

(Please see visit [www.UKLS.org](http://www.UKLS.org) for trial questionnaires)

## **UKLS First Invitation Letter - the original approach to 250,000 individuals in the population**



Director of Public Health  
PCT

DATE

Dear (Name)

We are writing to ask you if you would be willing to help us in our research efforts in setting up a national screening program to screen for lung cancer. Lung cancer kills more people than any other cancer and is very difficult to treat as it is usually diagnosed in its late stages.

We are sorry if we are writing to you at a time when you may already be affected by this disease, however, your name has been chosen at random.

The purpose of this study is to determine whether screening will detect lung cancer at an earlier stage, when treatment is more effective and could therefore help prevent deaths from lung cancer. The Department of Health have given us a large grant for this study.

The study is called the UK Lung Cancer Screening Trial (UKLS). We need to involve 4,000 men and women, half of whom will be screened and the other half will have no screening. The screened group will have a special x-ray called a CT scan. If you are willing to help us, a computer will select the people and later on decide which group you could be in. The results will decide whether the NHS should start a screening programme for lung cancer, alongside those for cervical and breast cancer. Recruitment clinics are being held at Papworth Hospital near Cambridge and Liverpool Heart and Chest Hospital. You have been randomly selected from individuals aged 50 to 75 years of age from your local Primary Care Trusts. We would be grateful if you would read the enclosed UKLS fact sheet and then complete the 'UKLS Questionnaire' and return it in the enclosed envelope.

If the computer selects you to participate based on the questionnaire answers we will send you further information on the UKLS trial.

If you decide not to participate we would be grateful if you could complete the short questionnaire "Not wishing to participate in the UKLS" and return in the enclosed envelope. We will not contact you again. It will not affect your healthcare in any way if you do not take part.

We hope that you will want to take part in the study because it will help us find out if screening can prevent deaths from lung cancer

Yours sincerely,

Director of Public Health – (PCT)  
UKLS Contact Details

## **UKLS Patient Information Leaflet – enclosed with first invitation letter**

### **United Kingdom Lung Cancer Screening Trial (UKLS)**

**This fact sheet gives an overview of the trial. A more detailed information booklet will be sent if you decide to take part.**

#### **Why do we need a screening test for lung cancer?**

Lung cancer is the most common cause of death from cancer in the UK. The majority of people unfortunate enough to develop this cancer have few symptoms until it has spread outside the lungs. By this time it is difficult to treat and most cases are incurable. In contrast, treatment is more successful and the outlook is good for the small proportion of people diagnosed before the lung cancer has spread. If we are able to find lung cancer at this early stage through screening when treatment is more effective, then we could prevent people dying from lung cancer.

#### **What screening test is being used?**

We will be using a CT (computed tomography) scan. This is an x-ray of the chest.

#### **Am I eligible to take part?**

In order to be eligible to take part you must:

Be 50-75 years of age.

Not have had a previous diagnosis of lung cancer.

Not currently be taking part in any other screening programme for lung cancer.

#### **What does taking part involve?**

You will need to fill out the enclosed “UKLS Questionnaire” and return to us. A computer will look at your answers and may then select you to take part in the trial.

You will be sent a more detailed information booklet about the trial and an appointment to attend your local recruitment centre.

At the recruitment centre you will watch a DVD about the trial and then meet a research nurse. You will be asked to register for the trial and the nurse will then take a sample of blood, a mouth swab or wash and a nose brush. You will be given a pot to take home to send back to us with a deep cough sample.

A computer will decide whether you are to be in the group to be screened or not to be screened. The groups are chosen at random and are not dependent any information you give us.

If you are in the screening group you will be sent an appointment for a CT scan.

If you are not in the screening group you will not be required to attend any further appointments.

If an abnormality is found by your CT scan, you will be referred for further tests to an NHS specialist.

You may be asked to complete a number of health related questionnaires after you join the trial.

