Participant Information Sheet

PROSPECT-PLEURA

You are being invited to take part in a medical research project called PROSPECT-PLEURA. This research is sponsored by Lancaster University and recruitment is taking place at University Hospitals of Morecambe Bay NHS Foundation Trust (UHMBT).

What is the study about?

A pleural effusion is when fluid collects between the lungs and chest wall. It has many different causes, ranging from harmless conditions to aggressive cancers. As part of determining the cause, a sample of the pleural effusion is collected and analysed under a microscope by an expert. But even after this, in over ¼ of cases a cause can't be identified right away. Instead, a patient may have to wait until a diagnosis can be reached.

The purpose of this study is to improve the ability to diagnose the underlying cause from pleural effusion samples. This will allow clinicians to reach a diagnosis quicker, start treatment earlier and may give back precious time if cancer is the cause of the pleural effusion.

Why have I been approached?

You have been approached because you have a pleural effusion from which your lung specialists wants to take a sample; and this study requires pleural effusion samples.

Only a small amount of pleural fluid is needed for standard NHS diagnostic pathways, and there is almost always more fluid in your chest than needed.

Do I have to take part?

No. It's completely up to you to decide whether you take part. Your pleural effusion will still be sampled and undergo standard NHS analysis if you don't want to take part. If you decide that you do not want to take part, it will not affect the care you receive at UHMBT.

What will I be asked to do if I take part?

If you decide you would like to take part, you would be asked to donate some of your pleural effusion to the research project.

For participants having pleural fluid removed for symptom relief, the sampling procedure will be unchanged, as we will take a small amount of the fluid already removed to use for the research.

For participants having pleural fluid sampled to help obtain a diagnosis, your pleural sampling procedure might be one or two minutes longer than if you weren't participating whilst we collect additional fluid for the research sample. This slightly longer procedure will not expose you to any new risks.

You can ask someone which type of procedure you are having before you agree to participate.

All samples will then be analysed in a laboratory by researchers based at Lancaster University for molecular clues.

You will also be asked to allow the researchers at UHMBT to access your health information from your medical records and share relevant information with us, from up to 1 year before you had your pleural effusion sampled, and up to 3 years after the date you donated your pleural effusion sample – which could mean health information from before you decided to take part is used. This allows us to match the cause of the pleural effusion to the molecular clues we will detect when the sample is analysed at Lancaster University laboratories. Pleural effusions can sometimes be a sign of serious disease. You would be asked to allow access to your health information from your medical records even in the event of your passing.

Your involvement will be limited to donating pleural effusion samples. There will not be any other study activities that require your participation.

If in the future your pleural effusion comes back and your lung specialists decide to take a repeat sample or remove it for symptom relief, we would like to ask some of the participants in this research to donate a second sample.

If you are selected to donate a second sample, we will remind you of your engagement in the research and confirm if you still consent to taking part and donating a second sample. You will be able to opt out if you want to at this point and it will not affect your medical care at UHMBT in anyway.

People will be selected to donate a second sample depending on if it will help with scientific analysis. It may not be related to your health. Please ask your lung specialist if you have questions about your pleural effusion coming back.

What will happen to my pleural effusion samples?

Your pleural effusion samples will be transferred to Lancaster University, where they will be securely stored until they can be analysed in a laboratory. Samples taken for research are not used for getting a diagnosis, and the results will not be communicated to you.

We may wish to extend this project or complete a follow-on research project. If so, we will continue to store your pleural effusion sample at Lancaster University and may re-analyse it. If an extension or follow-on study is not organised, at the end of the research project all pleural effusion samples will be either donated to a UK research tissue bank, or destroyed.

Are there any risks?

The risks of your procedure are the same as those explained to you by your lung specialist when they take your pleural effusion sample, whether you take part in the research or not.

You will only be undergoing a procedure that your lung specialists have decided is medically necessary.

For participants having pleural fluid sampled to help obtain a diagnosis, your pleural sampling procedure might be a one or two minutes longer than if you weren't participating whilst we collect the research sample. This slightly longer procedure will not expose you to any new risks.

Are there any benefits to taking part?

