Translational
Healthcare Technologies

Safety and Feasibility of a Novel Device System for Tissue Visualisation and Characterisation

Participant Information Sheet

The Precision Lung Study

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Document Control Sheet

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Document Review

Role	Organization	Name	Signature	Date
Senior Clinical Project Manager	University of Edinburgh	Jean Antonelli		
Senior Research Nurse	NHS Lothian	Katie Hamilton		

Document Approval

Role	Organization	Name	Signature	Date
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This document is valid from the date of the final signature in the table above

Participant Information Sheet

The Precision Lung Study

Safety and Feasibility of a Novel Device System for Tissue Visualisation and Characterisation

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 and why have I been invited to take part?

When someone has symptoms that indicate a potential lung condition (e.g., asthma, COPD, cancer, pneumonia etc), a number of lung health tests will be carried out to help support a diagnosis. For a doctor to determine the specific cause of the disorder, they often request a scan of the lungs. Should the doctor spot something on the scan that needs further investigation, like a mass or a build-up of fluid, a bronchoscopy is usually required.

You are being asked to consider taking part because you are currently being seen by medical staff in the Royal Infirmary of Edinburgh to have tests carried out to determine if you have a lung disease. One of the tests that your doctor would like to carry out is a bronchoscopy to see what is happening in your lungs. Information about the bronchoscopy procedure will be provided by your clinical care team. This information sheet will discuss the Precision Lung Study, and the additional activities involved should you agree to participate.

Precision Lung is a research study taking place at the Royal Infirmary of Edinburgh. It aims to test the safety and feasibility of two new imaging technologies – **an imaging device** called Eyes on Target (EoT), which has a miniaturised fibre-optic camera and a 1.2mm working channel (*see Figure 1 – magnified image of fibre end)*. This is no larger than the fibre that would be used clinically. The EoT fibre connects to, and works with, **a new imaging system** called KronoScan.

When these technologies are used together, they allow doctors to see deep inside the lungs during a standard clinical bronchoscopy.

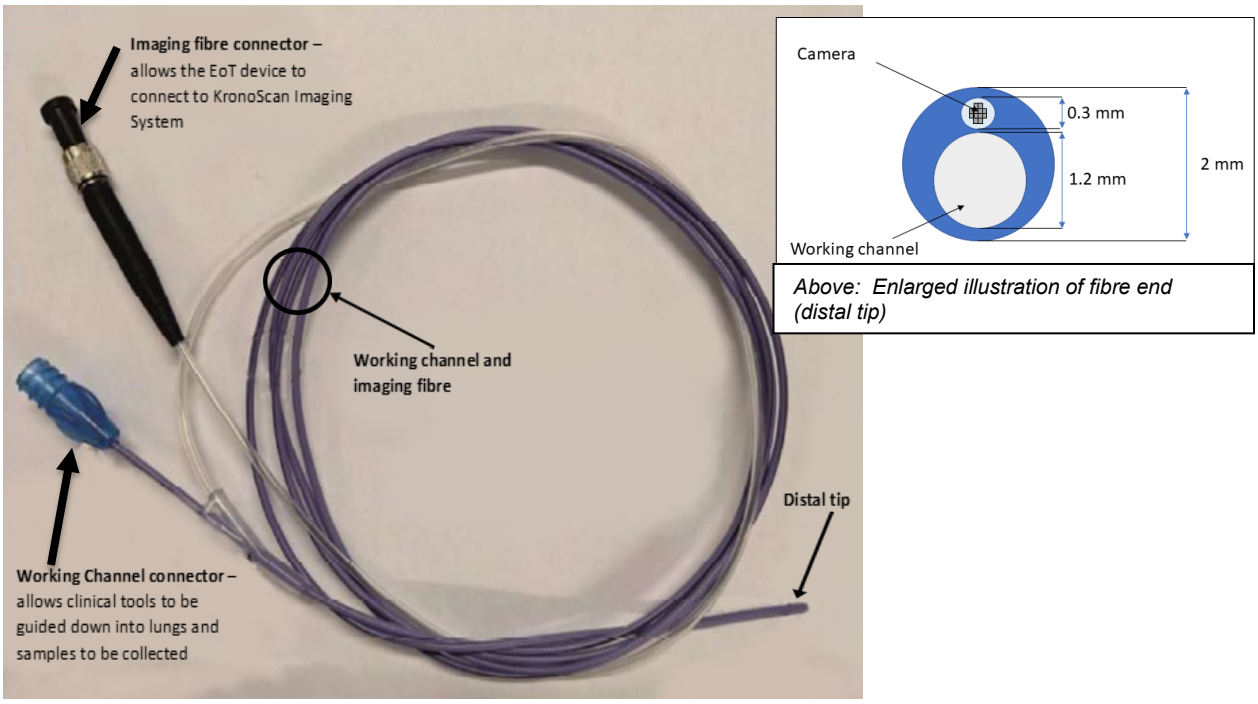

Figure 1 - Eyes on Target device with illustration of distal tip showing diameters of each channel

