Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: A Combined Biomarker Model for Risk Stratification of Indeterminate Pulmonary Nodules A multicenter prospective observational study IRB#230365
Version Date: 6/13/2023

Part 1 of 2: MASTER CONSENT

NCT06074133

Name of participant: _____ Age: _____

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all study sites. Part 2 of the consent form is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the legal consent form and must be provided to you.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

We are attempting to develop a prediction model of lung nodule outcomes by combining a malignancy risk score, blood biomarkers, and your chest image. This combined model should reduce invasive procedures (nodule biopsy) for patients with benign disease and should help diagnose cancer earlier.

There will be about 100 people taking part in this pilot study at four different institutions: Vanderbilt University Medical Center (VUMC), Tennessee Valley Healthcare System (TVHS) Nashville, University of Colorado Hospital and VA Eastern Colorado Health Care System in Denver (Denver VAMC). Each site will enroll 25 participants.

If you decide to participate, we will meet with you for a baseline study visit (includes signing a research consent form, completing a questionnaire, and collecting a blood sample), 3-6 months after and once a year for next 2-5 years depending on your standard of care follow ups.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to participate in a research pilot study because you have been diagnosed with lung nodule(s).

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Blood collection

Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint.

Genetic material

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Grogan and his staff will have access to your PHI.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Risks that are not known:

Patients asked to participate in this study may have a serious disease. Because of your potential illness or the treatment, you may normally receive for your illness, you may have complications or side effects that may be serious or even life threatening. This may happen whether or not you participate in this study.

Good effects that might result from this study:

The research conducted on these samples may eventually lead to a better understanding of new ways to diagnose lung cancer through non-invasive biological and imaging markers. We do not expect you to benefit directly from being in this study.

Procedures to be followed:

You will be followed to make sure you are doing okay and to assess any medical results that can be associated with your health. Your de-identified samples, de-identified chest CT images and your clinical information may be made available to others to use for research. To protect your privacy, we will not release any protected health information (PHI). You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatment options, or how to prevent this and other health problems. Your samples may be used to make new products or

tests. These may have value and may be developed and owned by the study staff, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Questionnaire
We will complete a questionnaire asking about your contact information and relevant medical history information, such as smoking history, history of present illness, and past medical history.

Blood Collection
We will collect blood samples just for research at the time of your baseline study visit, 3-6 months after and once a year for next 2-5 years. Length of the follow up will depend on the type of lung nodule and your standard of care follow ups.
You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

You are being asked to give a sample of blood for genetic research. What we learn about you from this sample will not be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not request your genetic information that comes from this research.

A single blood sample of about 3 tablespoons (up to 40 ml) will be drawn from a vein in your arm using a needle. The blood sample is the source of your genetic material and blood proteins. If you are having blood drawn for other reasons, we will try to get our sample at the same time, so you do not have to have blood drawn more than once.

Medical Records
Your medical records will be reviewed, and the results of tests associated with your medical diagnosis and will be recorded for this study. This information is helpful in connecting the research results with medical findings. We will continue to follow the progress of your health to determine how the genetic markers predict your diagnosis.
We will also access your chest CT image done as a standard of care performed within 60 days of enrollment and any follow up chest CT image.

Study calendar

	Baseline Visit	3-6 Months	Every year f/u for up to 2 to 5 years
Eligibility form	X		
Consent	X		
Questionnaire	X	X	X
Research blood draw	X	X	X

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Clinical Trials Registry.
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
You will not receive results from participating in this research study.