Participant Information Sheet

LungSpy

Probing Molecular Signatures in Human Lung Disease Using Novel Optical Technologies

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Bronchoscopy is a procedure that allows the clinical care team to look at your lungs. During a bronchoscopy, a thin tube with a camera at the end, called a bronchoscope, is passed through the mouth or nose and moved down the throat and into the airways. It helps to investigate, diagnose and treat certain conditions affecting the lungs.

This study aims to investigate whether new technology can be used to explore your lung in greater detail than a standard bronchoscopy. Our imaging technology is made up an imaging fibre (small camera) and imaging systems (video equipment) to enable us to see deep into the lungs during a bronchoscopy procedure (see Figure 1 below). We would like to use one of two types of imaging systems we have developed.

We may also use very small volumes of liquid imaging agents (we call them Smartprobes), these would be passed down part of the imaging fibre into the lung. Smartprobes are designed to “light up” when they come into contact with infection or inflammation. The Smartprobes would be used in areas where the clinical team suspect that there may be infection or inflammation but also in areas of your lungs where none are suspected.

We hope results from this trial will help us determine whether the imaging technologies described above can differentiate between healthy and damaged or diseased tissue in the lung. In the future, we hope this technology can be used to rapidly and effectively diagnose patients with lung disease.

Why have I been invited to take part?

You have been asked to take part because you are currently being seen by medical staff in the Royal Infirmary of Edinburgh as part of ongoing investigations and have been advised to have a bronchoscopy as part of your clinical care. We will always try to ensure that the research part of the bronchoscopy is performed during the routine bronchoscopy requested by your clinical team. However, we may ask you to have a research only bronchoscopy. This is entirely up to you and

you can decline without giving any reason. The results from the research part/research only bronchoscopy will not be used to guide your clinical care.