Alt text: *a picture of the Eyes on Target device, with relevant parts labelled, insert picture shows an enlarged illustration of the distal tip of the EoT device with sizes of working channel and imaging fibre (camera) detailed.*

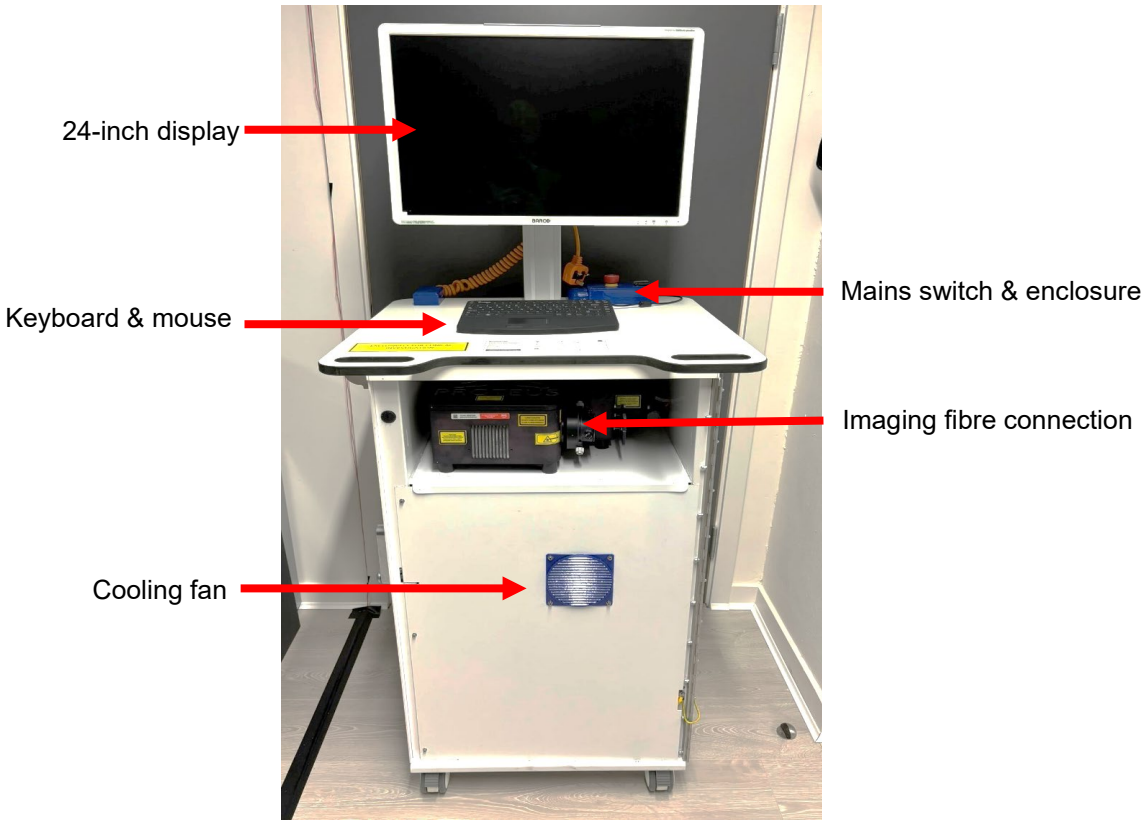

Figure 2- KronoScan Imaging System

Alt text: *a picture of the KronoScan Imaging system showing the display screen, the mouse and keyboard, where the imaging fibre (EoT) connects, all housed on the purpose-built trolley.*

The building blocks that make up our tissues and organs behave differently if they are healthy or diseased. These very subtle differences can be seen when an area of the lung is lit up using rapid pulses of light.

Using the EoT device, light can be transmitted deep inside the lungs and allow images to be captured via the camera. The images are then displayed on the screen of the KronoScan system, this allows the doctor to spot potentially diseased lung tissue, which would otherwise be invisible to the naked eye (*see Figure 3*). We also hope that this technology will allow the doctor to take a more accurate tissue sample as the camera (EoT) can remain in place whilst sampling, something not possible with currently available tools.

