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**MEDLEY: Methods of Early Detection of Lung CancEr in PrimarY Care**

# Participant Information Sheet and Informed Consent Document

A large-print version of this sheet is available on request.

## Study Summary

**Why am I being invited?**

We are inviting you to take part because you were referred from your GP for a chest X-ray. The reason your GP referred you was because you have symptoms that could be caused by lung cancer.

**What is the purpose of this study?**

We are looking to understand whether a low-dose CT scan should be used instead of chest X-ray to investigate symptoms of possible lung cancer.

**What will taking part involve?**

- You will receive a low-dose CT scan *and* a chest X-ray at hospital.
- You will still receive NHS usual standard care for anything these scans may find.
- Your original chest X-ray request set up by your GP will be cancelled.
- You will be asked to complete 2 questionnaires.
- We will check your medical records on 2 occasions to see how you are doing.
- Your care and diagnosis will not be slowed down by taking part in the study.
- You will be in the study for up to 12 months.

**Who is taking part?**

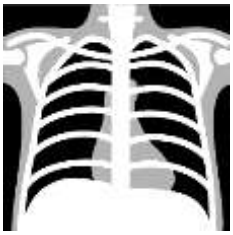
We are aiming for 900 people – all of whom have been referred for a chest X-ray – to take part from a minimum of 5 hospitals across the UK.

**What are the risks and benefits?**

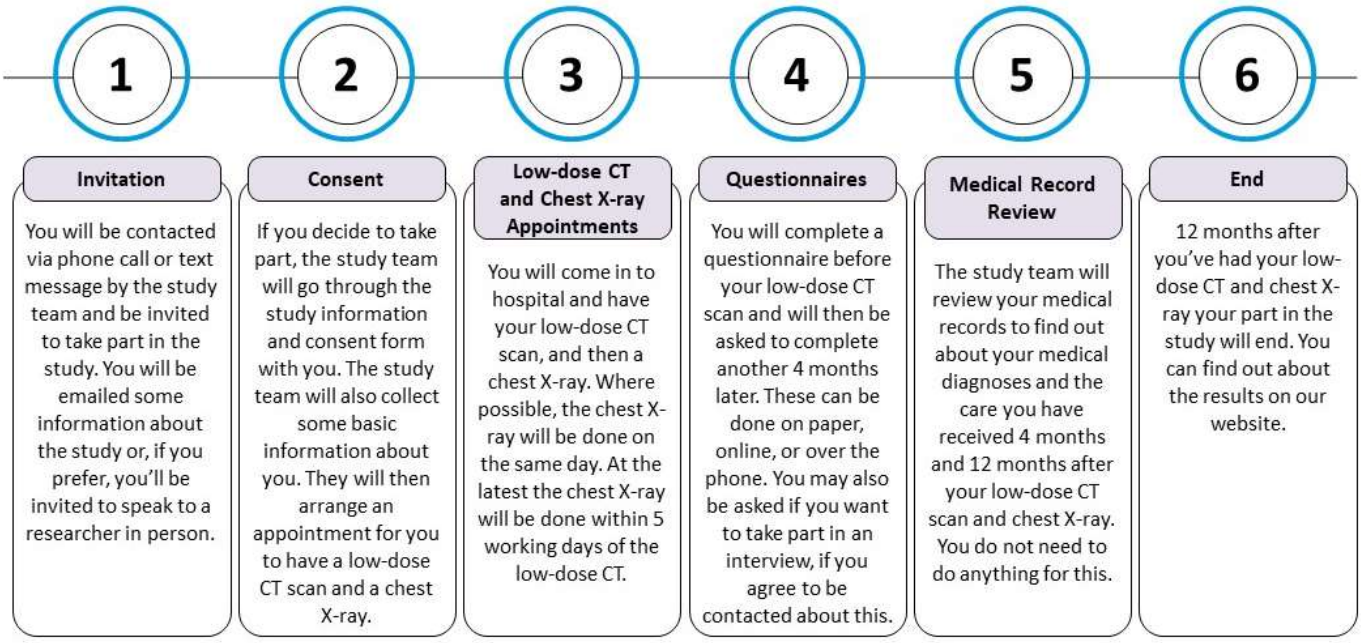
You will be offered a low-dose CT scan, which may detect problems that don't show up on a chest X-ray. By having this scan, you will be contributing to important research that could help detect lung cancer earlier, when it is more treatable. You will be exposed to slightly more radiation than standard care, and may have to have some extra tests and/or treatments depending on any findings of your scans.