#### **How long will the study last?**

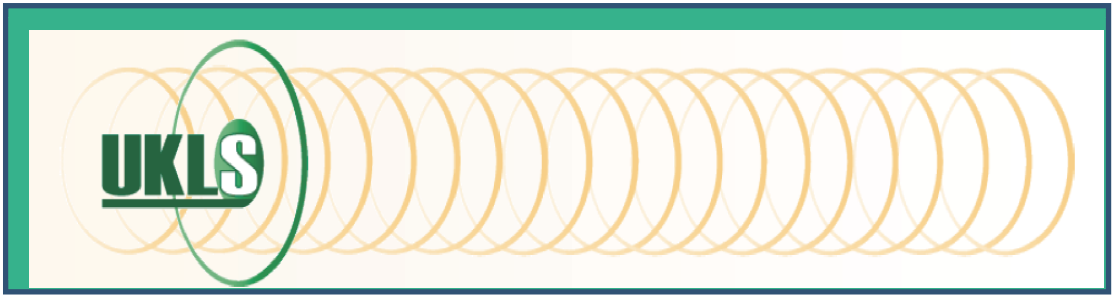
The study will take 10 years to complete. If you agree to take part you will be followed up for 10 years through your medical records.

**How do I take part?**

Please fill out the enclosed “UKLS Questionnaire” and return to us in the enclosed envelope. Thank you very much for taking the time to read this fact sheet. There will hopefully be a great benefit to future generations, both in prevention as well as early diagnosis and improved treatment of lung cancer.

UKLS Patient Information Booklet – sent to participants responding positively to the first invitation letter

UKLS Patient Information Booklet – a more detailed information booklet which was sent out with the second questionnaire once an individual had indicated they wanted to participate



# Lung cancer, screening and the UK Lung Cancer Screening (UKLS) trial

An information booklet for people thinking about taking part in the UKLS lung cancer screening trial.



Liverpool Heart and Chest Hospital   
NHS Foundation Trust



Papworth Hospital

Liverpool Heart and Chest Hospital

## **Invitation to take part in the UKLS Trial**

We would like to invite you to take part in a large national research project which we hope will benefit people at risk of developing lung cancer. Before you decide whether or not to take part, it is important for you to understand why the research is happening and what it will involve. Please take time to read this information booklet carefully and discuss it with your family and friends if you wish.

### **What is the aim of this booklet?**

This booklet tells you about lung cancer, lung cancer screening and how the trial will work. It aims to give you information that will help you choose whether or not you wish to take part in the UK Lung Cancer Screening (UKLS) trial.

### **What is lung cancer?**

Cancer develops when cells become abnormal and grow out of control. Over time they form a clump known as a tumour. Lung cancer develops in the tubes that carry air in and out of the lungs (your airways) or within the lung. It can then spread outside the lung to other parts of the body.

Lung cancer often develops slowly. It is thought that cells first become abnormal at least five years before the cancer can be detected. The reasons for this delay include:

- most tumours grow slowly
- the lungs are large
- the lungs do not feel pain
- some of the symptoms are similar to those of other lung problems such as bronchitis or chronic obstructive pulmonary disease (COPD).

By the time lung cancer is diagnosed, it has often spread outside the lung. If this happens, the cancer can only rarely be cured.

The UKLS aims to discover whether finding lung cancer at a very early stage means that it can be treated successfully.

## **Who is at risk of developing lung cancer?**

Anybody can develop lung cancer, but people who smoke (or used to smoke) are at the greatest risk. The risk increases with the total number of cigarettes you smoke. If you stop smoking, the risk gets less over time.

Passive smoking (breathing in someone else's tobacco smoke) over a long period of time may also cause lung cancer.

Non smokers may develop a particular type of lung cancer (called adenocarcinoma). This can happen in a part of the lung where damage has happened for a number of other reasons (such as breathing in asbestos).

## **What is lung cancer screening?**

Lung cancer screening uses an advanced x-ray technique, called computed tomography (CT) scanning, in order to find lung cancer before symptoms develop so that early treatment can remove the cancer and deaths from lung cancer may be prevented. More people die from lung cancer in the UK every year than from any other form of cancer. About 40,000 people develop lung cancer each year in the UK and many of these are smokers. However, non-smokers and ex-smokers can also develop lung cancer. Finding lung cancer by screening instead of symptoms may mean that treatment is more effective. Lung cancer screening aims to find changes in the lung at the time of the scan but it cannot prevent you from getting lung cancer in the future.

