoma Tobacco helpline through our online portal. Separate smoking cessation interventions designed for children are warranted and preferable as the smoking characteristics and cessation-related needs of children and adults are likely to be very different.

H. Vertebrate Animals. Not Applicable.

I. Select Agent Research. Not Applicable.

J. Consortium/Contractual Arrangements. Not Applicable.

K. Resource Sharing Plan. 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.

L. Statement of Work (1 page)

Timeline. Study preparation will be completed during the first month of the funding period. Recruitment and enrollment will continue during months 2-7. All 12-Week follow-up visits will conclude by month 10. Data analysis and manuscript preparation will begin in month 10 and continue through the end of the year.

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