NCT# 04855357

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: A community-based trial of a voluntary smoke-free home intervention in permanent supportive housing for formerly homeless adults

Principal Investigator:	Maya Vijayaraghavan, MD MAS Assistant Professor, University of California, San Francisco Email: [redacted] Phone: [redacted]
Study Coordinator:	Jessica Alway, MPH Email: [redacted] Phone: [redacted] Phoebe Lee, BA Email: [redacted]

This is a research study to test an intervention to increase adoption of a smoke-free home among residents in permanent supportive housing. The Principal Investigator, who is the person in charge of this study, or one of the other members of the study team from the UCSF Department of Medicine, will explain this study to you.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves. You are being asked to take part in this study because you are a current smoker and live in permanent supportive housing in the San Francisco Bay Area. If you have any questions, you may ask the researchers.

Why is this study being done?

The purpose of this study is to test an intervention to increase voluntary adoption of a smoke-free homes among residents in permanent supportive housing. A smoke-free home is a home where no smoking is allowed inside. The intervention will include distribution of written and graphic materials about the harms of secondhand smoke exposure, smoke-free home pledges and signs, and strategies to adopt a smoke-free home and address roadblocks to adoption. Participating permanent supportive housing sites will be randomly divided into two groups (Groups A and B) Sites that are in Group A, will receive the smoke-free home intervention first. Once Group A sites have completed the final study follow-up, all residents in Group B will be offered the intervention, about 6 months after Group A participants receive the intervention. Therefore, all enrolled resident participants in the study will have the chance to receive the intervention but staggered by about 6 months. We will evaluate whether participants in Group A, who receive the intervention first, are more likely to voluntarily adopt a smoke-free home compared to participants in Group B. We will also measure whether or not participants were able to stop smoking during the intervention. This study is being funded by the National Institutes of Health. The investigators have no financial conflict of interest.

How many people will take part in this study?

We expect to recruit 400 resident participants in this study, from 30 to 36 permanent supportive housing sites.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

First, you will need to have the following "screening" tests or procedures to find out if you can participate in the main part of the study:

- Pre-screening questionnaire that includes questions on your current smoking status
- Measurement of the air you breathe to determine whether or not you smoke. A level of 8 and over indicates your eligibility for the study.
- You will be screened for symptoms of COVID-19. Please see attached UCSF COVID-19 screening sheet for your information. If you report recent, unprotected close contact with someone who had COVID-19 or if you had any symptoms of COVID-19 within the two weeks prior to the study visit, we will reschedule your visit or conduct it over the phone.

If the screening exam shows that you can be in the main part of the study, you choose to continue and you are in Group A, this is what will happen next:

1) Research staff will help you to fill out a pre-intervention questionnaire on your attitudes toward smoking, smoking cessation, use of cessation aids, mental health and substance use history if it applies to you, smoke-free home rules, demographics, questions related to COVID-19, cost of cigarettes, smoking cessation, and use of cessation aids.
2) You will then be provided with intervention materials that include a 1) step-by-step guide on how to voluntarily adopt a smoke-free home, 2) information on secondhand smoke, thirdhand smoke, alternative combustible tobacco and nicotine product use, cannabis-tobacco co-use, effects of SHS on kids and pets, 3) a worksheet on calculating personal costs related to tobacco use, and 4) smoke-free home pledges/signs.
3) We will also be training staff in your building, such as your case manager, to offer you referrals for smoking cessation counseling and smoke-free home counseling. You may choose to have this voluntary counseling at any time during the course of the study and after. We may ask your permission to observe some of the interaction between you and your case manager around smoking.
4) We will conduct follow-up questionnaires at 3 months and 6 months using the same questionnaire as the baseline questionnaire. We will also collect the air you breathe out into a special container. This air will be analyzed to find out how recently you smoked.
5) To measure a smoke-free home, we will place a small air nicotine monitor in your room to assess presence of smoke in your room. If you are selected, then we will obtain permission from you at the time of the assessment to place this monitor in your home for 1 week. Monitors will be placed at least 1 foot away from windows, corners of the room, and exits.
6) We will contact you monthly by phone (if you have one) or get in touch with your case manager to remind you of your study visits.

