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

STUDY TITLE: Smartphone Based Smoking Cessation Intervention

SPONSOR: NIH/NCI
PRINCIPAL INVESTIGATOR: Michael S. Businelle, Ph.D.

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in them. 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 currently smoking
- You are interested in quitting smoking
- You are attending the Tobacco Treatment Research Program (TTRP) cessation program or you responded to an advertisement for this study.

Why Is This Study Being Done?
The purpose of this study is to:

- Compare the effectiveness of 2 smoking cessation treatment approaches: 1) the Smart-Treatment (Smart-T) smoking cessation smartphone application, and 2) a popular smoking cessation smartphone application.
- Identify predictors of successful smoking cessation and relapse, which is defined as use of tobacco after the specified quit date.
- Determine the effects of Smart-T messages on relapse risk factors.

What is the Status of the Drugs (Devices or Procedures) Involved in this Study?

- Nicotine replacement therapy (patch, gum, and lozenges) is currently approved by the US Food and Drug Administration.
- The Vitalograph Breath CO Monitor is approved by the US Food and Drug Administration.
- The Bedfont iCO Smokerlyzer is approved by the US Food and Drug Administration.

How Many People Will Take Part In The Study?
About 550 people will be screened for this study and 450 will take part in this study. All individuals will participate at this location.

What Is Involved In The Study?

You will be randomized to a group that receives either the Smart-T application or the alternate application for smoking cessation. All participants will be offered free nicotine replacement medications (i.e., Nicotine patches and gum or lozenges). You will download the smartphone application onto your personal phone, if you do not own a smartphone or your smartphone is not compatible with the application a loaned phone will be provided to you by the study. 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 the research staff will choose which group you will be in.

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

- You will be asked to answer questions and confirm you are a smoker to determine if you are eligible to participate in this study (CO is collected during in-person visits to verify smoking status). In order to measure your expired carbon monoxide level (i.e., the amount of carbon monoxide present in your breath when you breathe out), you will be asked to take a deep breath in, and hold this breath for about 20 seconds and then breath out slowly and steadily through the mouthpiece of the Vitalograph BreathCO monitor. If you are being screened via remote appointments, you will be asked to text us a picture of your cigarettes.
- If you meet the qualifications for this study you will be asked to complete additional questionnaires today, and we will measure your height and weight (those appearing in person only). Questionnaires will ask about your health, education, income, gender, background, smoking history, alcohol use and other health behaviors, neighborhood, mood, stress, coping, and social support, and your opinion of the quality of treatment that you received. You will receive $30 on a study MasterCard today for completing all study surveys.
- You will be asked to quit smoking 7 days from today if you are completing this visit in person, or 7 days after you receive the study materials by mail if completing today's visit by
- phone. You will download the Smart-T app or the popular smoking cessation app onto your personal smartphone, or a smartphone will be loaned to you. If you own a smartphone that is compatible with the smartphone app, you can choose to use your personal phone to complete surveys and you will receive an extra $15 per month to offset data plan costs if you complete at least 50% of your monthly surveys. You will use the smartphone to complete daily surveys for the next 27 weeks. The smartphone will ring and vibrate 5 times per day for the first 5 weeks to alert you that it is time to complete a brief survey, then 3 times per day for the next 9 weeks, and 1 time per day for the following 13 weeks. You will respond to surveys by using the smartphone touch screen. You will also be asked to click a button in the app when you smoke cigarettes. In addition, the phone will attempt to capture the geographic coordinates of your location via global positioning systems (GPS) multiple times each day. GPS coordinates are being collected to examine the effect of location on variables that may increase the likelihood of relapse.
- Smartphone surveys will each take approximately 30-120 seconds to complete. You will be compensated for completing the phone surveys. Specifically, for the first week you can earn up to $25 (i.e. those who complete 80% or more of the weekly surveys will receive $25, those who complete 70%-79% will receive $18 in gift cards, and those who complete 50%-69% of the weekly surveys will receive $12 in gift cards). The following 4 weeks of the study, up to $50 will be loaded onto your MasterCard gift card each 15 day period for completing the 5 daily surveys (i.e., those who complete 80% or more of the weekly surveys will receive $50, those who complete 70%-79% will receive $36 in gift cards, and those who complete 50%-69% of the

weekly surveys will receive $24 in gift cards). During the next 60 days of the study (weeks 6-14), the phone will prompt you to complete 3 surveys each day and you can earn up to $36 each 15 day period (if you complete 80% or more of the surveys you will receive $36 per 15 day period, 70%-79% = $28 per 15 day period, 50%-69% = $18 per 15 day period). During the final 90 days of the study (weeks 15-27), the phone will prompt you to complete 1 survey each day and you can earn up to $30 per 15 day period depending on the percentage of surveys you complete (if you complete 80% or more of the surveys, you will receive $30 per 15 day period, 70%-79% = $22 per 15 day period, 50%-69% = $14 per 15 day period). If you complete less than 50% of the surveys in any given 15 day period, you will not receive compensation for that 15 day period. You will be able to track the percentage of surveys that you have completed by clicking the "Payment" button in the smartphone app. You will not receive payment for phone surveys until you confirm or update your contact information (i.e., you can click a button in the app to update your contact information, or we will attempt to contact you every 15 days to update/confirm your contact information). If you borrow a study phone, we will send you a postage paid envelope to return it to us at the end of the study.