Only one randomised controlled screening trial (NLST)<sup>1</sup> so far has shown that screening by CT scanning is effective. The NLST trial has been recently published and was conducted in the USA. The results showed that the mortality from lung cancer was reduced by 20%. Thus it is likely that in the same population, CT screening is effective. However, populations differ and there are other questions that remain unanswered, regarding the integration of CT screening into a national programme and which patients benefit most. The unanswered questions led a group of experts from many countries to conclude that further trials (including UKLS) were

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<sup>1</sup> National Lung Cancer Screening Trial, USA

needed to answer these important questions and to guide the design of future screening programmes.

### **What is the lung cancer screening trial?**

The United Kingdom Lung Cancer Screening (UKLS) trial is a study of lung cancer screening in the UK. We aim to recruit 4,000 people in the first stage of the trial. If the results of our trial show that CT scanning of the lungs in healthy people is worthwhile then, in the future, CT scanning may be used throughout the country for lung cancer screening. This would be similar to the breast, cervical and bowel cancer screening programmes used today.

### **Why am I being invited to take part?**

You have provided details about your lifestyle and based on this information we would like to invite you to take part in the UKLS trial. We want to recruit people aged 50 to 75 years old. We have chosen this age group because we believe that if lung cancer screening is shown to be worthwhile, these are the people most likely to benefit.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information booklet to keep and asked to sign a consent form. You are still free to change your mind or withdraw from the trial at any time and without giving a reason. If you decide not to take part, we will not contact you again and the care you receive from your general practitioner (GP) will not be affected. We would, however, be grateful if you could fill out the attached questionnaire called 'UKLS non-participant questionnaire' and return it to us. This information is very important and will help us to plan future screening programmes.

### **What will happen to me if I take part?**

You have already been asked some basic questions about smoking, your lifestyle, occupation and known health problems. The next stage is an invitation to a recruitment clinic.

At the UKLS recruitment clinic, you will be met by the receptionist and invited to watch a DVD which will give you further information about the trial. You will then be met by a UKLS research nurse who will answer any questions you may have and will then ask you to sign a consent form. At this point you will be enrolled into the trial. You will then be asked some more detailed questions about your lifestyle and family history of disease. You will be asked to give your answers on a computer by touching the screen, which will greatly assist us in developing a better way of identifying individuals for lung cancer screening programmes. You will also be asked to blow into a tube a few times (lung function tests) to look at the health of your lungs. A member of the UKLS team will take a sample of blood, a mouth swab or wash and a nose brush. The nasal sampling has a very small risk of causing a nose bleed. You will be given a pot to take home so that you can return a deep cough sample, which will be explained to you at the recruitment visit. Finally, if you are a current smoker, you will be provided with information to help you stop smoking. Your visit to the recruitment clinic should take about an hour. Your GP will be informed that you are a participant in the UKLS trial.

To find out whether CT scanning of the lungs will be beneficial, we need to divide those who join our trial into two groups. Half of the people joining the trial will be offered a CT scan of their lungs and the other half will not. Both groups are equally important because we are going to observe what happens in each group. Then, at the end of the trial, we shall compare what happened to the group who were scanned to what happened to the group who weren't. To run the trial properly, people must be put into a group at random (using a computer), so neither you nor your doctor can choose which group you are put into. You will find out which group you are in about four weeks after you are enrolled.

In this trial we would also like to look at the effect of screening on the well-being of those who take part, so you will be asked from time to time to take part in surveys about your experience of the UKLS.

Regardless of whether you are in the screening or non-screening group, we will check on your health through your medical records over the next 10 years. If for any reason during the trial, you lose the capacity to consent, we will retain all the previously



collected data and specimens, however, we will not contact you again with any questionnaires or follow-up appointments.