This study will be the first time the EoT device is being used in humans, but it has undergone extensive (pre-clinical) testing in the lab. KronoScan has been used in a previous study with no safety concerns arising.

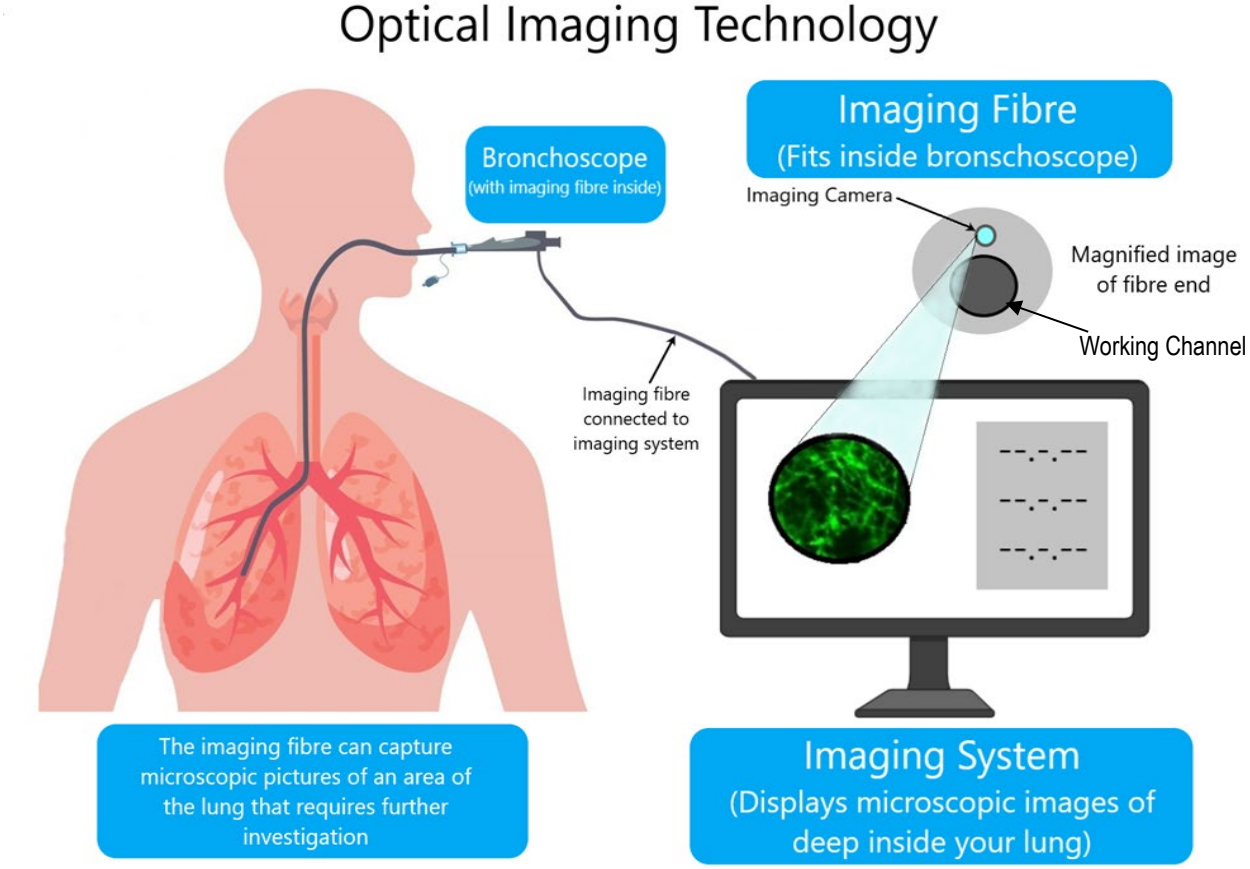

Figure 1- Optical technology used in the research procedure

Alt text: *On the left is an illustration of a human upper body with lungs shown and a bronchoscope inserted through the mouth down into the lungs. On the right is an illustration of a computer screen showing a green circle on the display which represents what the imaging camera captures when inside the lung. Above the computer screen is a close-up diagram showing a magnified image of the fibre end which fits inside the bronchoscope. This magnified image shows the camera and the working channel.*

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign the attached 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. A clinically trained member of the research team 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. The consent form is likely to be signed on the day of your planned bronchoscopy, but the information sheet has been provided ahead of time to allow you time to read and consider whether you would like to participate or not.