**What if I change my mind?**

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. If you want to change your level of involvement, just let your doctor or nurse know. The standard of care you receive will not be affected. If you decide not to have either scan, you will need to re-arrange a chest X-ray with your GP.

| Chest X-ray | Low-dose CT |
|---|---|
|  |  |
| Takes a simple two-dimensional picture of the inside of the chest | Takes a three-dimensional picture of your chest by taking lots of individual X-ray pictures and putting them together |
| Involves standing in a special room in front of the machine while the radiographer takes the X-ray image | Involves lying flat on a table which slides through a round machine. Your head and legs will be outside the machine. |
| Takes 10-15 minutes | Takes 10-15 minutes |
| Uses radiation: about the same amount as someone would be exposed to in a few days from day-to-day background radiation | Uses radiation: about the same amount as someone would be exposed to in about half a year from day-to-day background radiation |
| | A low-dose CT scan exposes people to less radiation than a usual CT scan. Sometimes injections ('contrast') are used for a usual CT scan. These injections are not needed for low-dose CT scans |

# Study Timeline

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ctru University of Leeds

## Introduction

We would like to invite you to take part in a research study called "MEDLEY". Please take time to read this information carefully, and do discuss it with others if you like. Ask us if anything is unclear, or if you would like more information. Once you have read this information, a member of the research team will talk to you about the study again and you can ask any questions you like.

There is an optional appendix to read at the end of this information sheet. You do not have to look at it before making your decision, but you may find it useful or interesting to read.

## What is the purpose of the study?

Lung cancer is the third most common cancer in the UK, but the common symptoms of lung cancer, like a persistent cough, are common symptoms of lots of other conditions. So sometimes catching it early can be difficult. Detecting lung cancer earlier could lead to better outcomes for patients.

MEDLEY will help the health service to understand whether low-dose CT should be used instead of chest X-ray as the first-line investigation of symptoms of possible lung cancer. In the study, you will get a chest X-ray and a low-dose CT scan, whereas in normal NHS care you would just have a chest X-ray.

## Why have I been invited and who is taking part?

You have been invited to participate in this study as you have been referred from your GP for a chest X-ray. This is because you have symptoms that could be caused by lung cancer. Many of these symptoms are very common. The NHS does well over a million chest X-rays a year for people with symptoms like yours, but the chance that someone who is sent for a chest X-ray actually has lung cancer is only about 2%. We are aiming for 900 people from a minimum of 5 hospitals across the UK who have been referred for a chest X-ray to take part.

You do not have to take part: your participation in MEDLEY is completely voluntary. If you choose not to take part, your care won't be affected. You may withdraw your consent at any time, without giving a reason.

## What will be involved if I take part in the study?

If you agree to take part, you will have both a low-dose CT scan and a chest X-ray instead of going for just a chest X-ray. You would need to have the low-dose CT scan and chest X-ray preferably on the same day, or within 5 working days where this isn't possible. Your low-dose CT will be first. The study team will collect some basic information about you either over the telephone, or from your medical notes, before you come in for your scans (low-dose CT and chest-X ray), and they will ask you to complete a questionnaire, if you agree. Each scan takes around 10-15 minutes to complete.

A radiologist will then review your scans and the results will be reported back to your hospital (You will not need to come to hospital again because of the study). Then your hospital doctor will decide what, if any, further tests and/or treatment you will receive as a result of your scans. Some of these may be carried out at hospital or arranged by your GP. Any diagnoses and further care you receive would not take any longer to receive in the study than if you had chosen to not take part in the study.