Although you may find participating rewarding, as the research might be able to help others who find themselves in your position in the future, there are no direct benefits in taking part.

How will we use information about you?

Both UHMBT and Lancaster University will need to use information from your medical records and from your GP for this research project. This information will include your:

- Name and signature
- Contact details (UHMBT only)
- Age, sex and ethnicity
- Date of birth (UHMBT only)
- NHS number and hospital number (UHMBT only)
- Relevant medical test or scan results
- Relevant medications
- Pleural effusion histopathology reports
- Clinical outcomes

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Lancaster University is the sponsor of this research. Lancaster University is responsible for looking after your information.

We may share anonymised or code number versions of the study data for this research project with the following types of organisations, but this will not include your identifiable information:

- Other researchers or research institutions
- Commercial partners
- Scientific data repositories

We will keep all information about you safe and secure by:

- Using a code number instead of your name on your pleural effusion sample(s) and laboratory analyses
- Keeping your research data (scientific analysis data from your pleural effusion and your health information data from your medical records) on secure cloud storage systems
- Storing your personal data securely on Lancaster University cloud servers separately to your research data
- Controlling who has access to your personal data, so only those who need access to it for the research will be granted access

International Transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Advancing scientific and medical understanding of pleural disease

- Developing pleural fluid medical tests
- Developing treatments for pleural disease

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Other researchers or research institutions
- Commercial partners
- Scientific data repositories

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from UHMBT. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep a version of the research data linked to you by a code only and no personal information, and a copy of your consent form at Lancaster University for a minimum of 10 years. The research data will then be fully anonymised without the code link and securely archived or destroyed. Your consent form will be securely destroyed.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet: www.lancaster.ac.uk/research/data-protection
- by asking one of the research team on the contact details below
- by sending an email to the Information Governance Manager at information-governance@lancaster.ac.uk, or
- by ringing Lancaster University and asking to speak to the Information Governance Manager on +44 (0)1524 65201.

Who has reviewed the project?

This study has been reviewed and approved by the Health Research Authority and Health and Care Research Wales. It was review by the North West - Greater Manchester West NHS Research Ethics Committee and given a favourable opinion.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the principal investigator or a UHMBT research department representative:

UHMBT Principal Investigator
Dr Timothy Gatheral
Email: timothy.gatheral@mbht.nhs.uk
Phone: 01524591376

UHMBT research department representative
Kerry Simpson
Email: Kerry.simpson@mbht.nhs.uk
Phone: 01524512189

If you would like to know about the results of the study once it is completed, you can request a Final Study Report from the chief investigator:

Chief Investigator
Dr Lucy Jackson-Jones
Email: l.jackson-jones@lancaster.ac.uk

What happens if I am harmed as a result of taking part?

Lancaster University holds appropriate indemnity cover which includes but is not limited to Public Liability, Professional Indemnity and Employers Liability Insurance. If you are harmed whilst taking part in this study as a result of negligence by Lancaster University or its staff members, you may have grounds for legal action and should obtain independent legal advice. Non-negligent harm is not covered, and any claims that arise may be referred to the insurance provider for assessment. Should you require more information on the indemnity cover that Lancaster University holds, please contact the chief investigator, whose details are given above.

If you are harmed whilst taking part in this study as a result of actions undertaken by the NHS or its staff members, you may have grounds for legal action, but should contact the NHS trust where you took part to discuss this further.

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to a researcher, you can contact:

Dr Jemma Kerns
Director of Research, Lancaster Medical School
Email: j.kerns@lancaster.ac.uk

If you wish to speak to someone independent of Lancaster Medical School, then you can contact:

Professor Steven Jones
Chair of FHM REC
Email: s.jones7@lancaster.ac.uk
Faculty of Health and Medicine
Lancaster University
Lancaster
LA1 4YW

If you wish to make a complaint to the NHS Trust where you took part, you can contact:

Patient Advice and Liaison Service
Telephone: 01539 715577 - 24 hour line for all hospital sites. This is an answerphone only service; you will receive a call back during office hours.
Email: PALS@mbht.nhs.uk
Face to face: Bookable by telephoning 01539 715577.

Thank you for taking the time to read this information sheet.