### **What are lung function tests?**

Lung function tests (also known as pulmonary function tests) are used to look for the cause of breathing problems (like shortness of breath) and are also used to see how well treatments for breathing problems, such as asthma medicines, are working. They can be used to check for conditions such as asthma, lung tissue scarring, sarcoidosis, and COPD (chronic obstructive pulmonary disease). The tests may also be used to check whether a condition is getting worse.

Lung function tests measure:

- How much air you can take into your lungs. This amount is compared to that of other people your own age, height, and sex;
- How much air you blow out of your lungs and how fast you do it;
- How well your lungs deliver oxygen to your blood; and
- How strong your breathing muscles are.

### **What is the computed tomography (CT) scan?**

If you are part of the screening group, you will have a CT scan of your lungs. This scan of the chest uses x-rays and a computer to produce pictures of the lungs (it's also known as CAT scanning). During the CT scan you lie down on the scanner and hold your breath for a few seconds while pictures of your lungs are taken. Your appointment should take about 15-30 minutes. All of the CT scan pictures are stored in a computer and read by a radiologist. You will be told about the results of your scan by a clinical member of the UKLS team within four weeks of the scan. If no abnormalities are found, you will not need any further tests but we will contact you to fill out questionnaires so that we can find out about your future health and how you felt about being screened. If any important abnormalities are found you would be given an appointment to see a chest specialist at your local NHS hospital. The specialist may advise follow-up with another CT scan or other tests. If the lung specialist thinks you might have lung cancer, they will discuss treatment options with

you. Your GP will be kept informed of your participation in the UKLS trial and of all scan results and any treatment recommendations, and will be able to discuss them with you.

### **What are the possible side effects of CT scans?**

Because CT scanning uses x-rays to obtain pictures, you will be exposed to some radiation which you would otherwise not receive. However, the dose of x-rays used for the screening CT scan is less than you normally receive in a year from the natural surrounding environment and the risk of it causing harm is therefore very low. If an abnormality is detected, you may need follow-up CT scans and if lung cancer is strongly suspected, further tests will be required. The radiation dose for follow-up CT scans would be higher than for the first but the risk is still low and the benefits of detecting lung cancer at an early stage must be considered.

### **When do I get my CT results and what do they mean?**

You should receive a results letter from the UKLS trials team within four weeks of having your CT scan. There are three types of results that you could receive;

A **normal result** means no tumour or nodule was found. We expect that most people will receive a normal result. A normal result does not guarantee that you do not have or will never develop lung cancer in the future, so staying aware of any symptoms of lung cancer in the future is very important.

An **unclear result** means that your screening CT scan was not quite normal and further tests are needed. Getting an unclear result may not mean you have cancer, just that you will most likely need a follow-up CT scan. If you receive an unclear result you will be invited back to the hospital to have another CT scan. Most people will then receive a normal result.

An **abnormal result** means that the CT scan may have found signs of a cancerous nodule in your lungs. It is not a diagnosis of cancer, but it does mean that you will be offered a follow-up CT scan and other tests. Sometimes scans show other conditions that are not lung cancer but do require medical attention. If this is the case, your GP

will be informed and contact you to ensure the abnormality is dealt with appropriately.

### **What happens if my CT scan finds something?**

You will be cared for through the NHS and given an appointment with a lung cancer specialist doctor to discuss having a more detailed examination of your lungs. This will involve some further tests and the specialist team will explain what is required. If lung cancer is found, a doctor will discuss treatment options with you and your wishes will be taken into account. If you have to undergo any investigations or treatment procedures, we will collect any left-over tissue specimens for future research.

### **How reliable is lung cancer screening?**

In some cases lung cancer could be present but may not be found by CT scanning. Cancers in the main airways in the middle of the chest may be difficult to identify on CT and not all small cancers in the lung are recognised, even by the most skilled radiologists.

### **Are there any risks if I take part?**

Sometimes non-cancerous abnormalities are found by screening which you would otherwise have never known about. If you need an operation to remove a lung abnormality or need to have a lung biopsy any possible risks will be fully explained to you by an NHS specialist before the procedure is undertaken.