**Follow up schedule:**

- We will ask you to complete a questionnaire 4 months after your scans if you choose to. This should take 5-10 minutes to complete. You can complete a copy on paper, online or over the telephone with a member of the research team. We will send you a reminder if we don't receive a completed questionnaire from you.
- The study team will collect data from your medical records after 4 and 12 months.
- You might be invited for an optional interview. If you agree to be contacted about this, we will explain what this entails when we get in touch. This is for selected patients only, so you may not be contacted about this even if you consent to be. Your information will be shared with researchers at Queen Mary University of London (part of our study team) if you consent to this. You can still take part in the study if you are not interested in being interviewed.

Your involvement in the research would be for a year. After 12 months, your involvement in the study will have ended and your care will not be affected.

Please let us know if any of your contact details change whilst you are taking part by contacting the research team via email at medley@leeds.ac.uk . If we lose touch with you, we will continue to send questionnaires and collect data from medical records, unless you tell us that you no longer want to receive questionnaires and/or have data collected. Data collected from you would still be made available for future research, unless you tell us that you do not wish for it to be shared. No one outside the original research team will be able to see who you are.

## What is a low-dose CT scan and a chest X-ray?

A chest X-ray and a low-dose CT scan are procedures that use radiation to produce images of your body, and in this case of your lungs. These are carried out at hospital by a healthcare professional. The images are checked by doctors and are used to diagnose cancers or pick up other possible problems. Currently, a chest X-ray is the standard test done for those who have symptoms of possible lung cancer. A low-dose CT scan gives more detailed images than a chest X-ray, so is better able to pick up some diseases The patient needs to lie flat for several minutes for the images to be taken, compared to a chest X-ray which takes an image immediately, with the patient standing in front of the machine. The chest X-ray takes a 2D image, and the low-dose CT creates a 3D image, which provides more detail. With a low-dose CT scan, the patient is exposed to a larger amount of radiation than with a chest X-ray, but for both tests the amount of radiation is very low and the benefit has been judged to outweigh the risk by a radiologist. You may have heard of a contrast CT, which requires an injection, or an MRI. For a low-dose CT, you will not need any injections and the scan is much quicker than an MRI.

## Who will see my low-dose CT and chest X-ray scans?

The images from your scans will be shared with a radiology image interpretation service (Heart&Lung Health) along with your name, date of birth, NHS number, and any other relevant medical history. These are NHS experts who will review your scans and report back to the research team. They will also

receive a copy of any relevant previous images and medical history. This is to help them get a better understanding of your condition over time, which will help them with their findings.

## What are the potential benefits of taking part?

By taking part in the research, you would be helping us learn whether low-dose CT should be used instead of chest X-ray as the first-line investigation of symptoms of possible lung cancer. Your participation will help us to answer this question, and help us improve the care of patients such as yourself in the future. We do not know if you will personally benefit from taking part in this research, but it is possible, in the unlikely event that you had a serious disease such as lung cancer:

- A low-dose CT scan could detect a lung cancer when it is smaller, and may not be visible on chest X-ray, and the avoidance of delay may result in better outcomes.
- A low-dose CT scan also may detect diseases not picked up on chest X-ray, which might result in earlier treatments and better outcomes.

Most participants will not have lung cancer, so the number of participants who could have better cancer outcomes is expected to be small.

## What are the potential disadvantages and risks?

We are asking you to give up some of your time to take part, but this should be minimal. The aim is to have both scans on the same hospital visit, and there will be £5 per patient available towards your travel.

There are some risks in taking part in this research compared with your usual care, so please make sure to discuss possible risks with the research team. These are:

- **More exposure to radiation –** exposure to radiation can itself cause problems, very rarely actually causing cancer. However, the amount of radiation for the LDCT scan is very small (approximately the same amount as found in the environment over 10 months) and the likelihood of dying of a cancer caused by the radiation is very low indeed (approximately 0.009% chance).

- **Having extra tests or treatments –** low-dose CT scans give more detailed images than chest X-rays. You could end up having tests and treatments for findings that may not have caused problems for you. This could include benign findings (non-cancerous) or cancers that would not have caused you harm. These extra tests or treatments may cause you to worry, and they also come with their own associated risks and potential harms.

