Consent Form
University of Oklahoma Health Sciences Center (OUHSC)
Stephenson Cancer Center
TSET Health Promotion Research Center

Study Title: Automated Mobile Contingency Management for Smoking Cessation: A pilot RCT (SCC PREVAILgo)
Sponsor: Stephenson Cancer Center
Principal Investigator: Darla E. Kendzor, Ph.D.

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

Why Have I Been Asked to Participate in This Study?
You are being asked to take part in this trial/study because you are interested in quitting smoking and you have an annual household income of <200% of the federal poverty threshold.

Why is This Study Being Done?
The purpose of this study is to evaluate the effectiveness of using a fully automated mobile phone approach to offer financial incentives (gift cards) for quitting smoking. Financial incentives will be combined with telephone counseling and nicotine replacement therapy for smoking cessation.

What is the Status of the Drugs Involved in This Study?
Nicotine replacement therapy (patches, gum, and lozenges) is currently approved by the US Food and Drug Administration (FDA) for quitting tobacco.

How Many People Will Take Part in The Study?
Up to 40 people will take part in this study.

What is Involved in The Study?
You will be randomized to one of two groups, either the standard quit smoking treatment (counseling + nicotine replacement therapy) or the standard treatment plus financial incentives for proof that you have quit smoking. All participants will be offered free standard tobacco cessation treatment. You will download the smartphone app onto your personal phone or use a study issued smartphone. Randomization means that you are put in a group by chance (like the flip of a coin). A computer program will make this random assignment. Neither you nor clinic/research staff will choose which group you will be in. You have a 50/50 chance of being placed in either group.

If you take part in this study, you will have the following tests and procedures:

- You will be asked to answer questions to determine if you are eligible to participate in this study.
- If you are eligible, you will be asked to complete surveys via smartphone or other device at the start and end of the 13-week study for which you will receive a $30 payment for the completion of each. You will receive a text or email link to the survey.

- You will receive standard tobacco cessation treatment. Standard treatment includes 6 counseling sessions with a certified tobacco treatment specialist via telephone or video conferencing and 12 weeks of nicotine replacement therapy (nicotine patches and gum or lozenges).
- You will be asked to download a smartphone app on your personal smartphone or a smartphone will be loaned to you. The smartphone app will prompt you to complete a daily diary and 2 random assessments on your phone 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. You will earn $10 per week if you complete at least 80% of these assessments, and $5 per week if you complete 50-79% of assessments. Additionally, the smartphone application may record your location via global positioning systems (GPS) each time you answer questions or answer questions in the app.
- You will be asked to provide breath samples by using the smartphone app and the Bedfont iCO breathalyzer. The breath samples will assess your smoking status (smoking or quit) and your level of smoking from 1 week before you quit smoking through 12 weeks post-quit date. You 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. The smartphone app will use facial recognition software to verify that you are the person providing a breath sample. You will be paid $1 per breath sample submitted.
- If you are assigned to the group that earns financial incentives for quitting you may earn $20 for quitting on the scheduled quit day (with 2 breath samples submitted to corroborate), and you will earn daily payments for quitting each day that you are smoke free thereafter. Payments will start at $3 per day and increase each week by $1 if you remain abstinent. The daily incentive increases weekly with continued abstinence until you reach $8 per day during week 6 after your quit date. If you smoke at any time, you will not earn the incentive that day. However, you may begin earning incentives on your 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.
- If you are assigned to the standard treatment only, you will not receive financial incentives for quitting. Instead you will be paired with a participant in the incentives group, and you will receive the same payment as that participant. You will not have control over how much you earn, but earnings will be paid out on Fridays if your paired participant received incentives that week.

Scheduled Visits:

Baseline**:** If you are eligible, you will be asked to complete a 2-part baseline. During part 1 of the baseline visit you will be asked to answer surveys on a tablet, phone, or laptop computer. You will speak with a tobacco cessation counselor to set a quit date, and to prepare for quitting tobacco. You will be provided with nicotine replacement therapy (patches and gum or lozenges). Part 1 is expected to take 2-3 hours. After completing part 1, you will be scheduled for part 2, where you will download a smartphone application on your personal phone or you may be given a study phone. At this visit, you will be provided with instructions on using the smartphone app and the Bedfront iCO Breathalyzer. You will be asked to quit smoking seven (7) days after this visit. Part 2 is expected to take about 30 minutes. You will receive $30 on a MasterCard for completing both parts of the baseline.

Weeks 1-4: Each of these visits will consist of a video or phone counseling session. Each session may cover the following topics: 1) impact of tobacco on health/benefits of quitting, 2) stress

management, 3) making positive lifestyle changes, 4) coping skills, and 5) relapse prevention. Counseling sessions may also include a mental health component.

