Tobacco Cessation in Public Housing

NCT04889638

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If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Comprehensive tobacco cessation for residents of Baltimore City Public Housing**

Application No.: **IRB00224186**

Sponsor/Supporter/Funded By: **Community Partnership and Collaboration Core Pilot Grant**

Principal Investigator: **Panagis Galiatsatos, MD, MHS**
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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- This 6-week study is looking to see how helpful an on-site smoking cessation program will be when delivered to residents at Douglass or Brooklyn Homes. We are also interested in your opinions as to how to make this program better and how it could be used for residents at other units under the supervision of the Baltimore Housing Authority.
- To be eligible to join:
  - You need to be a daily or at least weekly user of cigarettes
  - You should be interested in quitting or reducing your smoking
  - You need to have active health insurance
  - You need to have a working cell phone

- The possible risks of this study are associated with the usage of the prescribed tobacco cessation medications. For example, we will be prescribing nicotine replacement therapy in the form of a gum, lozenge or patch. Some may be prescribed an oral non-nicotine medication called Chantix. To make sure those risks are low, we will be following you closely and we will be giving you a way to contact us at any time if you experience problems or concerns. Also, we will not be prescribing any therapy to you that we don't think is safe for you.
- There are no costs to being a part of the study. You will not have to pay for any of the medications since we will directly bill your health insurance. If you are asked to provide a co-pay, we will pay the requested amount.
- You will be in this study for up to 6 weeks, 4 of which will be in the smoking cessation program.

2. Why is this research being done?

This research is being done to improve smoking cessation resources in public housing in Baltimore City. Our study is looking to see if our study approach is helpful and how can we make it work better for you and other residents in Baltimore City public housing.

Are there any investigational drugs/devices/procedures?
We are using 2 classes of medications to help you quit smoking. The first type is nicotine replacement therapy which may come in 3 forms: gum, lozenge and/or skin patch. The second type is a type of oral medication that helps get rid of the urge or craving to smoke and is called Chantix. Chantix is not a nicotine replacement therapy.

The use of nicotine replacement therapy (gum, lozenge and/or patch) and Chantix is approved by the Food and Drug Administration (FDA) for the treatment of nicotine addiction. All the medications are approved for the use as smoking cessation aids.

Who can join this study?
Any adult resident at Douglass or Brooklyn Homes who is 18 years of age or older, and self-report they are daily or weekly users of cigarettes may join. We also require you have a working cell phone number and active health insurance, since both are needed to access all parts of our project.

You **cannot** join this study if you are pregnant or breastfeeding, or are already enrolled in a tobacco cessation program.

How many people will be in this study?
We will enroll a maximum of 60 participants in the study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- Commit to a 4-week study that will be administered both in-person at your housing site and remotely. Remote study visits will occur by either a video conference call or standard audio phone call. We expect sessions may last from 10-20 minutes. At each session, the following 2 things will be discussed:
    - Drug education, proper drug usage and side-effect monitoring of a 4-week supply of nicotine medications that will be delivered to your home address prior to starting the first study visit. Prescribed fast-acting medications help you with your immediate nicotine cravings. The prescribed long acting medication help you with the constant feeling that makes you feel like you must smoke. You must be prescribed both medications to be a part of the study

  - Motivational counseling to help you quit or reduce smoking
- At the last session, you will not be offered any further medications or counseling to help you reduce smoking, but we will give you the contact information of programs and clinics that can provide further smoking cessation care.
- As part of the study, we will be texting you every week to remind you of the dates and times of the study visits. We may text you more frequently in the first 2 weeks of the study if we prescribe you a drug called Chantix.
- Complete a questionnaire each week that will ask you questions about your cigarette smoking behaviors.

Will research test results be shared with you?
There are no research tests being conducted on you during your participation in this study.

How long will you be in the study?
You will be in this study for up to 6 weeks, 4 of which will be in the smoking cessation program.

4. What happens to data that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data we collect about you are important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?
Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:
- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB), a group of people that reviews human research studies, is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

The use of your data is required for participation in this research study. If you are not comfortable with the use of your data in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

This study requires taking 2 types of tobacco cessation medications. One type is called nicotine replacement therapy and comes in the form of gums, patches or lozenges. The other type is non-nicotine

tobacco cessation therapy that comes in the form of a medication called Chantix. The gum or lozenge helps you with sudden cravings you might experience when you reduce or quit smoking. The patch or Chantix helps block the pleasant effects of nicotine on the brain, which can help break the addiction cycle.