## If I want to, will I definitely be able to take part?

The study team will have done some initial checks of your health records, but there is always a possibility you may not be suitable for the study. **For example, if you are pregnant or breastfeeding, please inform the research team, as you are not able to take part** because you cannot have a low-dose CT scan for this study. The researcher will talk to you about this, and may ask you to consent to a pregnancy test.

## What if I change my mind?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say, because this can be useful when we produce the results of the study.

Before deciding to stop, you should talk to a member of the study team. They can advise you and may be able to deal with any concerns you have. If you decide to stop taking part at any time, it will not affect the standard of care you receive.

If you decide not to come for both of the study scans, you will continue to receive usual care, but you must re-arrange to have a chest X-ray. You will have to get in contact with your GP to re-arrange this, because your original chest X-ray request will be cancelled when you consent to participate in this study. **It is really important to still have a chest X-ray**, because your GP was concerned about your symptoms, and you were invited to take part in the study because they were possible symptoms of lung cancer. You will be sent a letter to remind you to re-book your chest X-ray. If you withdraw from both scans, we will still send you questionnaires and collect information from your medical records, unless you tell us otherwise.

## What if I lose the ability to make my own decisions during the study?

If during the study your clinical care team determine that you have permanently lost the ability to make your own decisions, any information collected up until this point will remain on file and will be included in the analysis. We will not collect any new information from this point. If you have already completed your scans the outcome of the clinical review will be included in the analysis.

## What if something goes wrong?

Every care will be taken during this study. However, in the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available and you may have to pay your related legal costs. Your hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the study and the University of Leeds accepts no liability for negligence on the part of your hospital's employees. Any harm arising from the conduct of the research at NHS organisations is covered by the NHS indemnity scheme. If you wish to complain about any aspect of the way you have been treated, please contact your research doctor in the first instance. Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

## How will my information be used?

The Clinical Trials Research Unit at University of Leeds (https://ctru.leeds.ac.uk/), will need to use information from you and from your medical records for this research project.

This information will include your

- Initials

- NHS number/CHI (Community Health Index) number (relevant in Scotland only)
- Name and date of birth
- Contact details (address, telephone number, email address) – if you receive a text or email from us, it will have MEDLEY as the sender ID.

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 or contact details. Your data will have a code number instead.

University of Leeds is the Sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- The research team at your hospital will enter most of the information needed for the study directly into the University of Leeds secure study database. They may also send some information by post.
- Sometimes we will also get information about you by email. Emails will never contain your name, only your study identifying number and sometimes your initials and date of birth.
- Finally, some particularly sensitive documents will be sent to us via a 'secure file transfer'. This means information is sent by the internet in a very secure way. This will include your completed consent form, so that we can be sure you have agreed to take part in the study.
- Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

We may share data about you outside the UK for other research projects. 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 only be with recognised research organisations.

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;

- 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 we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for the minimum period of time required by laws and other rules about research. These say it must be possible to check the results of the research for a period of time after it has finished. This means we will need to keep your identifiable information until at least X years after the research has finished. The study data will then be securely archived or destroyed.

Your GP, and the other doctors involved in your healthcare, will be informed of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.

Your questionnaire responses and some information about you, and the tests and treatments you have, will be shared with members of the study team at the University of Exeter. You will not be personally identifiable. This is to help them work out if replacing chest X-rays with low-dose CT scans could be good value for money for the NHS.

**If you choose e-consent:**

If you are giving your consent electronically (using an electronic form during a telephone or video call) we will ask for your permission to enter your email address, date of birth, and initials into the eConsent system before you use it. This information is visible to the hospital research team and to members of staff at the CTRU, University of Leeds. If you agree to have your details added to the eConsent system but then decide you do not want to take part in the study, your details will be removed and securely destroyed within 30 days.