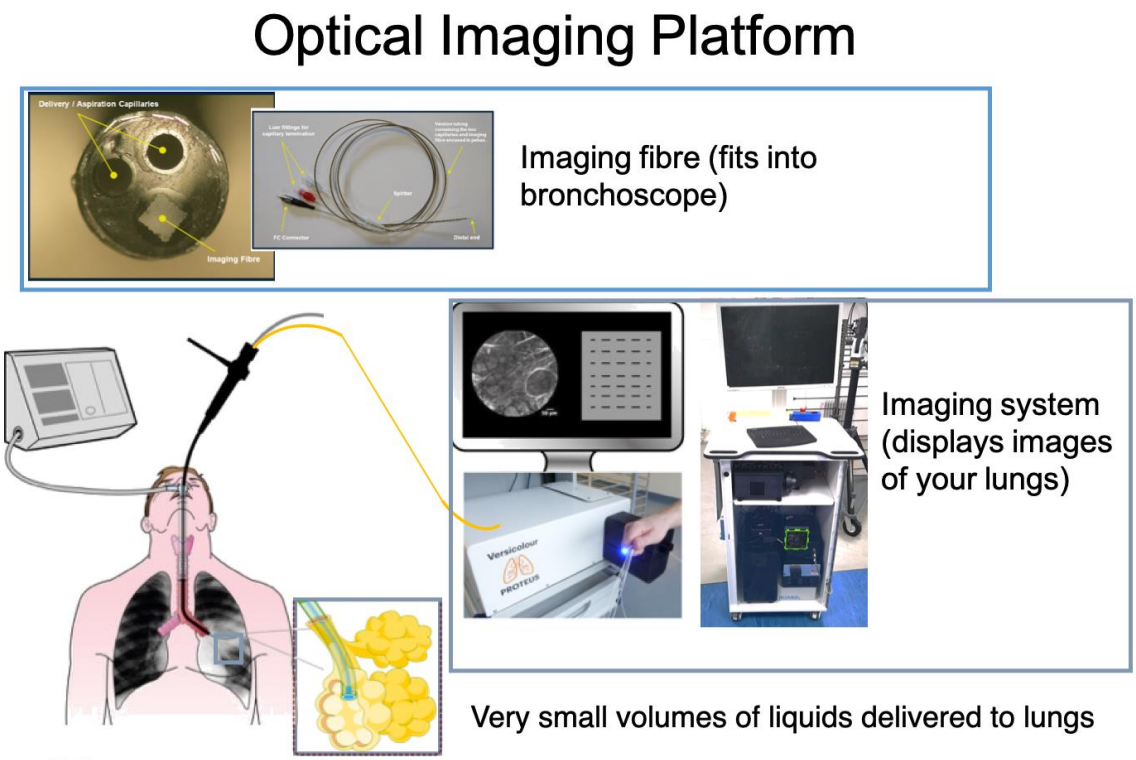

Figure 1: Bronchoscopy procedure with imaging fibre, imaging system and Smartprobes.

Do I have to take part?

No, it is up to you to decide whether or not to take part.

You can take as long as you need to decide whether or not to take part. Please feel free to discuss the trial with your clinical care team, friends and family.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

Consent and Screening

You have been provided with this information sheet to read and keep, and a member of the research team, either a doctor or a nurse, will discuss the study with you, allowing you time to ask any questions you may have. If after reading the information sheet and discussing the research study, you decide that you wish to take part, we will ask you to sign a consent form.

Once the consent form has been signed, the research team will confirm if you are eligible to take part in the study. We will collect some relevant data from you and from your medical notes. This will include some personal data such as name, date of birth and Community Health Index (CHI) number. The CHI number will be used for administration of the trial and to check your clinical results. We will

also record details of your medical history and conduct a cardiorespiratory examination (this will include checking your blood pressure, pulse, temperature, breathing and listening to your chest).

If you are female and of child bearing potential, we will perform a urine pregnancy test.

As part of the screening visit we will discuss a suitable date and time for the bronchoscopy procedure. Wherever possible, the research team will schedule the research procedure to take place during a bronchoscopy that you are already scheduled to undergo.

All screening and research procedures will take place at the Royal Infirmary of Edinburgh.

Day of Procedure

The research procedure will be scheduled for as soon as possible after the screening visit and may be the same day. The research procedure and what will happen pre and post procedure is outlined below.

Chest x-ray (unless a suitable x-ray has been taken in the previous 2 months)

Cardiorespiratory exam - this will include checking your blood pressure, pulse, temperature, breathing and listening to your chest (if > 7 days since screening)

Urine pregnancy test (unless screening and research procedure are on the same day)

Preparation for the bronchoscopy: you will be made comfortable on a bed, usually lying flat. You will be given oxygen to breathe through your nose and a sedative injection into a vein in your arm. A local anaesthetic will be applied to the back of your throat. Once the area is numb, the bronchoscopy procedure will be performed.

Bronchoscopy research procedure

- The bronchoscope will be navigated into your lungs
- A camera will be passed down the bronchoscope to the areas of interest
- Small amounts of Smartprobes (less than a teaspoon of fluid) passed down a thin tube beside the camera into your lungs
- Images of your lungs will be captured by the camera onto the video equipment (imaging system)
- The imaging and fluid delivery may be repeated in different areas of your lungs

As part of your bronchoscopy, your clinical team and the research team may need to collect some fluid samples from your lungs - this is called a **bronchoalveolar lavage** or BAL for short. It involves flushing some saline through the bronchoscope and collecting a fluid sample.

A **microlavage** (similar to a BAL but using very small (< 1ml) volumes of fluid) may be performed in the areas imaged

Post procedure monitoring and examination (this will include checking your blood pressure, pulse, temperature, breathing and listening to your chest) and checking that you feel ok after the procedure .You may also require a chest x-ray.

Discharge if the research team are happy with the post procedure checks;
- **in-patient:** you will return to your ward and the decision to discharge you from the hospital will be made by your clinical care team
- **out-patient:** you may need to remain in outpatients' a little longer under the supervision of the clinical care team. Otherwise you will be discharged home.

24 hours after the bronchoscopy is complete, a member of the research team will contact you to see how you are. If you are in hospital, you will be visited on the ward. If you have been discharged home, you will be contacted by telephone.

