

# Research Registry Information Sheet

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**Sponsor:** WellStar Health System

**Protocol Title:** Lung Screening Research Registry

**Principal Investigator:** Robert Hermann, M.D., F.A.C.P.

**Co-Investigators:** Vickie J. Beckler, R.N., Aaron Cann, M.D., Ph.D., William R. Mayfield, M.D., Alan R. Muster, M.D.

## Introduction and Purpose

You are being asked to be in a research registry that will collect and securely store data in a confidential cancer screening database because more research is needed to help define and identify risk factors. The information collected will be used to study:

- Cancer trends and outcomes in various at-risk populations
- Morphology and progression of lung and heart diseases including cancer over time
- Benefits of screening various at-risk populations

The National Lung Screening Trial (NLST) was limited only to those smokers between the ages of 55-74 with a 30 pack year smoking history or had quit within the past 15 years, yet tens of thousands of people continue to die each year from lung cancer that fall outside these criteria. Large portions of the population remain at risk and are currently being denied access to the only proven method for early detection. Since more research is needed to determine if people outside these criteria would benefit from screening, WellStar has sponsored this lung screening Research Registry. All screening participants are encouraged to participate.

## What will my participation in the Research Registry involve and what information will be collected?

Your participation involves allowing us to maintain the information that is collected from the Lung Cancer Screening History Assessment that you complete today and the results of your screening CT exam(s) in a special database specifically created for research. In the event a lung cancer is suspected or diagnosed, information about any follow-up procedures, treatment, or care may also be collected. This information may include results from laboratory tests and diagnostic procedures or treatment plans to include chemotherapy or radiation. This information may be collected until closure of the Research Registry or your withdrawal from the registry. Your personal identifying information would be removed prior to being used for any research.

## Who can see my information?

Only the Principal Investigator listed above and designated lung screening research registry staff may have access to your identifiable information. The research registry staff may share the information generated from this research with regulatory agencies such as the US Food and Drug Administration and Western Institutional Review Board. This information is shared so the research can be ethically conducted and properly monitored.

### **What are the risks, benefits and costs?**

There is minimal risk that someone might breach computer safeguards and access your information. The same security measures will be taken as with all WellStar medical records to protect your personal health information by:

- Limiting access to the Research Registry to only authorized WellStar research registry investigators and staff; and
- Requiring individually protected password access to the information.

You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this registry and future research projects. There is no cost to participate and we may contact you for future research studies for which you may be eligible. You will not receive any payment for participating in this research registry.

### **Is my participation voluntary?**

Participation is voluntary and you do not have to participate in the Research Registry. You will not be penalized or lose benefits if you decide to not participate. You may withdraw your participation at any time by writing or calling the Principal Investigator listed below; however, any information collected before you withdraw may still be used for research. Your part in this research registry may be stopped at any time by the Principal Investigator or the sponsor without your consent for any reason, including:

- If it is in your best interest; or
- Closure of the registry.

### **Who do I contact for questions or concerns?**

For questions about the research or to withdraw your participation, contact:

Robert Hermann, M.D.  
Principal Investigator  
522 North Ave  
Marietta, GA 30060  
678-594-4302

Vickie J. Beckler, R.N.  
Lung Screening Coordinator  
522 North Ave  
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For questions about your rights as a research subject, contact the Western Institutional Review Board (WIRB) at 1-800-562-4789. WIRB is a group of people who perform independent review of research.