Institutional Review Board
3600 Civic Center Blvd., 9th Floor
Philadelphia, PA 19104
Phone: 215-573-2540
(Federalwide Assurance # 00004028)

DATE:	01-Dec-2023
TO:	Farouk Dako
CC:	Rosen, Caroline M Thomas, Kathleen
RE:	
IRB PROTOCOL#:	852598
PROTOCOL TITLE:	Community Support Program for Lung Cancer Screening Abstract
SPONSOR:	NO SPONSOR NUMBER
REVIEW BOARD:	IRB #8

IRB AMENDMENT: NOTICE OF APPROVAL

Dear Dr. Dako,

The documents noted below, for the above-referenced protocol, were reviewed by the Institutional Review Board using the expedited procedure set forth in 45 CFR 46.110 and approved on 30-Nov-2023.

Consistent with the regulations set forth in 45 CFR 46.109(f), continuing review of this research is not required. IRB approval of this protocol will not expire and continuing review applications should not be submitted. However, you are still required to submit modifications and reportable events to the IRB for review.

The documents included with the application noted below are approved:

-HSERA Modification, confirmation code djhdcffi, submitted 11/1/2023

ONGOING REQUIREMENTS:

- You must obtain IRB review and approval under 45 CFR 46 if you make any changes to the protocol, consent form, or any other study documents subject to IRB review requirements. Implementation of any changes cannot occur until IRB approval has been given.
- Reportable event, such as serious adverse events, deviations, potential unanticipated problems, and reports of non-compliance must be reported to the IRB in accordance with Penn IRB SOP RR 404.
- When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

COMMITTEE APPROVALS: You are responsible for assuring and maintaining other relevant committee approvals. This human subjects research protocol should not commence until all relevant committee approvals have been obtained.

If your study is funded by an external agency, please retain this letter as documentation of the IRB's determination regarding your proposal.

If you have any questions about the information in this letter, please contact the IRB administrative staff. A full listing of staff members and contact information can be found on our website: http://www.irb.upenn.edu

***This letter constitutes official University of Pennsylvania IRB correspondence. ***

UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Screening:
Community Support Program for Lung Cancer Screening

Principal Investigator:
Farouk, Dako
3400 Spruce Street HUP Cardio
Philly, PA 19104-0000
267-309-1241

Emergency Contact:
Ask for doctor on call
215-662-4000

Research Study Summary for Potential Participants:
You are being invited to participate in a research study. Your participation is voluntary. You should only participate if you understand the requirements and risks. You should ask the study team any questions you have before joining the study. If you have any questions, please contact the Institutional Review Board (IRB). The IRB phone number is 215-898-2614.

The research study aims to create a program for lung cancer screening attendance. We will work with community partners to help patients attend their screenings. We hope to improve attendance to LCS follow-up guidelines.

Why am I being asked to volunteer?
Eligibility Criteria to Join the Study:

- You have an upcoming or missed follow-up LDCT (low dose CT).
- You are a Philly resident.
- You are between 18-89 years' old.

If you join the study:

- A community support program rep. (CSPR) will contact you. They will contact you through My Penn Medicine. They will also call, text, message, or email.
- The CSPR will help you with travel and the appointment. We will record your appointment date, your zip code, and appointment attendance.
- We will use Lyft to provide rides from your home to and from your appointment. Ride vouchers will have a limit of $30, which we expect to cover the round trip.
- The CSPR can arrange Lyft travel for you.
- The study team might contact you after your screening to answer a survey. The survey is designed to improve the study. The survey is an optional part of the study. You do not have to answer any questions to participate.

Your involvement will last for 6 months.

We plan to open the study April 2023 and recruit for 12 months.
Study participants will stay enrolled until after their scheduled appointment.

You will get financial support for travel arrangements to your appointment. The long term benefit is improving lung cancer screening awareness. There are minimal risks to joining the study.

If you want to participate, we will review the full information with you. You are free to say no or leave the study any time.

Your doctor may work in this research study. You do not have to participate. There are no issues if you don't want to participate. Being in a research study is different from being a patient. Your doctor cares about your health and the study.

What is the purpose of this research study?

- This project aims to improve attendance to follow-up appointments. This project will work with community partners to help patient attendance.

How long will I be in the study?

- You would stay enrolled until after your appointment.
- The study is expected to last twelve months.

How many other people will be in the study?

- Penn researchers plan to enroll between 450-600 patients.

What are the possible risks or discomforts?

- The study is minimal risk.
- The research may involve unknown risks but this is unlikely.

What if new information becomes available about this study?

- We may find more information that could be important to you. This includes information that might cause you to chance your mind about the study. We will let you know if such information becomes available.

What are the possible benefits of the study?

- You will receive education and funded travel.
- Long-term community benefits in lung cancer screening education.

What other choices do I have if I do not participate?

