

**CONSENT FORM****University of Oklahoma Health Sciences Center (OUHSC)****Stephenson Cancer Center****TSET Health Promotion Research Center****Small Financial Incentives to Promote Smoking Cessation in
Safety Net Hospital Patients****Sponsors: National Institutes of Health/National Cancer Institute/Tobacco Settlement
Endowment Trust****Principal Investigator: Darla E. Kendzor, 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 because:

- You are currently smoking
- You are interested in quitting smoking
- You are seeking treatment through the Tobacco Treatment Research Program (TTRP)
- You are uninsured or receiving Medicaid benefits

Why Is This Study Being Done?

The purpose of this study is to:

- Compare a standard smoking cessation treatment to a treatment that offers gift cards for proof that you have quit smoking.
- We also want to identify factors that lead to either quitting smoking or going back to smoking.

What is the Status of the Devices involved in this study?

The **Vitalograph BreathCO Monitor** and **NicAlert saliva cotinine test strips** are approved by the US Food and Drug Administration.

How Many People Will Take Part In The Study?

Up to 350 people will take part in this study, all at this location.

What Is Involved In The Study?

You will be randomized to the usual quit smoking treatment (counseling + medication) or the usual treatment plus gift cards for proof that you have quit smoking. 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.





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

We may contact you by telephone, text message, email, or letter to remind you of your appointments and to check on your tobacco cessation status or ask that you complete a short web-based questionnaire concerning your tobacco cessation status.

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.

You will be asked to answer questions and provide a breath sample (for carbon monoxide measurement) to determine if you are eligible for the study. In order to measure the carbon monoxide in your breath, you will be asked to take a deep breath in, and hold your breath for as long as possible and then breathe into a monitor for about 20 seconds. If you meet the criteria for this study you will be asked to answer questions, and have your height and weight measured. You will also be asked to quit smoking one week from today, return to the smoking cessation clinic each week for the next 5 weeks to answer questions, provide breath samples, and be weighed. You will answer questions about your health, socioeconomic status, smoking history, alcohol use, recreational drug use, such as marijuana and other health behaviors, neighborhood, how you spend the gift cards you are compensated with, mood, stress, coping, and social support.

You will be given a smartphone that you will carry for the next 5 weeks. The smartphone will ring and vibrate 5 times per day to let you know that is time to answer the questions. You will answer the questions by using the smartphone touch screen. You will also be asked to click a button on the phone when you smoke cigarettes and when you feel like smoking. Smartphone questionnaires will each take about 2 minutes to complete. **The phone will record your location via global positioning systems (GPS) each time you answer questions on the phone.** We may contact you by telephone to troubleshoot technical problems with the smartphone.

When you return 5 weeks from today, you will earn up to \$150 in gift cards for answering the smartphone questions. The amount that you earn for completing the smartphone questions depends upon the number of random assessments that you complete. If you complete less than 50% of assessments you will receive \$0 in gift cards, if you complete 50%-74% of assessments you will receive \$75 in gift cards, if you complete 75%-89% of assessments you will receive \$100 in gift cards, and if you complete 90% or more of the assessments you will receive \$150 in gift cards. You will be able to see the percentage of assessments you completed by clicking a button on the smartphone. If the phone is not returned for any reason, then you will not receive payment for the smartphone assessments.

If you are randomly assigned to the standard treatment PLUS gift cards for proof that you have quit smoking you will be able to earn gift cards for proof that you have quit smoking at each visit. You will be able to earn a \$20 gift card for quitting on the quit day, and this gift card amount will increase by \$5 with each week you stay quit (i.e., \$25 in gift cards 1 week after quitting, \$30 in gift cards 2 weeks after quitting, \$35 in gift cards 3 weeks after quitting, and \$40 in gift cards 4 weeks after quitting). If you are still smoking at any visit, you can earn gift cards at the next visit if you do not smoke after you leave the clinic that day, but the gift card payment



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IRB EXPIRATION DATE: 06/30/2022



will go back to the starting level of \$20. You will also earn a \$50 gift card for proof that you have quit smoking 8 and 12 weeks after the quit date.

