

Participant Opt-Out Information Sheet

The Royal Melbourne Hospital



Title	Lung nodule and screening management program.
Project Number	2024.381
Principal Investigator	Dr Asha Bonney
Associate Investigator(s)	Dr Alistair Miller and A/Prof Renee Manser
Location	Royal Melbourne Hospital, VIC, Australia

Part 1 What does my participation involve?

1 Introduction

You are receiving this information sheet as your health care provider would like to refer to our program for assistance with your health care.

The lung nodule and screening management program is a new referral pathway to specialist lung nodule and lung cancer screening services at the Royal Melbourne Hospital. It has been designed to try and improve patient access to timely and appropriate care. It involves dedicated lung nodule and screening nurse and physician support providing expert advice to your treating clinician and facilitating review in our clinic at the Royal Melbourne Hospital if required for further assessment. As part of this project, we are collecting information patient's health information when referred to the program to better understand the need for this service and be able to improve the program. We are also collecting longer-term health information about lung nodules to gain a better understanding of their natural history and predictors of risk for lung cancer.

The study is being sponsored by the Victorian Government and the Royal Melbourne Hospital Foundation.

Participation in this research is **voluntary**. If you decide you do not want to take part, you do not have to, and you can choose to "opt out". You will receive the best possible care whether or not you take part.

You will be automatically included in the lung nodule and screening management program, unless you decide to opt out.

You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

The lung nodule and screening management program aims to analyse all information entered into the database about everyone's lung nodules and imaging abnormalities to determine if the program is effective in improving timely access to care and uptake of lung cancer screening. We also aim to describe the frequency of lung nodules and subsequent investigations. This database will also enable the researchers at the Royal Melbourne Hospital to assess the quality of their lung nodule and screening management program and to implement strategies to improve it.

3 What does participation in this research involve?

If you are happy to have your health information included in the lung nodule and screening management program you do not have to do anything. Information relevant to your lung nodules and imaging abnormalities will be collected from your hospital medical record, your doctor or health care providers rooms and pathology laboratories and entered into a secure database. In some cases, a researcher / your clinical team may contact you by either phone, email or letter to record any missing information. This information will be used for future research purposes and may be shared with national and international collaborators. Personal and identifying information will not be shared with researchers outside of the Royal Melbourne Hospital. For some participants, annual follow up electronic or paper questionnaires may be collected for up to five years, with the potential for ongoing follow up every five to 10 years.

The study doctor and research staff will review your medical records and collect the following information about your lung nodule and imaging abnormalities if available:

- Your age, sex, ethnicity, smoking history, environmental exposures, health conditions, family history of lung cancer.
- Information about your lung nodule and imaging abnormality.
- Results from further investigations of lung nodules/imaging abnormality including final diagnosis and treatment.
- Follow up management of your lung nodule/imaging abnormality.

Participating in the lung nodule and screening management program will not require you to have any additional procedures or tests that are not clinically warranted. You will receive standard medical care for your condition.

There are no costs associated with participating in the Study and Database, nor will you be paid.

4. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the lung nodule and screening management program at any stage. If you decide to 'Opt-Out' the information contained in the lung nodule and screening management program will not be removed and will remain the property of the program unless requested to be removed from the database.

If you would prefer not to participate in the Study and Database, you will need to tell us by completing the "Opt-Out Form" on page 4. If we do not hear from you within two weeks, we will assume that you are happy for us to collect your information.

Your decision to take part or not to take part, or withdraw, will not affect your routine care, your relationship with your doctor or your care at the Royal Melbourne Hospital in any way.

5. What are the possible benefits of taking part?

While we intend that this research study furthers medical knowledge and may improve lung nodule and lung cancer screening outcomes in the future, it may not be of direct benefit to you.

6. What are the possible risks of taking part?

If you decide to opt-out later, all information entered into the lung nodule and screening management program will remain the property of the data custodian unless specifically requested to remove the information at the time of withdrawal.

7. What if I withdraw from this research project?

If you decide to withdraw from this research project, you will need to notify a member of the research team and you will need to complete the “Opt-Out Form” on page 4.

If you decide to leave the research project, the research team will not collect additional health information about you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the project.

8. What will happen to information about me?

Information collected about you for the lung nodule and screening program will be de-identified (e.g. all identifying information will be removed) and will be allocated a unique identifier. The database platform managed by Royal Melbourne Hospital and are accessible only by the lung nodule and screening management program researchers. Results from the study will be shared as publications in peer-reviewed journals as summary data for the cohort only (no individual data).

9. Future use of Data

The de-identified (coded) data collected in this project may also be used in future research studies. The results of this study and de-identified (coded) data may be shared in the future with national and international collaborators, however the use of the data will be subject to ethics approval.

10. Further Information and who can I contact?

When you have read this information, Dr Asha Bonney or a member of the research team will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 0455 409 806 or RMHlungnoduleandscreeningreferrals@mh.org.au.

This information sheet is for you to keep.

11. Ethics Approval and Complaints

This study has been approved by the Human Research Ethics Committee of the Royal Melbourne Hospital. Any person with concerns or complaints about the conduct of this study should contact the Director, Office for Research (Complaints Manager) on 03) 9342 8530 or email research@mh.org.au.

Opt-Out Form

Title Lung nodule and screening management program.
Project Number 2024.381
Principal Investigator Dr Asha Bonney
Associate Investigator(s) Dr Alistair Miller and A/Prof Renee Manser
Location Royal Melbourne Hospital, VIC, Australia

Please do not sign this form if you want to participate in the Study/Registry/Database

This form is only to be completed if you do not want your information to be collected for the Study/Registry/Database

Declaration by Participant

1. I do not wish to participate in the lung nodule and screening management program and I understand that my decision will not affect my future health care.
2. I have read the attached Participant Information Sheet.
3. I understand the purposes, procedures and risks of the research described in the project.
4. I have had an opportunity to ask questions and I am satisfied with the answers I have received.

Name of Participant (please print) _____

Signature _____ **Date** _____

Please return signed form to:
Dr Asha Bonney
RMHlungnoduleandscreeningreferrals@mh.org.au