Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: Randomized Controlled Trial of Dyadic Financial Incentive Treatment for Dual Smoker Couples: Evaluation of Efficacy, Mechanisms, and Cost Effectiveness

Sponsor: National Cancer Institute

Principal Investigator: Michelle vanDellen

Phone Number: 762-499-4263

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to participate in a research study about smoking in romantic relationships. To be part of this study, you and your partner must be 18 or older, both smoke, live together, and have internet access.

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to understand how smoking changes in couples where both people smoke. Participation in this study lasts one year.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?

During one year, you will complete five 60-90 minute sessions online. Each session involves two parts. If you decide to participate in this study, you will be asked to complete both parts of each session. First, you will complete online questionnaires about your relationship, yourself, and your smoking. Second, you will participate in a video conference session. During this video conference, we will go over study procedures and ask you to breathe into a machine that measures your carbon monoxide levels. We will also ask you to test your saliva for cotinine (a chemical byproduct of using tobacco products). You will conduct both the breath and saliva tests on yourself using a kit we will send you in the mail. We will watch you complete these tests and record the results.

To make this study valid, some information will be withheld from you until everyone who is participating has completed their participation. After the study is completed, we will send you an email with a link that explains the details of the study and initial findings from the study.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?

If you agree to take part in this study, there may not be direct medical benefit to you. You may benefit from the study by having access to training on smoking cessation and nicotine replacement therapy. You may also learn about yourself, your smoking behaviors, and your relationship.

We hope that the information learned from this study will benefit other smokers who have smoking partners in the future. Smoking is associated with many health problems (for example, heart disease and lung cancer); learning about smoking behaviors in smoking couples may help us understand how to prevent smoking and assist people who want to quit to prevent disease and illness.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
Prior to enrollment, we may ask you to complete a medical screening questionnaire regarding conditions that put you at increased risk.

Participating in this study might take away from your time for work or leisure. The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

Participants in this study may choose to use provided Nicotine Replacement Therapy (NRT). NRT has side effects, including racing heartbeat and nausea. NRT is not recommended for individuals who are pregnant or have a history of heart disease. Although you will receive NRT for participating in this study, you do not have to use it to participate.

WHAT OTHER OPTIONS ARE THERE?
If you would like to earn these benefits without participating in the study, you may call 1-800-QUIT-NOW or visit quitnow.net. You may talk to your regular doctor or a local pharmacist to get recommendations for quitting smoking. Please talk to your regular doctor about these and other options.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There are no required costs to you to participate in this study. If you decide you would like to purchase additional nicotine replacement therapy (patch or gum), there may be a cost to you.

You will receive financial compensation five times throughout this one-year study. These payments will happen after each session. After completing Baseline, you will receive $60. You will receive $50 after completing each of four follow-ups. These happen 1-Month, 3-Months, 6-Months, and 1-Year after your completed Baseline session. If you complete at least three follow-up sessions, you will receive a $50 completion bonus. If you complete all four follow-ups, you will receive an additional $25 bonus. To receive payment after the Baseline session, both you and your partner must complete both parts of the Baseline session. To receive payment after the Follow-up sessions, you may receive payment even if your partner does not complete the session. However, you and your partner must still be in a romantic relationship for you to continue participating. In total, you may receive up to $335 for participating in this study. Your partner can also receive up to $335 for participating in this study, but you will each be paid separately.

Payment for participating in this study will be made by an electronic gift card. It may take up to two weeks to receive this gift card. To issue this gift card, we need to collect some of your personal information, including your birth date and address (physical or email). You will be asked to provide your residency status (a copy of your green card must be provided if applicable), and whether you are a University of Oklahoma employee for tax reporting purposes. If you are unwilling or unable to provide your residency status (and green card if applicable), or University of Oklahoma employment status, you will not be eligible to participate in this research study.

If you choose to stop your participation in the study, you will only receive compensation for the parts of the study you have completed. If we choose to stop your participation in the study, you will only receive compensation for the parts of the study you have completed. When your participation in the study ends, you will not have to return the nicotine replacement therapy or the devices we sent you.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 900 people will take part in this study nationwide.