Provided all is well, your involvement in the study will be complete after the 24 hour follow-up.

Figure 2: Summary of research involvement

Your clinical team may also need to obtain samples as part of your clinical care (e.g. blood, biopsy, fluid samples). Where possible, the research team will request any surplus quantities of these clinical samples.

We will record and store the images captured during the procedure. This will allow us to examine the images in detail afterwards.

The bronchoscopy procedure will take approximately 25-30 minutes to perform. The research procedure may lengthen the procedure by up to 25 minutes.

Is there anything I need to do or avoid?

If you agree to take part in the study, you will not need to do anything differently. You will be advised by the clinical team if there are any specific instructions to follow prior to the bronchoscopy procedure.

What are the possible benefits of taking part?

We are testing these new imaging technologies to see if they can help clinicians distinguish between healthy and diseased lung tissue. The information we gain from this study will help us improve our understanding of lung disease and inform future development of the systems.

What are the possible disadvantages of taking part?

This is the first time that the imaging fibre (camera) has been used in humans. It has been tested extensively in the laboratory to image lung cancer, infection and inflammation. The imaging fibre comes into direct contact with the lung, therefore prior to being tested in humans, it has undergone rigorous safety testing to ensure that the materials used will not cause any harm. The imaging fibre will only be operated by a qualified member of the research team.

The imaging systems (video equipment) will not come into direct contact with you. There are two possible systems that can be utilised during the study and the decision on which is best suited to you will be made by the research clinician. This is the first time one of the systems has been used in humans. The other system has been tested in two previous human research studies. Both systems have undergone all the required testing to ensure they are safe for use and will only be operated by qualified members of the research team.

We do not anticipate any adverse reactions to the Smartprobes that may be used in this study - only a very small amount of the Smartprobe will be used (also known as a microdose) and we have conducted extensive toxicology studies to demonstrate their safety for use in humans. Two out of the three Smartprobes have already been tested in humans and no side effects were experienced. If, however, an unexpected reaction was to occur, all of the necessary treatments are available in the hospital.

The risks of bronchoscopy are very low, with complications occurring in less than 1-2% of procedures. The main risk is air becoming trapped next to the lung which may require a chest drain. This is extremely rare. In addition, people can commonly experience cough, fever and sore throats within 24 hours following bronchoscopy. You will be advised by your clinical team how to manage these symptoms if they arise.

If you take part in this study you may have two chest x-rays (one before and one after the bronchoscopy). You normally would not have these x-rays if you were not taking part in the research. These procedures use ionising radiation to form images of your body and provide your doctor with clinical information. Ionising radiation can cause cell damage that may, after many years

or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to you. The radiation exposure associated with these two additional x-rays is equivalent to approximately 7 days natural background radiation in the UK.

What if there are any problems?

If you have a concern about any aspect of this study please contact the LungSpy research team on 0131 242 9180 or THT-Clinical@ed.ac.uk and we will answer any questions you may have.

Our technology has been shown to be safe. Also, performing a bronchoscopy has very little risk. However, as for all clinical studies we are obliged to mention that unseen risks can accompany any procedure. In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without explanation.
Your decision to withdraw from the study will not affect the standard of any treatment you receive now or in the future.

If you decide to withdraw from the study, we will ask you to complete a withdrawal form. On the form you will have 2 options for your withdrawal:

1. Withdrawal from study intervention (e.g. use of technologies during your bronchoscopy) with continued collection of clinical and safety data.
2. Withdrawal from all aspects of the study with continued use of data collected up to that point.

Is there any re-imbursement for taking part?

If taking part in this research results in additional out of pocket expenses, we are able to cover your travel costs such as reasonable bus/taxi fares and car parking fees.

The results of this study may be used for the future commercial development of a new test. Your participation in this study will not entitle you to benefit financially from the company developing the test.

What happens when the study is finished?

Following completion of the 24 hour follow-up with the research team, your involvement in the study will end.

The research team will not be able to provide individual research results. Should you wish to find out more about the overall results of the trial, please contact the research team (THT-Clinical@ed.ac.uk) referencing Lung Spy. You can request this information is shared by telephone, email or in person.