Week 12**:** At this you will be asked to answer surveys on a tablet, phone, or laptop computer, and will be paid $30 to answer these questions. If you were loaned a study phone you will receive your final payment after you return the smartphone either in-person or by mail (postage provided).

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**

How Long Will I Be in The Study?

We think that you will be in the study for 13 weeks. Baseline and 12 Weeks Post-Quit visits may take place in-person or remotely. All other visits take place remotely. Smoking cessation counseling will continue through 4 weeks after your quit day, and smoking cessation medications will continue through 12 weeks after your quit day. You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the research staff first. If you withdraw, you will no longer receive the smoking cessation treatment or financial incentives for quitting that are included as part of the study. However, we can provide a referral to other treatment options.

What Are The Risks of The Study?

While participating in the study, you are at risk for side effects associated with FDA-approved tobacco cessation medications. Please read the medication package inserts for detailed information.

As you try to quit smoking, you may have symptoms of nicotine withdrawal. When you quit, this withdrawal may cause symptoms like cravings, or urges, to smoke; depression; trouble sleeping; irritability; anxiety; and increased appetite. These symptoms are no different than those you would experience if you did not participate in this study.

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.

You should discuss possible medication side effects with your regular doctor. Many side effects go away shortly after the nicotine replacement therapy is stopped, but in some cases side effects can be serious or long lasting and permanent. The treatment may involve risks that are currently unforeseeable.

Risks related to studying the process of quitting tobacco may also include 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 usual care, as loss of confidentially and medication side effects may be experienced in either case.

Protections against risk: You will use your phone, or a phone loaned to you by the study. You will complete assessments through a secure app and all data will be automatically saved and sent to the study server. For those who receive study smartphones, the research staff will use a unique Google Play Store login to download the study app onto the phone. Passwords will only be known to research staff. When the study is over, if you were loaned a study phone, you will return the phone to us. All data collection through the phone app will end. Study data will then be removed from the study phone. Participants who use their personal phones will use their personal Google Play Store account to download the Insight app. At the end of the study, all study data will be removed from your phone and all data collection through the phone app will end. Study staff will tell you how to delete the app from your phone.

Reproductive Risks

If you are a female, it is recommended that that you avoid becoming pregnant while using nicotine replacement therapy. Although the use of nicotine replacement therapy is believed to be safer than smoking, the risks to your child are not fully known. Taking tobacco cessation medications while pregnant or breastfeeding may involve risks to an embryo, fetus or infant, including birth defects which are currently unforeseeable. If you become pregnant during this study, you should immediately inform the study personnel, who will advise you to discontinue your tobacco cessation medication.

Are There Benefits to Taking Part in The Study?

If you agree to take part in this study, there may or may not be direct benefit to you. Counseling and nicotine replacement therapy will increase your chances of successfully quitting smoking. What we learn from this study may be used to increase our

understanding of the factors that make it hard to quit smoking, which may lead to quit smoking treatments that work better.

What Other Options Are There?
You do not have to participate in this research to get help with quitting smoking.

You have these options:

- You may participate in the Tobacco Treatment Research Program and receive counseling and smoking cessation medications while researchers measure your experiences and progress.

- You may contact the Oklahoma Tobacco Helpline at 1-800-Quit-Now (1-800-784-8669) or visit www.okhelpline.com

- You may talk to your doctor about getting medications to help you quit smoking.

- You may choose to not receive any treatment at this time.

Please talk to your regular doctor about these and other options.

What About Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identified by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies, and the National Institutes of Health/National Cancer Institute and its representatives. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

What Are the Costs?
There is no charge to you or your insurance provider to participate in this research study.

Will I Be Paid For Participating in This Study?
Yes. You will be paid up to $570 if you quit smoking for 12 weeks (or are paired with someone who quits for 12 weeks), complete all study assessments, and return the study phone. The total amount of payments will be reduced if you are unable to quit smoking and/or you do not complete all study activities.

For tax reporting purposes, you will be asked to provide your social security number, residency status, a copy of your green card, if applicable, and whether or not you are a University of Oklahoma employee.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time without penalty or loss of benefits, to which you are otherwise entitled.

We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare or willingness to continue your participation in this study.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

Who Do I Call If I have Questions or Problems?

If you have questions, concerns, or complaints about the study or have a research-related injury, contact the principal investigator, Dr. Darla Kendzor, at (405) 271-8001, ext. 50478. After 5 pm and on weekends, you may reach the investigators at (405) 271-6872.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection at (405) 271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at (405) 271-2045.

Signature:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18) (*Or Legally Authorized Representative)*	Printed Name	Date
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date