

UH-CAN LUNG



A study to see whether urine collection at home could improve lung cancer screening programmes.

Participant Information Sheet

Study name: UH-CAN LUNG

Chief Investigator: Professor Simon Crabb

Sponsor Reference: RHM CAN1876 **IRAS:** 356831

You are being invited to take part in a research study called UH-CAN LUNG which involves:



Reading this information about the UH-CAN LUNG Study



Reading and signing a consent form



Answering 5 questions in a questionnaire



Sending a sample of urine to our study team (optional)

Summary

We would like to invite you to join the UH-CAN LUNG study. We are carrying out a study of 1,000 people who have declined an NHS Lung Cancer Screening (which used to be called the Targeted Lung Health Check) to see if there are more acceptable screening options for people who may be at risk of lung cancer. We want to find out if people find it easier to send a urine sample and questionnaire back to us in the post, and whether these urine samples would be good enough quality to test. **We are not testing the urine for signs of lung cancer in this study, we are only measuring the quality of the urine. This may mean that in the future, urine home testing could be used to find out if a person is at risk of a serious health condition, such as lung cancer.**

This study does not replace Lung Cancer Screening and is not able to diagnose cancer. We encourage you to book an appointment with the Lung Cancer Screening team by calling 023 8120 8883.

If anything you have read is not clear, or if you would like this information translated into a different language, please contact us at uhcan@soton.ac.uk or call 023 8059 8140.

The information below may help you decide whether to take part. Thank you for taking the time to consider being involved in the UH-CAN LUNG study.

What is UH-CAN LUNG?

The aim of the UH-CAN LUNG study is to explore if people find it acceptable to send a urine sample for testing to increase the early diagnosis of lung cancer, which can mean that treatments are more effective, and that patients are more likely to survive. We would also like to find out whether urine samples collected at home are good enough quality to be used in the future for cancer screening.

Why have I been invited?

Records show you have previously been invited to a Lung Cancer Screening but have not booked an appointment. There can be many reasons for this. We would like to find out if sending back a urine sample might be a better option to use for future lung cancer screening. **We will not find out any information about your health as part of this study.**

Do I have to take part?

No. Taking part is entirely your choice to help us find out if urine samples could be used to screen for cancer in the future. If you change your mind, you can tell us at any time. You do not have to give a reason and neither your medical care or legal rights would be affected.

What will I be asked to do if I join UH-CAN LUNG?

- **Read and sign a consent form** to confirm you agree to take part in UH CAN LUNG. You can ask for a copy to keep by calling 023 8059 8140 or emailing uhcan@soton.ac.uk.
- **Answering 5 questions.** Fill out the one-page questionnaire.

- **Provide a small sample of your urine.** Instructions on how to do this are included, as well as pre-paid shipping materials. You can return the questionnaire without providing a urine sample, but before you decide, please read the full information provided.
- **Return the consent form, questionnaire and urine to the study team.** We would appreciate it if you could send this within 4 weeks of receiving your invite. Please send the urine sample in the post as soon as possible after collecting it.

What samples are involved?

We are asking you to give a urine sample for UH-CAN LUNG. We have provided a collection kit with instructions and a prepaid label to return items to the study team.

What will you do with my sample?

Samples will be stored at the University of Southampton. Staff here are experts at storing samples securely using the unique number you have been given, they will not be stored under your name. We will divide the sample into smaller samples for storage. One part of the sample will be tested at the University of Southampton, to find out how diluted it is.

We are also working with a company called Elypta AB, who are based in Sweden. This company is developing a new test to measure signs of cancer in urine samples. They do this by measuring a component found in urine, called glycosaminoglycans. A second part of your sample will be sent to Elypta AB, not to check for cancer but to test if the urine is good quality, and to see if samples sent in this way are useable.

Are you testing for cancer?

No. The study is only looking to see if people will send in urine samples collected at home, and if these urine samples would be good enough quality for testing after being sent in the post. We are doing this for research purposes only. The urine testing will not tell us whether you have cancer, or are likely to be at risk of cancer, and therefore any results will not be shared with your doctors or affect your medical care.

Will you contact me again in the future?