Visit 1: You will be screened for eligibility to participate in the study. If you are ineligible and decide to enroll in the Tobacco Treatment Research program you will receive a \$50 gift card. If you are eligible, we will randomly assign you to one of these groups:

1) Standard Care OR 2) Standard Care PLUS gift cards for proof that you have quit smoking. You will answer questions and we will measure your expired carbon monoxide levels, weight, and height. Visit 1 is expected to take about 2-3 hours to complete. Participants who enroll will receive a \$50 gift card for completing this visit.

Visit 2: This is your quit day (you will be asked to not smoke after 10:00 p.m. the evening before visit 2). You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your visit 1. Visit 2 will take about 1 hour to complete. All participants will receive a \$30 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 3: This visit will be one week after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 3 will take about 1 hour to complete. All participants will receive a \$30 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 4: This visit will be two weeks after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 4 will take about 15 minutes to complete. All participants will receive a \$30 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 5: This visit will be three weeks after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 5 will take about 15 minutes to complete. All participants will receive a \$30 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 6: This visit will be four weeks after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 6 will take about 1 hour to complete. All participants will receive a \$30 gift card for completing this visit. You will also earn gift cards worth up to \$150 based on the percentage of random assessments that you complete on your study phone. Specifically, if you complete less than 50% of assessments you will receive \$0 in gift cards, if you complete 50%-74% of assessments you will receive \$75 in gift cards, if you complete 75%-89% of assessments you will receive \$100 in gift cards, and if you complete 90% or more of the assessments you will receive \$150 in gift cards. The amount you receive is determined when the phone is returned at this visit. You will also be able to see the percentage of assessments you completed by clicking a button on the smartphone. If the phone is not returned for any reason, then you will not receive



payment for the smartphone assessments. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 7: This visit will be eight weeks after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 7 will take about 1 hour to complete. All participants will receive a \$40 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 8: This visit will be twelve weeks after your quit day. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. Visit 8 will take about 1 hour. All participants will receive a \$40 gift card for completing this visit. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status.

Visit 9: This visit will be 26 weeks after your quit day. This is your last study visit. You will answer questions, we will measure carbon monoxide levels in your breath, and also measure your weight, similar to your previous visits. We will collect saliva to measure cotinine which tells if you have been smoking. This visit will take about 1 hour, and you will receive a \$40 gift card for completing this visit. In some cases you will also receive an additional \$2 for completing each survey that assess motivation to quit smoking. Those who are not able to attend will be contacted by phone to obtain self-reported smoking status and will be mailed a saliva cotinine test with instructions on how to complete and return the test to the clinic.

If you are assigned to the standard treatment PLUS gift cards for proof that you have quit smoking, you will also receive the following:

Visit 2: You will earn a \$20 gift card for not smoking after 10:00 p.m. the night before and having a carbon monoxide level in your breath that is less than 10 parts per million.

Visit 3: You will earn a \$25 gift card if you have been continuously abstinent from smoking since your quit day (i.e., 10 p.m. on the night before visit 2) and you have a carbon monoxide level of 6 parts per million or less. If you previously lapsed but have not smoked since visit 2 and your carbon monoxide level is 6 parts per million or less, you will receive a \$20 gift card.

Visit 4: You will earn a \$30 gift card if you have been continuously abstinent from smoking since your quit day (i.e., 10 p.m. on the Sunday before visit 2) and you have a carbon monoxide level of 6 parts per million or less. If you previously lapsed but have not smoked since visit 3 and your carbon monoxide level is 6 parts per million or less, you will receive a \$20 gift card.