### **What are the possible benefits of taking part?**

As we do not know whether early diagnosis of lung cancer with CT scanning will be beneficial, it is not possible to tell you whether you are likely to benefit from entering the trial or not. Even if the trial is of no benefit to you personally because you have normal lungs it may benefit others taking part in the UKLS trial, as well as people in the future.

### **Where do I need to go?**

There are two centres taking part in the trial:

1. The Liverpool Heart & Chest Hospital NHS Foundation Trust, Thomas Drive, Liverpool, L14 3PE;
2. Papworth Hospital NHS Foundation Trust, Papworth Everard, Cambridge, CB23 3RE.

Both centres have dedicated rooms for the trial. When you arrive, you will be directed to a waiting room and met by the trial receptionist. If you attend the Papworth clinic, you might be offered screening in our on-site mobile screening unit.

If you provide evidence that you receive benefits, some support may be available to you for reasonable travel expenses.

### **What happens if new information becomes available during the trial?**

Sometimes during the course of a research study a new technique or new information becomes available which is relevant to the study. This is unlikely to happen in this trial because the type of CT scanner being used will be up-to-date and of high quality. However, should such a situation arise, the research nurse will tell you about it and discuss with you whether you wish to continue in the study or whether it would be in your best interests to withdraw.

### **What happens when the trial stops?**

Your records will be under the care of the trial centre for 20 years and your GP will continue your normal care during and after the trial.

### **What will happen to the results of the trial?**

The main results of this trial are not likely to be available for several years but early results relating to the number of lung cancers found by screening should be known after the first two years. Once carefully analysed, the results will be published in medical journals. If you would like a summary of the results as they become available please inform the research nurse at your trial centre.

### **Will my samples be used for any further research?**

If you agree to take part in this trial you will be asked to give a blood sample, a sample of spit, a mouth swab or wash and a nose brush. These samples will be stored at the University of Liverpool Biobank and will be used in future research projects with ethical approval. This may allow researchers to identify biological and genetic factors that affect the risk of future lung disease. This may be useful in developing future screening tests or in understanding more about the causes of lung cancer or other lung diseases. The UKLS research team will be responsible for keeping the samples safely and making sure that any information remains confidential. Results of any studies undertaken on your sample will not be fed back to you personally or placed in your medical records, as the tests are for research only. The research results will not have any implications for you personally. All future use of the samples will have to be approved by an Ethics Committee.

### **Will my taking part in the trial be kept confidential?**

If you consent to take part in this trial, your medical records and CT scan results may be inspected by authorised representatives within the trial and by the Department of Health regulatory authorities. Your name will not be disclosed outside the trial. You will not be identified in any publication or report of the trial.

### **What happens if something goes wrong?**

Your legal rights are not affected by giving your consent to take part in this trial.

### **Who is co-ordinating and funding the trial?**

The trial will be co-ordinated by the Liverpool Cancer Trials Unit (LCTU). It is funded by the Department of Health - Health Technology Agency.

### **Who has reviewed the trial?**

The trial has been reviewed by the Department of Health – Health Technology Agency, the Multi-Centre Research Ethics Committee (MREC) and by the Local Research Ethics Committees of the two centres involved.

### **I am a smoker but would like to stop smoking. Can I still take part?**

Yes and we would encourage you to stop smoking. Even if you stop smoking at any point in the future you are still able to take part in the trial. Just let us know the date you stopped smoking when you send back your next follow-up questionnaire. The UKLS team will provide you with NHS stop smoking materials or you can contact the NHS on 0800 022 4 332 or go to <http://smokefree.nhs.uk>.

### **Where can I get more information?**

Please feel free to telephone the research nurse on XXXX XXX XXXX in the UKLS

Project management office if you would like more information or have questions you would like to ask.

**More information about the trial can be found on the UKLS website [www.UKLS.org](http://www.UKLS.org)**

### **What should I do now?**

We hope that you are encouraged to join the trial. If you would like to take part, please return the enclosed 'UKLS participant questionnaire'. If however you decide not to take part, please fill in the 'UKLS non-participant questionnaire'.

*Thank you for reading this UKLS information booklet and we do hope you will want to participate in this very important Lung Cancer Screening Trial, which may prevent deaths from lung cancer.*