## What are my choices about how my information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your NHS records/hospital/your GP to help ensure the results of the study are valid. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

## Where can I find out more about how my information is used?

You can find out more about how we use your information in the following ways;

- our leaflet https://ctru.leeds.ac.uk/medley/ (Please feel free to ask for a printed copy of this if you cannot access this online version.)
- by asking one of the research team
- by sending an email to medley@leeds.ac.uk
- by ringing us on +44 (0)113 343 7641

- by contacting the University of Leeds Data Protection officer either via email to DPO@leeds.ac.uk or ringing them on +44 (0)113 343 7641

## What will happen to the results of the study?

When the study is complete, the results will be published in a medical journal. We will make sure you have a chance to find out the results of the research. You will still be able to have a copy of the research results if you stop taking part before the end. No individual participants will be identified in the results. Research like this can take years to complete. The results can take years to complete. You can stay in touch with our progress and find out the results of the study on our website https://ctru.leeds.ac.uk/medley/

## How to contact us

If you have any questions about this research, please talk to the study team at

<<Enter PI, nurse name >>

<< Contact details for site>>

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published various resources to help people learn more about research. Contact UKCRC: Tel: 0207 395 2271; email: info@ukcrc.org; website www.ukcrc.org. Further information about MEDLEY study is available at https://ctru.leeds.ac.uk/medley/

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| | |
|---|---|
| Participant ID: | Initials: |
| Date of Birth: | NHS/CHI (relevant in Scotland only)/Hospital Number: |
| ISRCTN: | Principal Investigator: |

# MEDLEY PARTICIPANT CONSENT FORM

***Please initial each box***

1. I confirm that I have read through the information about this research and have had the opportunity to ask questions. ☐
2. I understand that my participation in this research is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the study, the data collected from me will be used in analysing the results of the study. ☐
3. I understand if I do **not** have both a low-dose CT and a chest X-ray, I must re-arrange a chest X-ray myself with my GP as soon as possible. ☐
4. I understand that my healthcare records may be looked at by authorised individuals from the research team, regulatory bodies, or Sponsor to check that the research is being carried out correctly. ☐
5. I agree for my information to be shared with the provider of radiology interpretation services (Heart&Lung Health) (which will include name, date of birth, NHS number/CHI number (relevant in Scotland only), and relevant medical history including any previous scans). ☐
6. I understand that the information collected during this study will be shared with the study team at the University of Exeter. (You will not be personally identifiable). ☐
7. I understand that if during this study my clinical care team determine that I have permanently lost my ability to make my own decisions, no further study intervention will be given. I understand that data collected up until this point will remain on file and will be included in the analysis. ☐
8. I agree to a copy of this Consent Form being securely sent to the Leeds Clinical Trials Research Unit, which will show my full name, date of birth, NHS number/CHI number (relevant in Scotland only), and signature. (*note: signature is not applicable for telephone consent*). ☐
9. I agree that my GP, or any other doctor treating me, will be notified of my participation in this research. ☐
10. I agree to take part in the study. ☐

**The following points are OPTIONAL.**
Even if you agree to take part in this research, you do not have to agree to this section.

***Please initial Yes or No***

| | Yes | No |
|---|---|---|
| 11. I agree to complete questionnaires. I understand that my contact details will be passed to the CTRU so questionnaires can be sent to me. | ☐ | ☐ |
| 12. I agree that the information, including low-dose CT and chest X-ray images, collected during this study may be used to support other research in the future and may be shared with other researchers. (You will not be personally identifiable). | ☐ | ☐ |
| 13. I agree for my details (which will include my date of birth and NHS number) to be submitted to the relevant NHS databases via NHS England, so that information about my health status may be obtained by the Leeds Clinical Trials Research Unit if necessary. | ☐ | ☐ |
| 14. I am happy to be contacted by a member of the research team about taking part in a semi-structured interview. I understand that taking part in this is separate to the main study and is not mandatory. I understand my details will be shared with Queen Mary University of London. | ☐ | ☐ |

**Patient:**

Signature……

Name (block capitals)……

Date……

Please initial the box if consent was taken over the telephone. ☐

For telephone consent, the above details for the patient can be left blank.

**Investigator:**

I have explained the research to the above-named patient and they have indicated their willingness to participate.

Signature……

Name (block capitals)……

Date……

**Witness (for those unable to sign their own consent):**

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)