- You do not have to participate. You will have your scheduled lung cancer screening appointment.

Will I get paid for being in this study?

- You will get a Lyft voucher for $30 to cover the ride to and from your appointment. The mean roundtrip cost for an appointment is $22.
- The CSPR can arrange your Lyft at no additional cost.

- To give you the voucher, we will need your Social Security Number. Penn has to report payments over $600 to the IRS.

Will I have to pay for anything?

- You will pay any deductibles or co-pays based on your insurance. These charges are for routine office visits, scans, and blood work. Please talk to your doctor about out-of-pocket cost questions.

When is the study over? Can I leave the study before it ends?

- You may withdraw from the study at any time.
- This study ends when all screenings passed and all information has been collected. This study can end at any time. You will know if the study ends early and why.
- You can leave the study at any time by contacting the PI. Leaving will not affect your medical care. It is important to tell the doctor if you want to leave the study. A final study visit may be requested to ensure your safety.

How will Penn protect my personal information during the study?

- We aim to keep personal information collected for research private. We cannot guarantee total privacy. We may have to give out personal information if required by law. We will not publish your name or other personal information. The IRB at Penn will have access to your records.

Here's how Penn will protect your information during the study:

- Password protected computer-based files.
- Files accessible only to staff on study.
- Information stored in RedCap database using a study ID number.
- Separate log with name, medical record number, and contact information.
- List with study ID number, date of appointment, and zip code.
- Survey responses will use study ID numbers only.

Will information about this study be available to the public?

- Study information will not be public.

What might happen to my information on this study?

Future use of data:

- We will not save, store, or share your information for future research.

Electronic Medical Record and Study related information

What is an Electronic Medical Record (EMR)?

An EMR is your medical chart in electronic form.
If you don't have an EMR, Penn will make one for you. The study requires all participants to have an EMR. Making an EMR requires information like name, insurance type, doctor's name, etc. If you are a current or past patient at Penn then you have an EMR.

What can be in the EMR?
Information related to your involvement in the research E.G., lab tests, doctor notes, images, procedures, etc. will be in your EMR.
Some Penn staff outside research can access your EMR. Health insurance, benefit providers, etc. may have access if needed.

Penn may share information through health information exchanges (HIES). HIES share parts of your EMR with healthcare systems involved in your care. HIES aims to improve the quality and safety and of your healthcare. If you don't want your information shared through HIES, please call 215-662-4484.

Will I have access to research related information in the EMR?
Patients access to their EMR. You will have access to study information through MPM. We will collect demographic information and appointment attendance. You will see the results of your scan in your EMR.

Will I see research results relevant to my health?
- We are only collecting data on appointment attendance. You will not see research results from this study relevant to your health.
- You will receive the results of your screening via Penn Medicine.

What information about me can Penn collect, use, or share?
- Name
- Gender
- Social Security Number
- Street address, city, county, precinct, zip code, and equivalent geocodes
- Telephone number
- Electronic mail addresses
- Appointment attendance
- Survey responses

Why is Penn using my information?
The research team uses your information to contact you during the study. Penn uses your information and results of tests and procedures to:
- Do the research
- Oversee the research
- Evaluate research accuracy
- Evaluate and manage research functions

Who may use and share information about me?
These people may use or share your information for the research study:
- Dr. Farouk Dako, PI
- Kathleen Thomas, Director of Research Operations
- Caroline Rosen, Patient Navigator

- Debra Whorms, Resident
- Monica Matsumoto, Resident
- Nadira Gray, Community Support Program Rep

Who, outside Penn Medicine, might see my information?

- RSNA, Funding Sponsor
- U.S. Office of Human Research Protections (OHRP) (Oversight Group)

Once Penn shares health information to outside groups, protections may not apply. Protections come from federal privacy regulations.
The PI or staff will tell you if the list above changes. Added groups must follow Penn's privacy rules.

How long may Penn Medicine use or disclose my personal health information?
Your approval for use of your health information for this study doesn't expire.
Penn cannot re-use information collected in this study unless:

- You have given written approval
- Penn's IRB gives permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
You may withdraw permission at any time. You would need to send written notice to the PI for the study. If you withdraw permission, you will not be able to stay in this study.

What if I don't give permission to use and give out my health information?
You will not be able to be in this research study. You will get a copy of this document.

If you choose to participate:
You allow Penn to use and share your personal health information. This information is limited to what we collect for research.

Who can I call with questions or concerns?
If you have questions you should speak with the PI. You may contact the IRB as well (phone number on page one of this form). If you say you consent, you are agreeing to take part in this research study.
Your consent means:

- You read this form.
- You have no unanswered questions, and you want to volunteer.
- You allow Penn to use health information collected during the study.
- You allow Penn to share collected health information to outside groups.

You will receive a copy of this consent form.