{To be printed on local hospital headed paper}

Cambridge University Hospitals NHS
NHS Foundation Trust

UNIVERSITY OF CAMBRIDGE

erica

evaluation of the
role of inflammation in
chronic airways disease

PATIENT INFORMATION SHEET & INFORMED CONSENT FORM

You are being invited to take part in a research study. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

We are interested in developing new biomarkers for Chronic Obstructive Pulmonary Disease (COPD). A biomarker is something we can measure in a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease.

The particular biomarker called Fibrinogen has a relationship with inflammation, which may have a role in causing muscle or heart problems in patients with COPD. We also want to see if there is a relationship between this biomarker and other biomarkers in the blood and what happens to your lung disease in the longer term.

This may hopefully help doctors determine which type of treatment is best for newly diagnosed COPD patients in the future, and in developing new treatments.

2. Why have I been invited?

You have been invited to participate in this study because you have been diagnosed with COPD. This study is looking to recruit approximately 800 patients with COPD across the UK at 5 different sites including Nottingham, Cambridge, Edinburgh, London, and Cardiff.

3. Do I have to take part?

Participating in this study is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form. However, you are still free to change your mind and leave the study at any time without giving a reason. If you choose not to participate or to leave the study, your future medical treatment and normal standard of care will not be affected in any way.

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

If you agree to participate in the study, you will be asked to sign the Informed Consent Form at the end of this document. You will be given a copy of this to take away and refer to later.

We will ask you to attend the hospital for up to 2 visits over the course of 3 months and each visit should last no longer than 4 hours.

The following information will be collected; some of these assessments may be familiar to you as you may have been asked to do them previously as part of your routine care visits.

- Your study doctor will ask you questions about your date of birth and gender, your medical history, anything that makes your COPD worse, whether you smoke and any current medications you are taking.

- You will receive a number of different questionnaires that are commonly used in patients with COPD, to measure health, activity, fatigue, breathlessness and depression or anxiety.

- Your height and weight will be measured.

- Your body fat and fat free mass will be measured: This involves measuring the electrical resistance either between electrodes (sticky pads) placed on your hands and feet while you are lying down or by standing on an electric plate, depending on which site you attend. It is quick to perform and painless.

- Your blood pressure will be recorded 3 times after asking you to sit and relax as much as possible for around 5 minutes and then after 10 minutes of laying down.

- Post bronchodilator spirometry: This is a simple breathing test where it will involve you being seated and given up to 4 puffs (up to 400micrograms) of salbutamol inhaler. Around 15 minutes later, we will ask you to blow hard and fast into a tube for as long as you can; just like it is done in outpatient clinic.

- Lower limb function test: This is a simple test to measure the function of your legs. We will ask you to stand up then to walk at your usual pace and test your ability to stand from a chair. We will tell you exactly what to do before each test. The whole assessment takes less than 5 minutes to complete.

- 6-minute walking test: We will ask you to walk as far as you can during a 6 minute period and then measure the distance.

- Thigh muscle strength: You will be asked to lie on a specially designed couch and kick with your leg as hard as you can against a strap, while we measure the force produced and determine the strength of your thigh.
- Blood sample: A blood sample will be taken for laboratory tests. This involves putting a needle into a vein in your arm and collecting up to 50mls of blood. (Approximately 10 teaspoons) Approximately 10mls of this sample will be stored for future DNA analysis in a licensed facility. This is so we can look at the relationship between the genes and any physical similarities that occur in patients with COPD.

- Blood vessel stiffness measurement: This is a non-invasive test to see how flexible your main blood vessel (the aorta) is. A thin pencil-like probe will be placed on blood vessels at your neck and groin and electrodes will be placed on your chest to measure your heart rate. It is painless and will take no longer than 10 minutes. In addition, a probe will be placed on your wrist for about 30 seconds to also measure blood vessel stiffness.

- Blood vessel thickness: This is a non-invasive test to measure the thickness of your artery walls in the neck, by ultrasound. Measuring the thickness will be completed by specialists using the images. The Ultrasound scanning will be repeated three times. It is painless and will take approximately 5 minutes.

- SNIP – Sniff Nasal Inspiratory Pressure: This is a simple test to assess the strength of the respiratory muscle in your nose. The test involves placing a small sponge probe just inside the nostril and asking you to sniff. This will be done up to 10 times for each nostril. You will not experience any discomfort during the test.
- ECG – Electrocardiogram. This measures the electrical activity of your heart. It involves you lying down and having 12 electrodes (sticky pads) attached to the outer surface of the skin, (one on each wrist, one on each ankle and 6 around the heart) which is then recorded by a machine. This is a non-invasive procedure and takes no longer than 5 minutes. We may need to shave the areas where the pads will be placed if necessary.
- Urine – We will ask for a small amount of urine to be deposited in a small container we will provide when you visit the hospital

We will follow you up with questionnaires that will be sent to you by post or discussed over the telephone depending on your preference, every 6 months for up to two years after your last hospital visit. Some examples of the questions are listed below:

- Since we saw you last, have you had a severe pain across the front of your chest lasting half an hour or more?