What will happen to the samples collected?

Pictures and images taken from inside the lungs will be kept for analysis and presentation. You will not be recognised from these images and they will not contain any identifiable information (e.g. name, date of birth).

Microlavage samples obtained by the research team will be analysed in the laboratory at the University of Edinburgh.

Where samples (e.g. blood, biopsy, fluid) have been collected by your clinical care team, we ask your permission to retain any surplus quantities of these samples for storage and analysis at the University of Edinburgh. All such samples will be stored according to your study participant number (i.e. will be de-identified).

We may send your anonymised samples/images to external institutions as part of data analysis. None of your identifiable information will be sent to other parties.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. For details on what data will be held about you and who will hold and store this information please refer to the Data Protection Information Sheet.

With your permission, we shall inform your GP in writing that you have taken part in this trial.

We also ask for permission to access your medical records following the bronchoscopy procedure to permit comparison of the research results with results from your clinical tests.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

What will happen to the results of the study?

It is our intention that the results of the study will be published in scientific/medical journals and presented at medical and scientific meetings.

You will not be identifiable from any published results.

Your personal data will not be transferred to any external individuals or organisations outside of the University of Edinburgh or NHS Lothian. However, with your consent we may wish to share de-identified data with funders, collaborators, commercial companies and publicly available resources.

Who is organising and funding the research?

This study has been organised by the THT Study Management Group led by Professor Kev Dhaliwal and is co-sponsored by the University of Edinburgh and NHS Lothian.

The trial is funded by multiple funding bodies.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the safety, rights, wellbeing and dignity of patients. This study has been reviewed and given a favourable ethical opinion by the <<XXXX Ethics Committee>> and the NHS Lothian Research and Development Department.

The UK regulator for medicines and medical devices (Medicines and Healthcare Products Regulatory Agency, MHRA) have also reviewed and authorised this study.

Researcher Contact Details

If you have any further questions about the study please contact the study team: THT-Clinical@ed.ac.uk

The lead clinician is Professor Kev Dhaliwal and he can be contacted at Kev.Dhaliwal@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Professor Adam Hill by email Adam.Hill@ed.ac.uk

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team
2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk
0131 536 3370

Data Protection

The EU General Data Protection Regulation (GDPR), along with the UK Data Protection Act, governs the processing (holding or use) of personal data in the UK.

If you take part in this research study the information below details what data will be held about you and who will hold or store this.

University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will use information from you and/or 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. The co-sponsors will keep identifiable information about you for 15 years after the study has finished.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. 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.

Providing personal data indirectly e.g. from your medical records

The University of Edinburgh will collect information about you for this research study from your medical records. This information will include your name / Community Health Index (CHI) number/ email address / telephone number / sex / date of birth and health information, which is regarded as a special category of information. We will use this information to track your health status and allow the trial team can get more detailed or longer term information about the effects of the study treatments on your health.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

CONSENT FORM

Participant ID: ☐ **CHI:** ☐ Tel No: ☐

Please **initial** box

1. I confirm that I have read and understand the information sheet (Version 1, 11June2021) including the data rotection information for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
3. I give permission for the research team to access my medical records for the purposes of this research study (including accessing my clinical results relevant to this trial). ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. I give permission for my personal information (including name, date of birth and consent form) to be passed to the University of Edinburgh for administration of the study. ☐
6. I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐
8. I understand that data collected about me during the study may be converted to anonymised data and may be shared with external funders, commercial companies, collaborators and/or for publications. ☐
9. I agree to my de-identified data being used in future studies. Yes ☐ No ☐
10. I agree to my de-identified tissue being used in future studies and for this tissue to be sent externally for analysis. Yes ☐ No ☐
11. I understand that the data generated and tissue collected during this study may be used for future commercial development of products and I will not benefit financially from this. ☐
12. I agree to take part in the above study. ☐

Name of Person Giving Consent	**Date**	**Signature**

Name of Person Receiving Consent	**Date**	**Signature**

1x original – Site File **1x copy – to Participant** **1x copy – into medical record**