The medications being prescribed to help you quit smoking may result in side-effects.

The following is the list of potential adverse events of the two types of nicotine replacement therapy that may be prescribed to you:

Medications	**Adverse reactions**
NicoDerm® CQ®	Skin irritation, dizziness, nausea, vomiting, diarrhea, headaches, rash, abnormal heart beat (fast heart rate or palpitations, difficulty breathing
Nicorette® Gum and Nicorette® Lozenge	nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, vomiting, rash, hypersensitivity reactions, sleep walking, accidental injury, interactions with alcohol, seizures, changes in mood, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, or suicidal ideation, mouth ulcers, jaw muscle aches, dizziness, hiccups, headache, dyspnea or difficulty breathing, abnormal heart beat (tachycardia, arrhythmias or palpitations)

The following is the list of common adverse effects (>5% and twice the rate seen in placebo-treated patients) Chantix®, a non-nicotine replacement therapy that may be prescribed to you during the study:

Medication	**Adverse reactions**
Chantix®	Nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting

The following are additional warnings and precautions for Chantix®:

Medication	**Warnings and precautions**
Chantix®	• Neuropsychiatric Adverse Events: Changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. • Seizures: New or worsening seizures have been observed in patients taking Chantix®. • Interaction with Alcohol: Increased effects of alcohol have been reported • Accidental Injury: Accidental injuries (e.g., traffic accidents) have been reported. • Cardiovascular Events: Patients with underlying cardiovascular disease may be at increased risk of CV events. These concerns must be balanced with the health benefits of smoking cessation. • Somnambulism: Cases of somnambulism have been reported in patients taking Chantix®. • Angioedema and Hypersensitivity Reactions: Such reactions that have been reported are infrequently life-threatening, • Serious Skin Reactions: Rare, potentially life-threatening skin reactions have been reported. • Nausea: Nausea is the most common adverse reaction

We will review the package insert of this list of common and rare side-effects of medications. All medications are FDA approved as a tobacco cessation aid. We will also provide you with a phone number to contact our research team at any time to review side-effects or concerns about the medications. We will review your concerns with our tobacco cessation medical specialists. Those specialists may also contact you if they have further questions or concerns. If our medical specialists believe that a medication should be discontinued, we will try to find an alternative tobacco cessation medication that can be used.

If our medication specialists believe that both tobacco cessation medications should be stopped, you will be withdrawn from the study. Upon withdrawal, we will provide you with contact information of local resources who can better help you quit smoking. We will also contact you at the end of the study to get your opinions about our study.

Interviews or questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

6. Are there risks related to pregnancy?

We will not enroll anyone who is pregnant or trying to get pregnant during the study. The American College of Obstetricians and Gynecologists believe that these medications have not been adequately studied in pregnant women. They believe these products should be prescribed and supervised directly by a healthcare professional.

7. Are there benefits to being in the study?

Reducing or quitting smoking is one of the best things you do for your health and your family's health. You may or may not benefit from being in this study.

If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?

You do not have to join this study. Other options to help you reduce or quit smoking include:

- Call the Maryland Tobacco Quitline (1-800-QUIT-NOW). This is a free service for Marylanders and sponsored by the Maryland Department of Health.
- Call for an appointment at the Tobacco Treatment Clinic at Bayview Medical Center.
- Call your primary care healthcare provider for recommendations.

If you do not join, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

It will not cost you anything to be in this study. Our study will first try to use vouchers to pay for any co-pays or deductibles not covered by your insurance. If necessary, our study team will assist in payment of co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

You will be reimbursed $15 for your completion of participation in the study.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Our medical specialists believe that we should discontinue both types of tobacco cessation medication aids.
- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant or thinking of becoming pregnant
- You started breastfeeding
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors,

outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
All data will be stored in a secure online system that are password-protected. Data that includes any identifiable information will only be shared among the Johns Hopkins University-based research team using this secure online format. Only the Johns Hopkins University research team will be able to access the password-protected data. All data will be accessed and analyzed on password-protected computers using the secure online software and storage systems.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study.

However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, Panagis Galiatsatos at 410-955-3467. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Panagis Galiatsatos at 410-955-3467during regular office hours and at his pager 410-283-3117 after hours and on weekends. If using the pager, after the tone, enter the phone number where you can be called, press the # key, and hang up. If this doctor is not available, the operator will page the "on call physician."

16. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).