- In the last 6 months, have you been on a pulmonary (lung) rehabilitation course?

- In the last 6 months, have you been told by a doctor that you have high blood pressure?

This is so we can get an idea of any changes in your health and see if any similarities occur between patients participating in this study.

The total length of your participation in the study will be up to 2 years which includes up to two visits and the follow-up questionnaires.

Long Term Follow-Up

We would then like to follow the health of each participating patient beyond this 2 year period. This will help us understand more about the long term similarities in COPD patients. To do this, we will ask your permission to use data held by the NHS and records maintained by the NHS Information Centre in the future. This will provide information about your health and also provide us with up to date contact details.

We would like to store some of your personal data on a secure, password-controlled database with access given to only a very small number of delegated study staff. We would also ask the 'Hospital Episode Statistics' centre if you were admitted to hospital after this study. These systems will be asked for information and stored in our database on a future/long-term basis for as long as the data is available. For this, we would need to send your name, gender, date of birth and NHS number with any request for information.

Inclusion in Other Studies:

Importantly, if you have participated in any of the following studies; ARCADE, ECLIPSE, PROACTIVE, Longitudinal determination of skeletal muscle dysfunction in COPD or MRC ABPI consortium WP4 **within the last three months,** you may have already had some of the tests mentioned above. Therefore, we would ask if you allow us to see the results of these tests so that you would only need to have the remaining assessments undertaken as part of the ERICA study. This would require you to sign another informed consent form giving us access to the assessment results from your previous study.

5. What will I have to do?

You will need to attend the hospital for up to 2 visits which will be arranged to fit around your availability.

It would be preferable if you could not smoke or use your inhalers for at least 6 hours before attending for each visit however you can use the inhalers if you feel necessary. We would also ask you to not eat anything 4 hours before each visit to ensure all patients can be similarly compared.

You should tell the study team if you feel unwell or different in anyway. If you have any major concerns or are feeling very unwell please contact your study doctor using the contact numbers at the end of this information sheet.

6. What are the possible disadvantages and risks of taking part?

Apart from the blood sample, all of the measurements are non-invasive and the study team don't foresee any risks involved.

However, the study will take up some of your time as it requires visits to the hospital. Some people may find the testing quite strenuous and repetitive; you may experience fatigue after the various assessments, and maybe even slight muscle soreness after the thigh strength test, but that should pass fairly quickly.

Taking blood may lead to minor discomfort and may cause bruising of your arm, light-headedness and/or fainting and pain at the site where blood was taken. Only experienced study staff will take the blood samples to minimise any of these effects.

7. What are the possible benefits of taking part?

We do not anticipate that you will personally benefit from taking part in this study, but information gained from your participation may benefit patients with COPD in the future.

However, we will perform a detailed assessment of your blood pressure and other cardiovascular risk factors (e.g. glucose, cholesterol levels) and we will make your results available to your GP if anything clinically relevant is found.

8. What happens when the study stops?

The results of the study may be published in scientific journals or presented at medical conferences after completion of the study. You will not be identified in any report or publication. As this is a study that is collecting data on a long-term basis; after the follow-up questionnaires, the study will still be collecting data from the NHS Information Service/Hospital Episode Statistics about your health status but we won't ask you to come for any more visits.

9. Expenses & Payment?

You will not receive any payment for participating in this study; however we can reimburse any reasonable travel and parking costs incurred by your participation in this study, so please keep any valid receipts for your claim.

10. What if I decide I no longer wish to participate in the study?

You are free to withdraw from the study at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to participate any further, no more assessments will be performed.

You will be withdrawn from the study, however any information already provided or results from assessments already performed on you or your samples will continue to be used in the study. No further information will be collected once you have withdrawn. Any remaining samples already provided for the study can be destroyed if they haven't been analysed and if results haven't been generated.

The study doctor may also chose to withdraw you from the study if they feel it is in your best interests or if you are unable to complete the visits or the study questionnaires as required.

Participating in this study will not alter the treatment you receive from your doctor and after the study ends you will continue on the treatment as prescribed by your doctor. Rarely, your study doctor may decide to stop the study. If this happens your study doctor will explain the reasons why.

11. What if there is a problem?

In the event that something does go wrong and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Addenbrookes Hospital or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you.

The University has obtained insurance which provides no-fault compensation i.e. for non-negligent harm; you may be entitled to make a claim for this.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your hospital on {Insert local telephone number}

12. Will my taking part in this study be kept confidential and how will my personal data be used?

By signing the informed consent form, you consent to the study doctor and their staff collecting and using medical and personal data about you for the study (study data). This includes: your date of birth, gender, your ethnic origin and personal data about your physical or mental health or condition. Your consent to the use of Study Data does not have a specific expiry date, but you may withdraw your consent at any time by notifying your study doctor.

