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

We are grateful to you for agreeing to take part in the DIAPHRAGM research study. We would appreciate it if you would consider participating in an additional part of this study, which is described below. Participation in this additional research is voluntary and you can continue to participate in the main study if you decide not to volunteer for this component

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Invitation Paragraph
We would like to invite you to take part in a research sub-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 sub-study is being carried to help us understand the biological basis of the biomarker levels we have already measured in your blood. We plan to use Magnetic Resonance Imaging (MRI) to accurately measure the amount of pleural thickening, including any visible tumour, which might be present. We will then look for any relationship between biomarker levels in pleural fluid and blood and these measurements.

Why have I been invited to take part?
You have been invited to take part in this additional sub-study because your medical team have decided that it would be sensible for you to have biopsy samples taken from the lining of your lung. **This does not mean that you have Mesothelioma**

Do I have to take part?
No, it is up to you to decide whether or not to take part. Taking part in the sub-study is voluntary, and is entirely separate from taking part in the main study. We will describe the study and go through this information sheet, which we will then give to you to keep. If you decide to take part, you will be asked to sign a consent form to show you have agreed to take part. If you decide to take part, you are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive or your future treatment.

What will happen to me if I decide to take part?
If you agree to take part in the sub-study, any tests or treatment your doctor recommends for you will not be affected by taking part in this sub-study. Before your admission for biopsy, we will arrange a suitable time for you to have a single visit for MRI scanning. The pleural fluid sample you consented to be retained when you consented to the main study will also be retrieved for use in this part of the research.

What does the MRI scan involve?

The MRI scan will be performed at the Research MRI Scanner at the Queen Elizabeth University Hospital, Glasgow. We can arrange a taxi to take you, free of charge, to and from your MRI scan and the scan should take no more than an hour.

On arrival at the MRI department a radiographer will go through a safety checklist and make sure that all magnetic objects (e.g. jewellery and bankcards) have been removed. Following this you will be asked to complete and sign a safety questionnaire. Once you have changed into a hospital gown, you will be asked to lie flat on an electric bed that will move you into the scanner. The scanner is basically long and tunnel shaped. You are gently slid into the centre of the tunnel on a moving bed and the scan pictures are taken. Some people find it a little enclosing, but you can come out at any time. If you are claustrophobic please tell staff.

When you are in the scanner you will need to wear a pair of headphones, allowing you to listen to music of your choice (you are welcome to bring your own CD) and allowing us to communicate with you. The headphones are also necessary because of the loud knocking noise that occurs when the pictures are being taken. You will be given an emergency buzzer and can very quickly be taken out of the scanner should you feel uncomfortable or if it is felt necessary. During the scan you will be asked to hold your breath at times to improve the quality of the pictures. A doctor will be in the control room throughout this procedure.

What are the possible risks or disadvantages of taking part?

MRI:

The MRI scanner is very safe as long as you have no metal implants in your body. Staff who are experienced in MRI scans will be present during your MRI scan and you will be asked a series of safety questions to ensure you have no metal implants/fragment in your body. If you do have a metal implant/fragment an MRI scan may not be safe and you would not be eligible for this additional study.

During the MRI scan a dye (contrast agent) will be injected into a vein in your arm. This makes any abnormal tissue appear brighter on the scan and easier to measure. The dye is called Gadolinium and is generally harmless and will be washed out of your system by your kidneys. There are however some potential side effects, although these are uncommon and generally mild. The most frequent side effects are headache, nausea, a sensation of heat, cold and/or pain at the injection site.. A very rare side effect is an allergic reaction to the dye therefore please inform the doctor if you have a history of allergies.

The dye can affect the kidneys if the kidneys are not working properly. Your doctor, using the blood test taken, will check how your kidneys are working before the scan. Your doctor will ask you if you have had problems with seizures in the past to make sure that you are able to have the dye.

Thoracoscopy/Image guided biopsy:

This is an essential part of your routine care and allows samples of the lining of your lung to be taken (pleural biopsy). It is a safe procedure and will be performed during a short admission to hospital. It will be discussed with you in great detail beforehand and you will be given separate written information regarding it.

How will my blood and pleural fluid sample be used?

In general, blood and pleural fluid 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 and pleural fluid to see if the biomarkers we are measuring are truly 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 and pleural fluid you donate will be split into two samples. One will be sent to a research laboratory 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 samples are damaged or lost during transport to the research labs. If not required for this study, it will either be discarded or 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. These samples will remain there until they are all used or you withdraw your consent. Results of tests will only be used for research and education. The blood and pleural fluid you donate will be kept in a secure local tissue bank until it is all used or your consent is withdrawn.

If you do not want your blood or pleural fluid to be used for medical research, then when you come to hospital or clinic and are asked for your consent to donate blood or pleural fluid you can say no. If you do decide to take part, you can change your mind at any time. If, however, you change your mind after your procedure, some of your blood or pleural fluid may have already been used for research.

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 is 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.

We will inform your general practitioner (GP) of your participation in this study.

We would like to use your NHS number to follow-up on your health.

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 sub-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 sub-study have been met by a grant from the Chief Scientist Office.

None of the doctors or other staff conducting the research are being paid for recruiting patients into the study.

Who has reviewed the sub-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.

Alternatively you can contact British Lung Foundation, website: www.blf.org.uk, telephone 03000 030 555 and address: British Lung Foundation, 73-75 Goswell Road, London, EC1V 7ER
If during the course of the sub-study you have any questions regarding your participation or would like further study specific information before making your decision please contact:

Doctor:

Name	**Dr Selina Tsim**
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.

CONSENT FORM FOR PATIENTS/ VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Patient Identification Number for this trial:
(to be obtained post registration/randomisation)

Title of Project:
DIAPHRAGM: Diagnostic and Prognostic Biomarkers in the Rational Assessment of Malignant Pleural Mesothelioma

Please initial EACH BOX

1. I confirm that I have read and understand the information sheet dated 27th August 2015 (Version 5) for the above sub-study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand the small additional risks involved in magnetic resonance imaging and confirm they have been explained to me ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the Cancer Research UK Clinical Trials Unit (Glasgow), the trial sponsor, the regulatory authorities, the research team and the NHS organisation where it is relevant to my taking part in the research. I give my permission for the research team individuals to have access to my records. ☐

4. I agree to the information detailed in the Patient Information Sheet to be collected as part of this sub-study. ☐

5. I agree to myblood and pleural samples being stored and used for research as detailed in the Patient Information Sheet. ☐

6. I consent to my GP being informed of my participation in this sub-study. ☐

7. I agree to take part in the above sub-study. ☐

Please sign and date below:

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Name of Participant	Date	Signature

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Name of Researcher	Date	Signature