Visit 5: You will earn a \$35 gift card if you have been continuously abstinent from smoking since your quit day (i.e., 10 p.m. on the Sunday before visit 2) and you have a carbon monoxide level of 6 parts per million or less. If you previously lapsed but have not smoked since visit 4 and your carbon monoxide level is 6 parts per million or less, you will receive a gift card worth \$20.



Visit 6: You will earn a \$40 gift card if you have been continuously abstinent from smoking since your quit day (i.e., 10 p.m. on the Sunday before visit 2) and you have a carbon monoxide level of 6 parts per million or less. If you previously lapsed but have not smoked since visit 5 and your carbon monoxide level is 6 parts per million or less, you will receive a \$20 gift card.

Visit 7: You will earn a \$50 gift card if you have not smoked over the past 7 days and your carbon monoxide level is 6 parts per million or less.

Visit 8: You will earn a \$50 gift card if you have not smoked over the past 7 days and your carbon monoxide level is 6 parts per million or less.

How Long Will I Be In The Study?

We think that you will be in the study for 27 weeks starting today. Gift cards for proof that you have quit smoking will be provided through 12 weeks after the quit date for those randomly assigned to the gift cards for quitting smoking group. The last visit will be scheduled for 26 weeks after the quit day.

The length of the standard smoking cessation treatment program will be determined by the participant, and will be available weekly for as long as desired.

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 NicAlert cotinine test strips.

Protections Against Risk: As a participant in this study, you will use a study smartphone or your personal mobile device to complete assessments through an encrypted mobile application and all data will be automatically saved and sent to the study server. If you receive a study smartphone, then 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 your time in the study, you will return the phone and all data collection through the Insight app will end. Study data will then be removed from the provided study phone. If you intend to use your personal mobile device for this study, then you will use your personal Google Play Store account to download the Insight app. At the conclusion of your time in the study, the study data will be removed from your personal device and all data collection through the Insight app will end. Researchers will provide you with instructions on how to delete the app from your personal device.

**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. It is possible that the gift cards provided as rewards for abstinence from smoking may increase your chances of quitting. 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 call (or we can connect you to) 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.

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. These organizations include the US Food & Drug Administration and the National Institutes of Health. 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.

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 has been 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 evaluation of 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?

Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). However, the standard quit smoking treatment (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). 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 the gift cards you may earn at each visit, depending on your treatment. Payments \$600 and greater will be reported to the Internal Revenue Service (IRS) as 1099 income.

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. You may discontinue your participation 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.

**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 Darla Kendzor, Ph.D. at (405) 271-8001, ext. 50478, 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.



**Table. Payment schedule by treatment group.**

	Standard Treatment	Standard Treatment PLUS Gift Cards
Visit 1 (Pre-Quit)		
Assessment	\$50	\$50
Visit 2 (Quit Day)		
Assessment	\$30	\$30
Payment for Abstinence	N/A	\$20 (if abstinent)
Visit 3 (1 Week Post-Quit)		
Assessment	\$30	\$30
Payment for Abstinence	N/A	up to \$25 (if abstinent)
Visit 4 (2 Weeks Post-Quit)		
Assessment	\$30	\$30
Payment for Abstinence	N/A	Up to \$30 (if abstinent)
Visit 5 (3 Weeks Post-Quit)		
Assessment	\$30	\$30
Payment for Abstinence	N/A	Up to \$35 (if abstinent)
Visit 6 (4 Weeks Post-Quit)		
Assessment	\$30	\$30
EMA/Return Phone	Up to \$150	Up to \$150
Payment for Abstinence	N/A	Up to \$40 (if abstinent)
Visit 7 (8 Weeks Post-Quit)		
Assessment	\$40	\$40
Payment for Abstinence	N/A	\$50 (if abstinent)
Visit 8 (12 Weeks Post-Quit)		
Assessment	\$40	\$40
Payment for Abstinence	N/A	\$50 (if abstinent)
Visit 9 (26 Weeks Post-Quit)		
Assessment	\$40	\$40
GRAND TOTAL:	up to \$470	up to \$720



**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