Occasionally, responsible individuals from the sponsor may require access to study information relating to you in order to check that the study has been done properly. They will keep all information confidential.

Once you have agreed to participate in this study you will be allocated a unique study number which will be used on all your study documentation. This number will be linked to your personal information; however you will only be able to be identified by this unique number. Any information that is sent will use this unique number.

By participating in this study, we will also follow your medical care and COPD on a long term basis. This involves the collection, processing, disclosure and transfer of your personal data for medical research purposes only. This will be done by sending named information to the NHS Medical Research Information Service and HES – Hospital Episode Statistics. All information will be stored and handled securely in accordance with the data protection law(s) to ensure that all information about you is handled in the strictest confidence.

In order to obtain this information and to send out your follow-up questionnaires, your study doctor will need to provide the coordinating study centre (Cambridge Clinical Trials Unit at Addenbrooke's Hospital) with some of your personal details as listed in section 4.

While you are in the study, your study doctor will not tell you the results of any of the tests conducted as part of this study unless the study doctor decides it is medically important to do so. At any time, you may ask your study doctor to let you see your personal information collected as part of this study, e.g. your name and address and to correct any details if necessary.

13. Will my GP be informed?

Your study doctor will inform your GP of your participation in the study and your GP will be informed of any clinically relevant results that may become available during the study.

14. What will happen to my samples?

Blood samples that are collected in this study will be analysed and stored at each site and then transferred to a centrally licensed facility for future analysis. Samples will be stored for approximately 5 years. Your samples will only be identified by your unique study number, and all other information will be kept in a secure, locked facility.

Genetic Analysis

The blood sample you give will be used to examine the genes which are known or likely to be important in determining genetic differences in COPD. As we are looking for non-disease specific genetic changes, these findings would not have any implication for your risk of developing disease in the future. The genetic samples will be given the same unique study number as the rest of your study-data and samples.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge who are the sponsors of the study will have access to the genetic data generated by the DNA analysis of your blood samples. These blood and genetic samples may be eventually transferred to a central location for analysis and anonymised data from this analysis may be made available through a secure public database to help other researchers. There is a remote, theoretical possibility that individuals can be identified by looking at genetic information alone, but only if this can be matched to other genetic information from samples that you have provided to another person or organisation independently. We regard this as unlikely, but it is important that you are aware of this theoretical risk. It is important to us that you are clear what we plan to do with the genetic information we find and why and that you are happy that we have put in place sufficient measures to preserve your confidentiality.

15. What will happen to the results of the study?

The results of the study will be anonymous and you will not be able to be identified from any of the data produced. When the results of this study are available they may be published in peer reviewed medical journals and used for medical presentations and conferences. However, there will be no feedback of clinically significant findings from the genetic analysis.

If you would like to obtain a copy of the published results please contact your study doctor directly who will be able to arrange this for you.

16. Who is organising (sponsoring) and funding the study?

This study is sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge. The study is funded by the MRC Technology Strategy Board.

17. Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests.

This study has been reviewed and given favourable opinion by Cambridge South Research Ethics Committee.

18. Further information and contact details

Please feel free to contact the study team below for any further information:

{Insert name } - Principal Investigator {Insert telephone number}
{Insert name} – Research Nurse {Insert telephone number}
{Insert name} – Study Coordinator {Insert telephone number}

In the event of an emergency please contact:

Out of hours contact number: {Insert local out of hours contact}

Thank you for taking this time to consider participating in this study

INFORMED CONSENT FORM

Study Name: Evaluation of the role of Inflammation in Chronic Airways Disease

Principal Investigator:

Participant Number:

If you agree with each sentence below, please initial the box

		INITIALS
1	I have read and understood the Participant Information Sheet version 1.1; dated 10 October 2011 for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that sections of my medical notes or information related directly to my participation in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4	I give permission for my GP to be informed of my participation in this study, sent details of the ERICA study and informed if abnormal results are found.	
5	I understand that the doctors in charge of this study may close the study, or stop my participation in it at any time without my consent.	
6	I understand that personal information will be stored at the Lead Coordinating site, sent to The NHS Information Centre and the NHS Central Register and may be used to help contact me and provide information about my health status.	
7	I give permission for the blood samples I have donated to be stored in laboratories/facilities for the research purposes described in this information sheet including genetic testing in the future. I understand that information from these tests will not be relayed to me	
8	I give permission for the blood/genetic samples to be transferred to a central site for analysis and for anonymised data from that analysis to be made available through a secure public database as described in the patient information sheet. I understand that this database would only be accessible to appropriate doctors and researchers who have been approved by a committee set up to ensure the results are only used to advance scientific and medical understanding.	

9	I give permission for the blood samples which have been donated by me to be used in future ethically approved studies.	
10	I agree to participate in this study.	

If Applicable

11	I give permission that collected data from a pre-existing study outlined in the patient information sheet may be used by study personnel and will be given access to the sponsor and regulatory authorities.	

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date