THIS STUDY HAS BEEN REVIEWED AND APPROVED BY A RECOGNISED RESEARCH ETHICS COMMITTEE

INFORMATION SHEET FOR PATIENTS/ VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Title of Project:
DIAPHRAGM: Diagnostic and prognostic biomarkers in the rational assessment of mesothelioma

Invitation Paragraph
We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
This study is being carried out to find new ways of diagnosing and predicting survival of a cancer of the lining of the lung called Malignant Pleural Mesothelioma (MPM) using a simple blood test known as a biomarker. **Although we are asking you to take part this does not mean you have this condition.** MPM is an uncommon cancer, often related to previous contact or exposure to asbestos. It can be extremely difficult to diagnose. We aim to find simpler initial diagnostic tests in the form of a blood sample to predict who is more likely to have MPM and would therefore benefit from early referral to a specialist centre.

Why have I been invited to take part?
You have been invited to take part in this study because you have had previous exposure to asbestos. In this study we need to ensure that the biomarker we are measuring is specific to Mesothelioma and is not simply related to previous asbestos exposure. We believe you would be a suitable 'control' subject for this study (i.e. a person who does **not** have Mesothelioma but who has been exposed to Asbestos)

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do you will be asked to sign a consent form to show you have agreed to do so. You are free to withdraw at any time, without giving a reason.

What will happen to me if I decide to take part?
If you wish to take part in the study, please phone the **Glasgow Clinical Research Facility (CRF)** on **0141 232 9533**, quoting the study name **DIAPHRAGM**. A clinical research nurse will then arrange a suitable time for you to attend a single visit to the Clinical Research Facility at the Queen Elizabeth University Hospital. The nurse will also arrange for a taxi to take you to and from the CRF on the day of your appointment (if you require transport). During your visit to the CRF, you will be asked to sign a consent form, your medical history and details of your previous exposure to asbestos will be recorded and a blood sample (18 mL or 4 teaspoonfuls) for biomarkers will be taken. We can arrange for a taxi to take you to and from this visit, free of charge, and it should take no longer than 30 minutes. As you will be aware, taking blood samples may cause some minor discomfort or bruising at the site from which the blood is taken.

How will my blood sample be used?
In general, blood samples are used for medical research in order to better understand a disease, including how it starts and develops. In this study, scientists will analyse your blood to see if the biomarkers we are measuring are unique to Mesothelioma. It is not clear at present whether these tests have any value in detecting mesothelioma. Therefore, the results of your blood test will not affect you, nor will you be informed of the results. You will, however, receive a summary of the results of the study once it has been completed. The blood you donate will be split into two samples. One will be sent to a research laboratory in America to be analysed in an anonymised fashion. The sample will remain there until it is all used or you withdraw your consent. The second sample will be stored locally. This sample will serve as a 'back-up' sample in case the sample is damaged or lost during transport to America. If not required for this study, it will remain in secure storage and may be used for ethically approved research in the future. All samples will be stored securely and confidentially using a study number that will be assigned to you, rather than your name or other information that could identify you. The blood you donate will be kept in the secure local tissue bank indefinitely until it is all used or your consent is withdrawn.

What are the possible benefits of taking part?
There is no direct benefit to you but it is hoped that by taking part in this research, you will be providing valuable information regarding Mesothelioma**.** In particular, this study may help us define better, quicker and less invasive ways of detecting Mesothelioma.

What are the potential risks in taking part?
As mentioned above, taking blood can cause some minor discomfort or bruising at the site from which the blood is taken. The person taking your blood will be fully competent at doing this safely.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak with the research doctor/nurse who will do their best to answer your questions. If taking part in this research study harms you, 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 your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism should be available to you.

If you have private medical insurance, you may wish to check with your company before agreeing to take part in the study to ensure that participation in the study will not affect your insurance cover.

Will my taking part in the study be kept confidential?
You can be assured that any data collected during the course of this study and any of the results published will not identify you personally. Your medical records will only be available to the research doctors, your hospital consultant, responsible individuals from the Cancer Research UK Clinical Trials Unit (Glasgow), trial sponsors and regulatory authorities.

With your permission, we will inform your general practitioner (GP) of your participation in this study.
With your permission, the Cancer Research UK Clinical Trials Unit (Glasgow) who are coordinating the study will collect your name or initials, date of birth and NHS number or Community Health

Index (CHI) number. This information will be stored securely on a password protected database and will be kept strictly confidential, with access provided only to authorised personnel.

Your consent for participation in this study also includes your consent to allow the use of the data in your medical/clinical record to be used for the purposes of Cancer Research. Your consent also includes allowing these data to be linked to data coming from other sources such as cancer registries and medical clinical records. All data (personal, clinical, economic and data coming from research on biological material) collected on your behalf will be treated in compliance with the European and UK applicable laws to ensure your confidentiality is maintained.

Who is organising and funding the research?

The research is being carried out by Dr. Kevin Blyth & Dr. Selina Tsim from the Department of Respiratory Medicine at the Queen Elizabeth University Hospital, Glasgow. The study is being coordinated by the Cancer Research UK Clinical Trials Unit, based at the Beatson West of Scotland Cancer Centre in Glasgow and is sponsored by NHS Greater Glasgow & Clyde. The costs of running and organising this study have been met by a grant from the Chief Scientist Office of the Scottish Government. None of the doctors or other staff conducting the research are being paid for recruiting patients into the study.

Who has reviewed the study?

This study was reviewed by a number of medical specialists during its development. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The West of Scotland Research Ethics Committee 1 has reviewed and approved this study to confirm that the 'rights and protection of patients' health have been considered. In addition, the study has been reviewed by the NHS GG&C Research and Development Department.

Contact for further information

If you have further questions about your illness or clinical studies, please discuss them with your doctor. If you would like independent advice or further information you may also find it useful to contact The National Asbestos Helpline, website: http:// Website: www.nationalasbestos.co.uk, Freephone. 0808 163 3706 and address: Innospec Park, Ellesmere Port, Cheshire, CH65 4EY

If during the course of the study you have any questions regarding your participation or would like further study specific information before making your decision please contact Dr. Selina Tsim on the following number quoting the study name DIAPHRAGM:

Study Name **DIAPHRAGM**
Telephone Number **0754 0230 911**

If you find the wording difficult to understand or would like us to explain things to you once more, please feel free to ask your doctor, or nurse.

Thank you for taking the time to read this information sheet. If you wish to take part you will be given a copy of this information sheet and a signed consent form to keep.