- You will receive a Bedfont iCO breathalyzer that will be used to measure the amount of carbon monoxide in your expired breath. The smartphone app will prompt you to provide a breath sample 3 times per week during the usual phone surveys. The app will use facial recognition software to verify that you are the one providing the breath sample. The app will walk you through this process.
- You will receive a 4 week supply of nicotine replacement therapy (NRT) today. You can receive up to 6 additional weeks of nicotine patches and up to 8 additional weeks of nicotine gum or lozenges by requesting through the application or contacting the research staff by pressing a button in the apps. Upon request, we will mail you the additional NRT. After 12 weeks, pharmacotherapy will be discontinued. All pharmacotherapies that will be offered to you have been FDA-approved for over the counter use for smoking cessation. Possible side effects of NRT include: nausea, dizziness, weakness, vomiting, irregular heartbeat, and skin irritation. Due to possible risks, women who are currently pregnant or who plan to become pregnant during the study period will be excluded from this study.
- Approximately 27 weeks from today, you will complete a longer survey on the phone (you will earn a $5 bonus if you complete the final survey within the first 24 hours that it is available). This survey will have two parts (i.e., app based survey and a 10-15 minute phone call interview that will be recorded and will ask your opinions about the study smartphone apps). Once you complete this final study survey, $50 will be loaded onto your MasterCard gift card.

Table 1. Summary of Study Visits and Surveys.

Timeline	Description of Study Visits

SCREENING and BASELINE VISIT or CALLS	• Complete eligibility screening measures • Expired carbon monoxide levels, weight, and height measured (in-person only) • If eligible, complete self-report questionnaires • Smartphone app instructions will be provided • If you do not own a compatible smartphone, one will be loaned to you • You will be randomized to one of the 2 treatment groups • This visit or calls will take 60 to 90 minutes to complete • You will receive $30 gift card for completing the Baseline assessment
SMARTPHONE SURVEYS	• The smartphone app will prompt: • 5 surveys per day for weeks 1-5 of the study (up to $25 for the first week and up to $50 for each 15 day period during the next 4 weeks) • 3 surveys per day for weeks 6-14 of the study (up to $36 for each 15 day period) • 1 survey per day for weeks 15-27 of the study (up to $30 for each 15 day period) Three times each week, the smartphone will ask you to attach the Bedfont iCO carbon monoxide monitor to the phone and follow instructions to complete a breath test. The app will use facial recognition software to verify that you are the one who complete the breath test. • The smartphone will collect GPS coordinates multiple times each day
WEEK 27 FOLLOW-UP PHONE ASSESSMENT	• The smartphone app will prompt a longer final survey (you will earn a $5 bonus if you complete the final survey within the first 24 hours that it is available) • Study staff will call to ask you some final study questions • This assessment will take 20-30 minutes to complete • Those who borrow a study phone will use the pre-paid packaging we send to you to return it (including charger) to us via mail • You will receive a $50 gift card after you complete the 2 parts of this assessment and return the study phone (if applicable)

Study Groups

Smart-Treatment (Smart-T) App. Study participants randomized to the Smart-T group will download the Smart-T app onto their personal phone or a study provided phone. The Smart-T app will use your answers to repeated smartphone questionnaires to create tailored messages that are designed to help you quit smoking and stay smoke free. Participants can also use the smartphone app functions to get tips about coping with relapse risks, call the Oklahoma Tobacco Helpline, call study staff, and get information about the nicotine replacement medication. Participants in this group will receive information on how to use the Smart-T app features at the baseline visit.

A popular smoking cessation app. Study participants randomized to this smartphone app will download this app and a survey app onto their personal phone or a study provided phone. Participants will receive information on how to use the app features and complete phone based assessments at the baseline visit. Participants in this group can track cravings, smoking triggers, motivations for quitting, and learn about the health consequences of smoking and quitting, smoking cessation medications, ways to handle urges to smoke, developing a multicomponent smoking cessation plan, and coping with lapse.

How Long Will I Be In The Study?
We think that you will be in the study for 27 weeks starting today.

You can stop participating in this study at any time, and this will not affect your eligibility to receive treatment through the TTRP. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

What Are The Risks of The Study?

Some of the questions may make you feel uncomfortable. If this happens, you may take a break or stop participating in the study at any time. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. All members of the research team are required to undergo training about how to keep information confidential. Your data will be labeled with an ID number that can be matched to your personal information (such as your name) that will be kept in a separate, locked filing cabinet. There are no known risks associated with the use of the Vitalograph BreathCO monitor or the Bedfont iCO monitor.

