Official Title: ONC-LUN-2406: User-Centered Design of a COPD Care Pathway for Patients With Cancer
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MIXED-METHODS IMPLEMENTATION OF A COPD CARE PATHWAY AMONG PATIENTS WITH CANCER

Study Information Sheet

Thomas Lycan, Jr., DO, Principal Investigator

## SUMMARY

Our research team invites you to participate in a research study. The purpose of this research is to develop a care plan for patients with Chronic Obstructive Pulmonary Disease (COPD). You are invited to be in this study because you have cancer or are a medical provider who treats COPD or cancer. All participants in this study will be asked for their opinions on care of COPD and cancer. Your participation in this research will involve one survey which will take about 10 to 20 minutes to complete. In addition, you may be asked to participate in an interview, focus group, or a tour of an oncology clinic, each of which will take between 15 to 90 minutes. Interviews, focus groups, and tours may be audio and/or video recorded. All research studies involve some risks. Some people might find answering questions about COPD management or cancer care uncomfortable. However, we do not expect the risk of harm or discomfort from participating in this research will be more than in daily life. We do not anticipate that you will receive any direct benefit from participation in this study. However, your participation may help improve the management and care of COPD and cancer for future patients.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Your alternative is not to participate. You will not lose any services, benefits, or rights you usually have if you choose not to participate.

If you are a student or an employee of Atrium Health or Wake Forest University School of Medicine, you do not have to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, assignments, employment, or medical benefits. If you have questions regarding your enrollment in the study and your status as a student or employee, please contact the research subject advocate for additional information.

The remainder of this form contains a complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is the Principal Investigator, Thomas Lycan, Jr., DO. If you have questions, suggestions, or concerns regarding this study or want to withdraw from the study, you can contact Thomas Lycan, Jr., DO, 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].

## INTRODUCTION

You are being asked to participate in a research survey. Your participation is voluntary. You do not have to participate in this survey if you do not want to. There is no penalty for choosing not to participate. You are being asked to join because you are a patient with cancer or are a medical provider.

## WHY IS THE STUDY BEING DONE?
This study is being done to help us improve our COPD care pathway so that it can be used to help patients with cancer who may also have COPD.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Around one hundred people will take part in this study at the Winston-Salem research site and its affiliated centers.

## WHAT ARE THE RISKS OF THE STUDY?
The risk of harm or discomfort that may happen due to participating in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. 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 access research records, will be made to keep your information safe.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
You are not expected to receive any direct benefit from participating in this research study. We hope the information learned from this study will benefit other people in the future.

## WHAT ARE THE COSTS?
There is no cost to participate in this study.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity or personal health information will not be disclosed unless authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required. For example, the Food and Drug Administration (FDA) may inspect research records and learn your identity if this study falls within its jurisdiction.

## WILL YOU BE PAID FOR PARTICIPATING?
You will be paid $25 if you complete all study surveys. You will be paid $50 if you participate in an interview, concept mapping, guided tour, or workshop.

## WHAT ABOUT MY HEALTH INFORMATION?
In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes demographic information (like age, gender, or race), information about managing COPD and cancer, responses to the survey questions, and notes from any interviews, tours, or workshops you participate in.

We will make every effort to keep your Protected Health Information private. We will store your Protected Health Information records in a locked office cabinet or on a password-protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This sharing of data is for reasons such as to

carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports, and to get approval for new products.

Some of the people, agencies, and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are helping with the research; central laboratories, reading centers, or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some people, agencies, and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. Other researchers may use this information. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If law or court order requires, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study maintained in the research records will be kept for at least six years after the study is finished. At that time, any research information not already in your medical record will either be destroyed or de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are finished.

You can tell Thomas Lycan, Jr., DO, that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

**Thomas Lycan, Jr., DO**
[redacted]

However, if you take away permission to use your Protected Health Information, you will not be able to be in the study any longer. We will stop collecting more information about you, but any already collected data can still be used for the research study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to participate or leave the study at any time. If you stop participating in the study, we encourage you to talk to the investigators or staff. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, you failed to follow instructions, or the entire study has been stopped. Information about you may be removed from the study data and used for future research or shared with other researchers without your additional consent.

By continuing, I agree to take part in this study. I authorize using and disclosing my health 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 participating in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution, or its agents from liability for negligence.