Official Title: A Pragmatic Randomized-Controlled Trial of a Digital Outreach Intervention for Lung Cancer Screening: mPATH-Lung (mobile Patient Technology for Health-Lung)

NCT04083859

IRB Approval Date: 11/28/2023

A DIGITAL OUTREACH INTERVENTION FOR LUNG CANCER SCREENING (MPATH-LUNG):
PROVIDER INTERVIEWS

Research Interview Study Information Sheet

David P. Miller, MD, MS, Principal Investigator

SUMMARY

You are being asked to participate in a research interview. Your participation is voluntary. You do not have to be a part of this interview if you do not want to. There is no penalty for choosing not to participate. You are being asked to participate because you previously completed a survey about your opinions of the mPATH-Lung program. About 24 primary care providers will participate in an interview (12 providers from Wake Forest Baptist Health, and 12 providers from outside Wake Forest Baptist Health). We are conducting this study because we want to learn how to help people decide if lung cancer screening is right for them.

Participation in this study will involve one virtual interview that will last no more than 30 minutes. An interviewer will ask you questions about what you think of the mPATH-Lung program. We want to understand what factors make you think mPATH-Lung is helpful or not helpful.

The interview will be recorded for later analysis by the study team. You understand that you will not be able to inspect, review, or approve the recordings before they are used in this study. The recordings will be destroyed once their use in this study is finished. Your participation is voluntary, and you may choose to stop participating at any time without penalty.

WHAT ARE THE RISKS OF THE STUDY?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests.

There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $50 gift card as a thank- you for your time.

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Drs. David Miller and Ajay Dharod are the developers of the mPATH™ application. Drs. Miller, Dharod, and Wake Forest University Health Sciences have an ownership interest in the application and may financially benefit from futures sales of the application related to this study. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. We want to protect your privacy, so we will not use your name or any identifying information in any report we might publish.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law pertaining to risk of harm to self or others.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my health

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information as described in this consent and authorization form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The person in charge of this study is David P. Miller, MD, MS. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study he may be contacted at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

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