Informed Consent Form

TITLE: Randomized Controlled Trial to Test the Efficacy of a Smoke-Free Homes Intervention in Promoting Cessation

NCT NUMBER: NCT04547686

IRB APPROVAL DATE: March 14, 2023

Emory University
Oral Consent Script
For a Research Study

Study Title: Integrating a Smoke-Free Home Intervention into the 5As to Support Cessation: Randomized Controlled Trial
Principal Investigator: Michelle Kegler, DrPH, MPH, Department of Behavioral, Social and Health Education Sciences
Funding Source: National Cancer Institute

Introduction and Study Overview
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to participate in this research or not. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You do not have to answer any questions that you do not wish to answer.**

Before making your decision, please ask questions about anything that is not clear. Your decision about whether or not to participate will **not** affect your services from your primary care provider. Participant names will not be attached to study records or results. Feel free to take your time thinking about whether you would like to participate. If you agree to participate in this study, you will not give up any legal rights.

Do you have any questions so far?

Study Overview
The purpose of this study is to see if smoke-free home rules support smokers in changing their smoking behaviors. We will recruit up to 1,344 smokers from local clinics to participate in this study. Your part in the study will take about 3 hours over the course of 12 months.

Procedures
If you agree to take part in this study, there will be several parts to your participation. First, we will be conducting a 35-minute interview by telephone to collect basic information about your smoking and smoking in your home and car(s). We will do this interview right after we get your permission to participate, today. After you complete the interview, we will mail you a $30 reloadable gift card to thank you for your time. Then, over a period of twelve months, we will call you two more times, at 6-months and 12-months from your start date. Each time we will do a short telephone interview that will last around 35 minutes. These interviews will be similar to the first interview and you will have an additional $30 added to your gift card for each interview you complete. Some of the interviews may be recorded for quality control. In addition to the 3 interviews, we will ask you to confirm your contact information part-way through the study. You will receive an additional $5 for taking the time to confirm or update your contact information.

As part of the study, you will also be placed into one of two groups by chance, like the flip of a coin. You have an equal chance of being in either group. One group will receive three mailings of educational information about smoke-free homes and cars and two coaching calls over a period of ten weeks. During the coaching calls, we will talk more about your smoking behaviors and smoking in your home and car(s). Coaching calls are expected to last between 20 to 30 minutes each and will also be recorded to make sure we didn't miss anything. If you are in the other group you will not receive the educational materials or the coaching calls.

Finally, you may receive one or two saliva sample kits to measure the levels of nicotine in your saliva. We will provide detailed instructions and assist you in providing and returning the samples. We will provide postage-paid packages to return the samples. You will receive another $50 on your reloadable gift card for providing and returning the saliva sample to the study team.

Do you have any questions?

Risks and Discomforts

The risks of participating in this study are very minimal. We will not discuss any sensitive topics and we do not expect the questions to cause you any distress. Participation in this study is voluntary and you have the right to withdraw at any time. You may also skip any questions that you do not wish to answer. The risk of breach of confidentiality is minimal.

Benefits

By taking part in this study, you may or may not benefit from the information you receive. You may or may not establish smoke-free rules and change your smoking behaviors. Study results may be used to help others in the future learn steps to help change their smoking behaviors.

Compensation

This research study is being done at no cost to you. You may receive $30 for each interview (up to $90) and a possible $100 for saliva cotinine tests. Additionally, you may receive $5 for verifying your contact information. In total, you may receive up to $195 for participating in the research study, if you complete all parts of the study.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, and the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Voluntary Participation and Withdrawal from the Study

You have the right to leave the study at any time without penalty. You may refuse to answer any questions that you do not wish to answer.

Contact Information

If you have questions about this study, your part in it, your rights as a research participant, or if you have questions, concerns or complaints about the research you may contact the following:

- Dr. Michelle Kegler at [redacted], or by telephone at [redacted]
  - if you have any questions about this study or your part in it, or
  - if you have questions, concerns or complaints about the research
- Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu
  - if you have questions about your rights as a research participant.
  - if you have questions, concerns or complaints about the research.

Consent

By agreeing to participate, you will not give up any of your legal rights. We will mail you a copy of this consent form, for your records.

Do you have any questions about what I have just read? □ Yes □ No

Do I have your permission to sign you up as a participant for this study? □ Yes □ No

If Yes:

_____

Name of Participant

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time

_____

Name of Person Conducting Informed Consent Discussion

Thank you for agreeing to take part in this study. We thank you for your time.