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Participant Information Sheet

1. Study title

An investigation into the molecular pathogenesis (cause) of lung disease

2. Invitation paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The project is concerned with the molecular causes of lung disease. To do this we need to be able to compare normal and abnormal lung tissue.

Lung diseases, such as emphysema and lung cancer, are a major cause of illness and death in the UK. We are interested in exploring the molecular pathways which underlie lung diseases. For example, it is hoped that by improving our understanding of the molecular changes which cause lung cancer, that newer, better ways of treatments will be devised.

The two major purposes of this study are to:

a) Establish a collection of normal and abnormal biopsies from the lungs of patients. These biopsies will be stored and molecular analysis will be performed on them.

b) Establish long term resources from biopsies of normal and abnormal lung. Normally biopsy samples do not survive for very long when cultured in the laboratory. We can get around this by using the biopsies to create something known as cell lines. Cell lines are made by altering biopsy samples in the laboratory in such a way as to ensure that the cells continue to survive, in theory, forever. This has a number of very important potential uses, including being able to define the molecular events involved in the development of lung disease.

4. Why have I been chosen?

You have been chosen because we are interested in patients:

a) who are undergoing bronchoscopy (telescope investigation of the lung) for the purposes of obtaining a biopsy;

We anticipate recruiting between 10 and 20 patients per year for this study.

5. Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

6. What is involved in the study?

a. What will happen to me if I take part?

This study will fit into your planned attendance at hospital for a bronchoscopy and you will not have an extra bronchoscopy for this study. The last page of this information sheet summarises what will happen in a flow chart.

If you take part, and you are having a bronchoscopy plus biopsy as part of your doctor's clinical management plan, then you will have one or two extra biopsies for the purposes of this study.

Most biopsies will be stored in a tissue bank for use in future laboratory experiments to investigate the molecular pathology of lung disease. In other cases the biopsies will be used to try to create cell lines as described in Section 3 b) above. You will be told before the procedure what the plan is for your biopsy.

All patients may be also be asked to give a blood sample for this study – approximately 15 mls or 3 teaspoons – and in some cases a sputum sample. The blood sample is so that we have a sample from you, which is not from the lung, to compare with the lung biopsies.

The sputum samples (if requested) will be used to compare results from lung biopsies with results from material (cells) spat up from the lungs in sputum.

No expenses will be paid.

7. What is the drug or procedure that is being tested?

Not applicable to this study.

8. What are known risks of the study or the side effects of any treatment received ?

If you are a bronchoscopy patient then you will already be having a biopsy as part of your bronchoscopy. As you will know, there is a very small risk associated with having a bronchoscopy. The risk of an extra biopsy for this study is difficult to estimate but will be very small. The most significant risk is of bleeding after a biopsy. You can expect to cough up small amounts of blood after a biopsy but if you bring up significant quantities or are concerned in any way you should contact the hospital as indicated on the hospital's information sheet for patients who have just had a bronchoscopy.

9. What are the possible benefits of taking part?

There will be no intended clinical benefit to you personally from taking part in the trial. It may be that research carried out on the samples you provide will help future patients.

10. The information held about the research subject

Some details will be collected about you including your age and sex, a record of your personal medical and drug history particularly with reference to lung disease, any relevant family history, your smoking history, lung function tests. Details of any lung disease including diagnosis, date of diagnosis, method of diagnosis, biopsy reports and clinical outcome may also be collected if applicable.

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address, date of birth and all identifiable information (including patient/hospital/NHS number) removed so that you cannot be recognised from it. University College London and University College Hospital will be the organisations involved in collecting the data. The principal investigator, Dr Sam Janes, will be responsible for safety and security of any data we collect.

If you are agreeable, we will notify your GP of your participation in this project. This is standard practice when the GP is not directly involved but is entirely at your discretion.

11. Studies on tissue

When a biopsy is taken as part of this study it is regarded as a donation as a gift and will be used in the future for investigations into the molecular changes underlying lung disease.

Any new research will be reviewed by a research ethics committee but consent for future studies may only be required if the committee considers that the study is likely to substantially effect the subjects interests.

12 Gene Studies

As part of the project we will be storing the samples taken to investigate genes and genetic pathways potentially involved in causing lung disease particularly lung cancer. As new genes or pathways are discovered we may also look at these in the future. This is one of the important reasons why we are creating an archive of biopsies of lung tissue.

There will be no attempt made to use your samples without your explicit consent to investigate any disorder, particularly any inherited disorder, other than lung disease.

Only the main investigators will be able to link your DNA to you. This type of data will not be shared with any external organisations.

13. What will happen if the findings may affect the subject personally?

The findings of this project will not affect you personally.

14. What if something goes wrong?

If anything goes wrong you will have a right to complain through the UCLH complaints procedure.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns of this study, the normal National Health Service complaints mechanisms should be available to you.

15) What will happen to the results of the research study?

The results of the research will be presented at national and international meetings and submitted to peer-reviewed journals for publication. We will be very happy to inform you at your request of any such publication. If you are one of the patients who we biopsy with a view to creating a cell line then we will be delighted to update you, again at your request, of the success or otherwise of the attempt to create a cell line.

You will not be identified in any report or publication

16. Who is organising and funding the research?

University College London NHS Trust are the sponsors of this research. The Medical Research Council are funding the research via a grant to the principal investigator.

Your doctor will not be paid for including you in this project.

The investigators are not paid for including you in this project.

17. Inducements

As with standard practice you will not be paid for entering this project.

18. Withdrawal from the project

Your participation in the trial is entirely voluntary. You are free to decline to enter or to withdraw from the study any time without having to give a reason. If you choose not to enter the trial, or to withdraw once entered, this will in no way affect your future medical care. All information regarding your medical records will be treated as strictly confidential and will only be used for medical purposes. Your medical records may be inspected by competent authorities and properly authorised persons, but if any information is released this will be done in a coded form so that confidentiality is strictly maintained. Participation in this study will in no way affect your legal rights.

It is important to be realise that any biopsy taken during the course of the study is treated as a gift and will remain in the custody of the principal investigator.

19. Who has reviewed the study?

This project has been reviewed and accepted by Committee A of the UCLH Regional Ethics Committee.

20. Contact for further information

Your first contact point for further information is the research nurse, Catherine Read. She can be contacted on 0207 3879300 Ext 4135, or by email catherine.read@uclh.nhs.uk.

We would like to take this opportunity to thank you very much for considering being a participant in this project.

You will be given a copy of this information sheet for your records.

Participants Undergoing Bronchoscopy