Acute Services Division

Regional Services Directorate

INFORMATION SHEET FOR PATIENTS/ VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Title of Project:

The Meso-ORIGINS Feasibility Study

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?

The study you have been asked to join is called 'The Meso-ORIGINS feasibility study'. The aim of this study is to learn more about a type of cancer called Mesothelioma. Mesothelioma is usually caused by exposure to a material called asbestos. We are trying to find out why this develops in some patients exposed to asbestos but not others. In the study we will ask feedback on what extra follow-up tests (if any) you would be willing to have for this purpose.

If we understand Mesothelioma better by carrying out this study, it may be possible to catch it earlier and start treating it.

Why have I been invited to take part?

You are being asked to take part because you have, or recently had, a pleural effusion (a collection of fluid around the lung), **NOT** because you have Mesothelioma. In fact, you may have had a biopsy sample taken recently from your chest which shows no evidence of Mesothelioma. Your doctor will have explained that a small proportion of patients in your situation develop Mesothelioma later in life. As part of your routine care we would therefore be planning to follow you up in the clinic for least 2 years to ensure that nothing changes. This study involves spending some time with a member of the research team during your planned clinic visits over the next 6 months only, allowing us get your opinions by filling out a questionnaire.

Do I have to take part?

No, it is up to you to decide whether or not to take part. We will talk you through the study and go through this information sheet. If you decide to take part, you will be asked to sign a form to show you have agreed to take part. If you decide to take part, you are free to leave the study at any time, without giving a reason.

What will happen to me if I decide to take part?

If you are interested in taking part in the study, we will discuss what is involved in the study in detail and give you the opportunity to ask any questions. This will take place at your clinic appointment following your thoracoscopy (this is the telescope test you may have had have had to investigate your pleural effusion). If you choose to go ahead, we will then ask you to sign a consent form for enrolment into the study.

At your next clinic appointment (this is usually 6 months after your initial appointment but might be sooner depending on your particular situation) we will ask you to complete a simple questionnaire about what kinds of follow-up tests you would be willing to have. We will help you complete this if you wish. You will also have a painless ultrasound scan of your chest and we will record what that shows. You will have had this scan several times before and it is part of your normal clinic follow up. Your participation in the study will end after that clinic appointment, with nothing else required.

What do the Ultrasound scans involve?

The ultrasound scans will be performed in the outpatient clinic by one of the chest doctors. The scan should take no more than a few minutes and is completely painless. You will have had one of these ultrasound scans before at your chest outpatient clinic or hospital admissions. This is part of your routine clinical care.

What are the possible benefits of taking part?

There is unlikely to be any direct benefit to you for taking part, but the results from this study will help us to perform a much larger study in the future (called Meso-ORIGINS). The feedback you give will help us match that study to patients' wishes and its results could greatly improve our understanding of Mesothelioma and how to treat it. This may be of great benefit to other patients in the future.

Can I claim expenses?

All study visits should take place on days that you will be attending hospital anyway, but if this is not possible we will refund travel expenses for any extra visits. You will need to provide receipts, or we will provide a mileage allowance if appropriate.

What are the potential risks in taking part?

There are no expected risks in taking part in this study as there are no extra procedures or tests that involve any risk.

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, trial sponsor (NHS Greater Glasgow & Clyde) and regulatory authorities.

Data Transparency Statements

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. NHS Greater Glasgow & Clyde (NHS GG&C) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after

your information and using it properly. NHS GG&C will keep identifiable information about you [for 7 years after the study has finished/ until 2026]. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting Dr Kevin Blyth (contact details below).

Your local NHS site will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from NHS GG&C and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital researchers will pass these details to NHS GG&C along with the information collected from you and/or your medical records. The only people in NHS GG&C who will have access to information that identifies you will be people who need to contact you to [insert reason] or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. NHS GG&C will keep identifiable information about you from this study for 7 years after the study has finished or until 2026.

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 costs of running and organising this study have been met by a grant from the June Hancock Mesothelioma Research Fund. 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 South Central Hampshire B Research Ethics Committee 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:

Name	**Dr Kevin Blyth**
Telephone Number	**0141 451 6099**

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.