Participants will use a study smartphone or their personal smartphone to complete assessments through an encrypted mobile application 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. At the conclusion of the participant's time in the study, participants will return the phone and all data collection through the Insight application will end. Study data will then be removed from the study phone. Participants who use their personal mobile device will use their personal Google Play Store account to download the Insight app. At the conclusion of the participant's time in the study, the study data will be removed from the participant's phone and all data collection through the Insight application will end. Researchers will also give participants instructions on how to delete the app from their personal device once they complete the study.

Nicotine Withdrawal. There is a strong likelihood that when you quit smoking, you will experience some nicotine withdrawal symptoms, including anxiety, restlessness, anger, irritability, sadness, problems concentrating, appetite change and weight gain, insomnia, and decreased heart rate. Withdrawal symptoms are usually short-lived. Most symptoms are significantly reduced within 1-2 weeks.

Nicotine Replacement Therapy (NRT; Patch and Gum/Lozenge). Nicotine patch and gum/lozenge are smoking cessation medications that can cause side-effects (e.g., nausea, skin irritation) that are generally mild. Women who are pregnant or breastfeeding should not take NRT. For more information about risks and side effects of this over-the-counter medication, ask the study staff or reference the nicotine patch, gum, and lozenge packaging.

<u>Risks for females:</u>
If you are a female, you must not be and should not become pregnant nor breast-feed an infant while in this study. Taking the study drug(s) or undergoing a particular procedure or treatment involved in

this study while you are pregnant or breastfeeding may involve risks to an embryo, fetus, or infant, including birth defects which are currently unforeseeable. In order to reduce your risk of pregnancy, you or your partner should use one or more methods of birth control, regularly and consistently, while you are in this study.

If you become pregnant or suspect that you are pregnant, you should immediately inform the study personnel. If you become pregnant or suspect that you are pregnant while in this study, discontinue use of NRT and contact your doctor.

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 medical benefit to you. The researchers cannot guarantee that you will benefit from participation in this research. It is possible that the Smart-T app or the popular smoking cessation app may increase the chances of quitting. In addition, the knowledge gained from this study may be used to improve our understanding of the barriers to quitting and predictors of relapse, and facilitate the development of more effective smartphone based smoking cessation interventions. We hope that the information learned from this study will benefit other people who try to quit smoking in the future.

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 participant in the Tobacco Treatment Research Program's smoking cessation program and receive usual care offered to all patients.
- You may call the Oklahoma Tobacco Helpline at 1-800-Quit-Now (1-800-784-8669) or visit www.okchelpline.com.
- You may talk to your physician about nicotine replacement therapy (available overthe-counter) and other pharmacological treatments (available by prescription) for tobacco dependence.

What about Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable 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. Organizations include the US Food & Drug Administration and other regulatory agencies, the 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. You will be asked to provide your social security number, your residency status, (and supply a copy of your green card if applicable), and whether you are a University of Oklahoma employee for tax reporting purposes. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. However, this website will not include

information that can identify you. At most, the website will include a summary of the study and results. You can search this website at any time.

To help protect your privacy, a Certificate of Confidentiality will be obtained from the federal government. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

If you are enrolled in the study after the expiration or termination of the Certificate, the protection afforded by the Certificate as described above will not apply.

What Are the Costs?
There is no cost to you if you participate in this study. Neither you, nor the insurance provider, will be charged for anything done for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

Will I Be Paid For Participating in This Study?
Yes. The table below shows the amount of gift cards you may earn for completing the baseline and follow-up questionnaires and surveys on the smartphone. Payments $600 and greater will be reported to the Internal Revenue Service (IRS) as 1099 income.
PARTICIPANTS WILL NOT BE COMPENSATED FOR ACCESSING ON-DEMAND APP FEATURES OR COMPLETING TREATMENT COMPONENTS.

Table 2. Schedule of Payments

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. However, at certain times during the treatment, it may be harmful for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular doctor. You may discontinue your participation at any time without penalty or loss of benefits

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.

	Compensation
Baseline Visit (today) Assessment	$30
Phone Based Surveys Weeks 1-5 (Days 1-37) 5 surveys per day 3 CO tests per week	Up to $25 for the first 7 days of the study., and up to $50 each 15 day period for weeks 2-5
Weeks 6-14 (Days 38-97) 3 surveys per day 3 CO tests per week	Up to $36 each 15 day period
Weeks 15-27 (Days 98-187) 1 survey per day 3 CO tests per week	Up to $30 each 15 day period
Week 27 Follow-up Assessment (Phone Survey and Call)	$50 + $5 bonus
Data Plan Costs	$15 per month if using personal phone
TOTAL: Up to $624 to which you are otherwise entitled.	

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. You consent to this temporary restriction.

Whom 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 Dr. Michael Businelle's research office at 405-271-8001 x50479 during regular business hours. After 5 pm and on weekends, you may reach the investigators at 405-271-4385.

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