If the screening exam shows that you can be in the main part of the study, you choose to continue and you are in Group B, the following will happen to you:

1) You will be asked to complete questionnaires at enrollment and at 3- and 6-months follow-up (the same questionnaires described above for Group A participants). We will ask you to blow into a cup to assess whether or not you smoked. You may be selected to assess the presence of smoke in your home through placement of an air nicotine monitor in your home for 1 week at 6 months follow-up.
2) You will wait for 6 months before starting the program. Participation in the intervention is voluntary. If you participate in the intervention, then you will receive the same intervention materials as describe above, and be asked to complete more assessments at 9 and 12 months follow-up.
3) We will contact you monthly by phone (if you have one) or get in touch with your case manager to remind you of subsequent study assessments.

Study location: All these procedures will be done at your permanent supportive housing site.

How long will I be in the study?

Participation in the study will take a total of about 3.5 hours over a period of 6 months if you are in Group A. If you are in Group B, your participation will take a total of 4.5 hours over 12 months.

- The pre-intervention questionnaire will take about half-hour to complete.
- It will take an additional one hour to cover all the intervention materials.
- The follow-up questionnaires at 3 months and 6 months follow-up will take approximately 30 to 45 minutes to complete.
- In between study visits, we will make monthly follow-up phone calls that will take approximately 5 minutes.
- It will take about 10 minutes to place and take out the air nicotine monitor to assess secondhand smoke at 6 months follow-up.
- If you are enrolled in group B of the study, your participation may be for 12 months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. If you withdraw from the study, any data, or specimens we have already collected from you will remain part of the study records.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Participation in this study may involve risk of loss of confidentiality; however, we will make every reasonable effort to keep your records confidential.

- You may feel uncomfortable answering one or more items on the questionnaires; however, you may refuse to answer these questions. You can choose to not participate in a discussion topic or answer any questions that make you uncomfortable.
- You may experience hunger as a result of reducing consumption or quitting smoking.
- You may experience fatigue and/or boredom during the intervention.
- If the intervention resulted in your stopping or reducing smoking, there is a chance that you may experience withdrawal symptoms. These symptoms may include irritability, anxiety, fatigue, or cravings for cigarettes. Should this occur, we will refer you to the neighboring community health center or on-site medical help to obtain treatment for smoking cessation withdrawal. In addition, Dr. Vijayaraghavan is a medical doctor who can talk to you about your symptoms and suggest strategies to stop smoking. We will also provide you with time to make adjustments to your smoking such as gradually reducing your cigarette consumption, or setting a quit date if you are ready to quit. .
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

You may or may not benefit from participating in the study.

What other choices do I have if I do not take part in this study?

You do not have to participate in this study. Your other choices may include:
- Getting treatment or care for your condition without being in a study
- Getting no treatment. Please talk to your doctor about your choices before agreeing to participate in this study

How will my *specimens and* information be used?

Researchers will use your *specimens and* information to conduct this study. Once the study is done using your *specimens and* information, we may use the *remaining specimens and* information collected for future research studies or share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information *and/or specimens* may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor: National Institutes of Health
- Representatives of the University of California

This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- Stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- Stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- Stop disclosures required by the federal Food and Drug Administration (FDA).
- Prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- From releasing information about your involvement in this research.
- From having access to your medical record information.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid, $20 for completing the baseline questionnaire, $15 for the 3-month questionnaire, and $25 for the 6-month questionnaire. We will provide you $5 for the monthly tracking visit in between study visits, and $5 for placing the nicotine air monitor in your home at 6 months follow-up. We will also offer you an additional incentive of $10 for referring any eligible participants to this study, for up to three participants during the study duration. In total, you could get up to $110 for participating in the study and referring additional participants.

We will also offer you an additional $10 if you participate in a CAB meeting.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Maya Vijayaraghavan, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her them [redacted]

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor National Institutes of Health, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. If you decide to take part in this study, you may leave the study at any time if you no longer want to participate. There will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can contact the research team with any questions, concerns, or complaints you have about this study [redacted]2. If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The National Clinical Trial (NCT) number for this study is NCT04855357.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent