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

(Form to be on hospital headed paper)

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 test the value of a blood test (or biomarker) in determining the cause of a pleural effusion (a collection of fluid around the lung) or a pleural mass (an area of thickening of the lining of the lung). As your doctor will have explained there are numerous causes for this problem and these can be difficult to diagnose, often requiring multiple tests. Many of the causes of a pleural effusion or pleural thickening are benign, however, our specific goal in this study is to assess whether this blood test can be used to diagnose a rare cancer called Malignant Pleural Mesothelioma (MPM), which can present with a pleural effusion or mass. **Although we are asking you to take part this does not mean you have Mesothelioma, in fact the vast majority of people who take part will not have this.**

Why have I been invited to take part?
You have been invited to take part in this study because you have a pleural effusion(a collection of fluid around the lung) or a pleural mass (as above). **This does not mean that you have Mesothelioma** but your medical team have decided you need further investigation, including sampling of the pleural effusion to send for analysis and/or biopsies of the lining of the lung (pleura).

Do I have to take part?
No, it is up to you to decide whether or not to take part. 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.

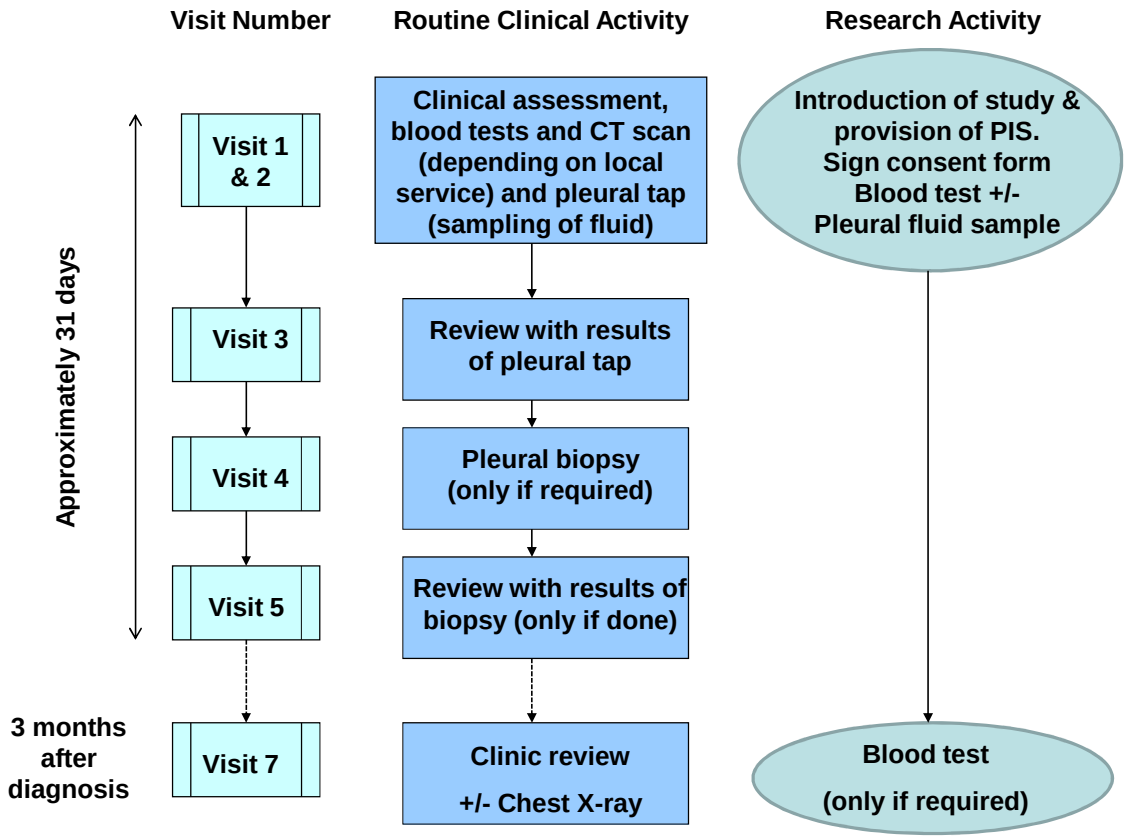
What will happen to me if I decide to take part?
The study involves taking a single extra blood sample, 18 mL in total (4 teaspoonfuls) when you come to the hospital to get a sample of pleural fluid taken, or when you return to clinic for your results. The blood you donate will be split into two samples. One will be sent to a research

laboratory to be analysed in a completely anonymised fashion. This sample will remain there until it is used up 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 laboratory. 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. If a diagnosis other than MPM is made from this pleural fluid sample, then no more study tests will be required

If a diagnosis of MPM is made, we would like to take 1 further blood sample (approximately 3 months after diagnosis) when you attend for your usual visit to the clinic. Wherever possible, this will take place when you attend for your usual visit to the clinic. If this is not possible, a single study visit will be arranged with you. As you will be aware, taking blood samples may cause minor discomfort or bruising at the site from which the blood is taken. The following flow chart demonstrates how these blood tests will fit in with your routine clinical visits. If you are currently in hospital because of symptoms caused by your pleural effusion, your first study 'visit' (involving completion of a consent form and a blood test)can be undertaken during your hospital stay.

If you are a patient in a **West of Scotland hospital,** a small sample (approximately 20ml) of pleural fluid will be retained when we take a sample of pleural fluid as part of your routine clinical tests. This sample of fluid will be labelled in a completely anonymised fashion and stored in a secure freezer. The fluid may be used in a subsequent part of the DIAPHRAGM study, depending on the outcome of your initial tests. If this is the case, you will be made fully aware of this by the study team, otherwise this pleural fluid sample will be destroyed and discarded.

Please note that it is only the circle shapes in this diagram that indicate research/study activities



Visit 6 has been intentionally omitted from this diagram as it does not apply to this part of the study

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 measurements we are testing 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.

If you do not want your blood to be used for medical research, then when you come to hospital or clinic and are asked for your consent to donate blood 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 may have already been used for research. If it is being stored, the blood you donate will be kept in the secure local laboratory/tissue bank until it is all used or your consent is withdrawn.

What are the possible benefits of taking part?
There is no benefit to you but 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, blood taking 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 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 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 Research and Development Department of your local hospital.

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 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 study you have any questions regarding your participation or would like further study specific information before making your decision please contact:

Doctor:
Name **Insert Local Contact Details**
Telephone Number **Insert Local Contact Details**

Doctor/Research Nurse:
Name **Insert Local Contact Details**
Telephone Number **Insert Local Contact Details**

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.