No. You will not receive results from your sample, and we will not contact you again about the study. We will find out how many people invited to the study decide to book a Lung Cancer Screening appointment during the study, and whether people are told they should have a low-dose CT scan of their lungs. If you sign the consent form, we will also find out the results of this screening appointment. If you would prefer us not to know if you book an appointment, you can opt-out of this data being shared with us by emailing uhcan@soton.ac.uk or leaving a message on 023 8059 8140. You can also withdraw from data sharing by completing page 2 of the questionnaire, and returning this using the pre-paid postage. Please make sure to include your sticker with your unique code.

If you would like to contact the Lung Cancer Screening service directly to opt-out of your data being shared, you can call them on 023 8120 8883.

What are the possible benefits of taking part?

Joining UH-CAN LUNG is an act to help others. You will be giving your sample and time for free to help researchers improve lung cancer screening options. If urine home collection is shown to be effective, this may make it easier for people to take part in screening programmes in the future. This could lead to cancer being found earlier, when it is often easier to treat. Participating in this study will not benefit you directly, but it may act as a reminder to book an appointment for lung cancer screening, which we encourage you to do.

What are the possible risks of taking part?

There is very little risk in taking part. The device for collecting the urine sample is not invasive. It could be that you are be falsely re-assured that taking part in this study is screening for cancer. It is not. We would encourage you to still engage with Lung Cancer Screening by calling 023 8120 8883.

We take care to keep your data (or information) protected and your identity private, but in the unlikely event that there was a security breach, there is a small risk that someone could see or use the data we have about you. Please continue reading to find out how we keep your information safe.

Who is organising and funding the research?

University Hospital Southampton NHS Foundation Trust is the study Sponsor and is partnering with the Early Diagnosis team at the Southampton Clinical Trials Unit, a team of cancer researchers based at University Hospital Southampton NHS Trust. The study is funded by The Jon Moulton Charity Trust, a charity that supports clinical trials.

Who has reviewed and approved UH-CAN LUNG?

All research in the NHS is examined by an independent group called a research ethics committee, to protect participant interest. This study has been reviewed and supported by The Oxford A Research Ethics Committee, and the Health Research Authority's Confidentiality Advisory Group.

Members of the public are involved in the development and running of the UH-CAN LUNG study, and our documents are reviewed and approved by patients and the public.

What will happen to the results of the research study?

Once the study is complete a report will be written and the results will be published and presented at scientific meetings to make them available to the public. Your name and other personal information will not be used.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your name, NHS number and address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name, NHS number or contact details. Your data will have a code number instead.

University Hospital Southampton NHS Foundation Trust is the Sponsor of this research and is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Southampton Clinical Trials Unit, to coordinate the study
- University of Southampton Tissue Bank, to store the urine samples
- Biotechnology company, to analyse the urine samples

We will keep all information about you safe and secure in the following ways:

- We will protect your identity by using a unique code instead of identifiable information - you can see this code on the labels you have been sent.
- We will keep all information about you in a restricted database.
- Only necessary and trained research staff will have access to information.
- We will keep study data for a maximum of 15 years. It will then be fully anonymised and securely stored or destroyed.
- You can stop being part of the study at any time, without giving a reason and without your care or legal rights being affected.

We may share or provide access to data about you outside the UK for research related purposes to:

- Allow your urine sample, if provided, to be analysed

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. If your data is shared outside the UK, it will be with the following organisation:

- Elypta SE, a company in Sweden developing a urine test for cancer risk

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- The country your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>

- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK in the following ways:

- Our leaflet - www.hra.nhs.uk/patientdataandresearch
- By sending an email to uhcan@soton.ac.uk
- By contacting the study Sponsor's Data protection Officer at
 - email: dataprotection@uhs.nhs.uk
 - Telephone number: 023 8120 5079

Who can I contact if there is a problem?

If you have any questions or concerns, please contact the study team on uhcan@soton.ac.uk

If you remain unhappy or concerned and wish to make a formal complaint you can do this by contacting the Patients Advice and Liaison Service (PALS). PALS can provide confidential, impartial advice regarding concerns and complaints. PALS helps to improve the NHS by listening to your concerns and suggestions. You can reach the UHS PALS team via:

- Email: pals@uhs.nhs.uk
- Telephone: 023 8120 6325
- Post: Patient advice and liaison service (PALS), Mailpoint 81, Southampton General Hospital, Tremona Road, Southampton, SO16 6Y

Thank you for taking the time to read this information sheet. If you are happy to take part in the UH-CAN study please now sign the consent form and proceed to answering the questions, collecting your urine sample and posting all items back to us.

Please keep your copy of this information sheet.