Informed Consent Form Cover Page

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INFORMED CONSENT DOCUMENT

Promoting the Use of Evidence-Based Tobacco Cessation Resources through Community Food Pantries: A Pilot Trial

You are being asked to participate in a research study conducted by researchers at Case Western Reserve University. This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

KEY INFORMATION FOR YOU TO CONSIDER:

Purpose: The main purpose of this study is to understand how to best promote the use of an evidence-based tobacco cessation resource among people who use tobacco and are interested in receiving information about quitting smoking. The Ohio Tobacco Quit Line is a free resource available to all adult residents of Ohio who are interested in quitting. Our goal is to understand whether people's general awareness about the quit line and their interest to use the quit line changes after completion of the study. This is a pilot study, which means that we are also interested in learning more information about whether the study procedures work smoothly or not.

Eligibility: To be eligible for the study, you must be over 21 years of age, a resident of Cuyahoga county who currently smokes cigarettes or another combustible tobacco product, and interested and willing to receive information about quitting. Study participants will also need to have at least a mailing address and a telephone number. A working email address is also preferred but not required.

Duration: The study will last about 3 months (or about 12 weeks) and all study activities will take place either over the phone or online.

DETAILED CONSENT

You were selected as a possible participant because you have expressed interest in this study during our recruitment events. You also meet our eligibility criteria listed above. We hope to recruit about 100 people to volunteer for this research.

Procedures

These steps are what will happen to you once you enroll in the study, in this general order:

1) Once you formally agree to be in this study, you complete a baseline survey. We will send you an online link to complete the survey, or you can take the survey by telephone if you wish. The survey will take about 45 minutes to complete, and will be asking you questions about you, your overall health, and your experiences with food access, tobacco use, and quitting. You will receive a $25 gift card for completing the survey.

2) Around the time you complete the baseline survey, the research team will refer you directly to the Ohio Tobacco Quit Line. They will call you separately to give you information about the free cessation resources available, such as counseling, text message support, and nicotine patches. Giving us permission to share your information does not automatically enroll you in the Quit Line, as they have their own enrollment and intake process. *You can choose NOT to be directly referred to the Quit Line.* If you choose to be referred, the Quit Line will be sending information back to the researchers that will only include how many of our participants enrolled in the Quit Line. Your contact info will not be included in that data. At this time, do we have your permission to refer to you the quit line? We will be sending them your name, date of birth, address, and phone number. However, we will not do so if you check the box below indicating you do NOT want to be referred.

   No, do NOT refer me to the Quit Line ☐

3) You will then be *randomly* designated into one of two groups. This is like a coin toss with a 50/50 chance, in which you nor the research team will be able to choose which group you are placed in.

   a. One group will receive check-in phone calls from a member of the research team. There will be two check-in phone calls, lasting about 15 minutes each, made about 1 month apart. We will be checking in on your current smoking and quitting situation.
   b. The other group will not receive any check-in phone calls from the research team.

4) At week 12 (in month 3), everyone will take a follow-up survey which will be very similar to the first survey you will take. This survey can also be completed over the phone or online and will take about 30 minutes to complete. For completing this survey, you will receive a $30 gift card for your time. After you complete this survey, your participation in this study is over.

Foreseeable Risks and Discomforts

All procedures may involve some level of risk to you. Any time information is collected, there is a potential risk for loss of confidentiality. Some of the activities we will ask you to complete might make you feel uncomfortable, such as taking a survey or participating in a brief phone conversation about quitting smoking. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time. You can also decline to be referred directly to the Ohio Tobacco Quit Line, if you do not want your information shared with them. Even if you do give permission to share your information, you can decline to enroll when they reach out to you. We believe there are no other known risks of harms or discomforts associated with this study beyond those encountered in normal daily life.

Anticipated Benefits

The possible benefits you may experience from the procedures described in this study include learning more about evidenced-based smoking cessation resources, such as services available through the Ohio Tobacco Quit Line. You may benefit from the opportunity for the research team to refer you directly to this resource.

Compensation

There will be no costs to you for study participation.
You will receive the following compensation: A $25 VISA gift card for completing the first survey, and a $35 VISA gift card for completing the 3-month follow up survey. Both gift cards will be sent in the mail to the home address you provide for us. The first gift card will be sent 2-3 business days after completion of the first

survey, and the second gift card will be sent 2-3 business days after completion of the final survey. The total compensation for completing both surveys is $60. If you withdraw from the study before the 3-month survey is complete, you will only be compensated for the first survey. You will receive no compensation if you are withdrawing from the study before the first survey is conducted.

Alternative(s) to Participation

Participation in the study is voluntary. The alternative is not to participate.

Voluntary Nature of the Study

Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University. There is no penalty or loss of benefits for not participating or for discontinuing your participation. You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team immediately. If you do withdraw from the study, the data we collected from you up until that point will be retained. However, we will no longer collect any more information from you. If you wish for your data to be destroyed, please contact the research team to request this.

Confidentiality

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, and regulatory agencies. Any sort of report we might publish, we will not include any information that will make it possible to identify a participant. However, you should understand that in cases where we suspect elder or child abuse or neglect or imminent harm to self or others, we will take the necessary action in an effort to prevent such harm or injury, including reporting to authorities.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. This CoC adds special protection for the research information about you. The CoC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. We may release identifying information in some circumstances, however. One example is if you agree that we can give out research information with your name on it. Other examples may include, disclosing medical information in cases of medical necessity related to your care, or taking steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse or neglect, or disclosing auditing information required by the agency or entity funding the research, or if there is federal, state or local law that requires disclosure. In addition, we may use certain information in future research as permitted by law.

Subject Identifiable Information

Information that identifies you (such as your name and contact information) will be kept with the research data until after the study is finished. This is to make sure your identity is uniquely different from others, and it is also so that we can track whether you received compensation for completing the survey. Information that identifies you, such as your first and last name, will be removed and replaced with a code. A master list linking the code and your identifiable information will be kept separate from the research data. This master list will be kept in two secure systems called “REDCap” that has been approved by the university for storing secure information. Other information, such as your phone number and email, will also be stored in the same secure system. The master list will be kept there until 2025, at which point it will be permanently deleted.

Data Storage
Research data will be maintained in a secure location at CWRU, in a system called Box. Only authorized individuals will have access to it. Research data will be stored electronically in an encrypted device that is password-protected, and in password-protected files.

Data Retention
The researchers intend to keep the research data indefinitely. Your identifiable information which are collected for this research may have the identifiers removed and be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. This means your answers to the survey may continue to be used by other researchers, but your name, contact information, and identifying information will be removed.

Contacts and Questions
The primary researcher conducting this study is Jin Kim-Mozeleski, Assistant Professor in the CWRU School of Medicine. You may ask any questions you have now. If you have any additional questions, concerns or complaints about the study, you may contact the study coordinator at FETCH@case.edu, or you can contact the primary researcher directly at 216-368-6793 or jxk1225@case.edu.

If you would like to talk to someone *other than the researchers* about questions or complaints regarding this study, research participant rights, research-related injuries, or other concerns, please contact:
Case Western Reserve University Institutional Review Board
10900 Euclid Ave.
Cleveland, OH 44106-7230
(216) 368-4514

Statement of Consent
Your agreement below certifies the following:

- You are at least 21 years of age.
- You have read (or been read) the information provided above. You will receive a copy of this form.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

You will be given a copy of this form for your records.

_____
Print Name of Participant

_____ Date/Time consented: _____
Signature of Research Personnel Obtaining Consent