WHAT IS THE STATUS OF THE DRUG AND DEVICES USED IN THIS STUDY?
In this study, you will be offered nicotine replacement therapy (patch + gum) that may be helpful if you choose to try to quit smoking. You will be given these products but it is your choice to use them. You may benefit from using them but you are not required to do so. Nicotine patches and gum are approved by the US Food and Drug Administration. You will also be provided a Smokerlyzer device to measure your carbon monoxide. You will use this device during video sessions. This device is approved by the US Food and Drug Administration. Neither nicotine replacement therapy nor the device are being investigated in this study.

WHAT IS INVOLVED IN THE STUDY?
There are five total sessions involved in this study (Baseline, 1-Month, 3-Month, 6-Month, and 1-Year). During each session, you will complete two tasks online. First, you will complete surveys using an online survey platform. In these surveys, you will answer questions about yourself, your smoking, and your relationship. Second, you and your partner will complete a video session with our research staff using a Zoom link we send you. For both parts of each session, we will identify your responses using a participant code that we assign to you.

Below is what participation in the study looks like and the compensation you may receive

When is this session?	Baseline Session	1 Month post Baseline	3 months post Baseline	6 months post Baseline	12 months post Baseline
How much time does participating take?	90 minutes	60 minutes	60 minutes	60 minutes	60 minutes
What will I be asked to do?	Questionnaires and video conference (carbon monoxide breath test + Saliva)	Questionnaires and video conference (carbon monoxide breath test)	Questionnaires and video conference (carbon monoxide breath test)	Questionnaires and video conference (carbon monoxide breath test + Saliva)	Questionnaires and video conference (carbon monoxide breath test + Saliva)
What payment will I receive?	$60	$50	$50	$50	$50

If you complete four out of the five sessions above, you may receive a $50 completion bonus. If you complete all five sessions, you may receive an additional $25 bonus.

WHAT ARE THE RISKS OF THE STUDY?
If you choose to quit smoking during this study, you may experience withdrawal. You may also experience side effects from using nicotine replacement therapy (patch and/or gum). The most common side effects from nicotine replacement therapy are skin irritation, mouth or throat irritation, difficulty sleeping, vivid dreams, rapid heart rate or palpitations, worsened high blood pressure, chest discomfort, nausea or an upset stomach, dizziness, and headaches. These side effects typically go away when you stop using the nicotine replacement therapy.

This research involves movement of data over the Internet and confidentiality during online communication cannot be guaranteed. Although the risk of confidentiality breach is kept low through good data management procedures, there is still a chance that information about you could be accessed without permission. This could potentially affect your employment status and insurance costs.

REPRODUCTIVE RISKS FOR WOMEN:
If you are a female, you must not be pregnant to begin this study. Should you become pregnant, inform the research team immediately. The research team will recommend that you do not consume Nicotine Replacement Therapy (nicotine patch or gum) if you become pregnant during the study, however, you may continue to participate in the other parts of the study.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?
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 may include the US Food & Drug Administration and other regulatory agencies, including the National Institute of Health. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

Posting Study on ClinicalTrials.gov:
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.

Certificate of Confidentiality:
To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 US Food and Drug Administration.

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.

Storing and Sharing Your Information:
Your sample may be used for future studies without your additional consent. We will remove direct identifiers from your information/and assign a code. They key for this code will be kept separately and

only the researcher for this study will have access to the code. If your information is shared with another investigator for research purposes, they may be granted access to this key code, if they receive approval to do so from the researcher and the OUHSC Office of Human Protection.

CAN I WITHDRAW FROM THE STUDY?
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 researcher first. Should you choose to stop participating, please let the research team know by email or text message.

There may be circumstances under which your participation may be terminated by the investigator without your consent. These include:

1) If you fail to follow study requirements.
2) If your relationship ends.
3) If your partner decides not to continue with the study.

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.

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, SUGGESTIONS, OR CONCERNS?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact Michelle vanDellen at 762-499-4263 24 hours a day.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and 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 continuing in the study after reading 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 should print a copy of consent for your records. A copy of the consent form is on file and can be requested from program staff at any time.

[Electronic Signature]