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 your name, date of birth, sex assigned at birth, telephone number and Community Health Index (CHI) number. Your CHI number will be used for administration of the study and to check your clinical results.

If you are a female of child bearing potential (*typically* aged between 16-50), we also need to confirm that you are not pregnant, so we will carry out a urine pregnancy test.

We will also record details of your medical history and the results from your most recent chest scan. We will listen to your chest with a stethoscope (known as a cardiorespiratory assessment) and check your blood pressure, pulse, temperature, and breathing rate. If you have not had a CT scan of your lungs in the last 3 months, your clinical team may request that one is completed prior to your bronchoscopy. The research team would like to review results of any CT scan or Chest X-ray taken as part of your clinical care.

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

During the Procedure

The bronchoscopy will be scheduled by your doctor/clinical care team. The screening visit will usually be the same day, prior to the bronchoscopy starting.

The research part of the bronchoscopy will be performed during your clinically indicated bronchoscopy. As part of the research procedure, the EoT imaging device will be guided down the inside of the bronchoscope to image deep inside your lungs. These images will be displayed on the KronoScan imaging system.

After imaging is complete, a number of very small samples will be taken from the area(s) of your lung where the suspected disease is, using routinely used, clinically approved tools. These samples may be taken whilst the EoT imaging device remains inside the bronchoscope, and/or

once it has been removed. The types and volume of samples taken will be decided by the clinician according to what they deem to be the most appropriate to provide you with a diagnosis.

Sample types may include, but are not limited to, biopsies, bronchial washing/lavage, needle aspirates and brushings (all types of sample collection that may be used during a routine bronchoscopy procedure). The volume of samples will also be decided according to clinical need, but could include up to 40ml of fluid (bronchial washings/lavages/aspirates), 3 brushings and/or 5 biopsy samples. These samples will be included in the samples sent to the NHS Lothian laboratory to provide you with a diagnosis (all samples collected are considered clinical samples for the purpose of diagnosis)

The devices do not provide a diagnosis, but instead help in the collection of samples that will then be analysed, along with any routine clinical samples, to allow your doctor to make a diagnosis. All samples collected will be used to provide your diagnosis.

Usually, the research element of the bronchoscopy, including sampling, will happen first but your clinician may decide at the time of the procedure to do the routine clinical sampling first.

Throughout the procedure, your condition will be monitored as per standard clinical.

The research procedure may lengthen the procedure by up to 25 minutes.

After the Procedure

Post-bronchoscopy care and discharge (home or back to the ward) will be done in accordance with standard clinical practice and under the direction of your doctor, this will include having a chest x-ray carried out following the bronchoscopy (before discharge home).

At approximately one hour after the bronchoscopy has been completed, a clinically trained and delegated member of the research team will conduct an assessment which records your pulse, blood pressure, temperature, and respiratory rate (clinical observations), if not completed as part of your standard clinical care.

This assessment is repeated approximately 4 hours after the bronchoscopy being completed (or prior to discharge home if this is sooner). In addition, a clinically trained member of the research team will carry out a further cardiorespiratory assessment. The cardiorespiratory assessment is extra to what will happen as part of standard clinical care following your bronchoscopy.

Follow-Up and End of Study Involvement

Approximately 24 hours and 7 days after the bronchoscopy procedure, you will have a follow-up call or, if you remain in hospital, a member of the study team will visit you on the ward. During these follow-ups, a member of the research team will ask how you have been feeling since the research procedure, and record details of any adverse events you may have experienced since the last visit. Completion of the 7-day visit marks the end of your involvement in the study - total duration of participation in this study is 1 week.

If the study team fail to make contact with you at a scheduled follow-up call, they will make 3 further attempts. If possible, a message will be left asking for you to call the study team back.

If contact is not achieved within 2 calendar days of the final study visit (Day 7 post bronchoscopy) we will record you as ‘Lost to Follow-up’ and no further attempts will be made. However, if you

wish, you can contact the research team using 0131 651 8294 or THT-Clinical@ed.ac.uk and ask for the Precision Lung team.

Where the team have been unable to contact you for either of the scheduled follow up visits/calls, we will review your electronic health records to see if any events (for example, re-admission to hospital) have been recorded.

If during either of the follow-up visits/calls, any adverse events are reported, the research team will aim to follow up with you until resolved or the study is complete, whichever comes first.

Expenses / Costs

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 process of study involvement is outlined in **Figure 4** below.

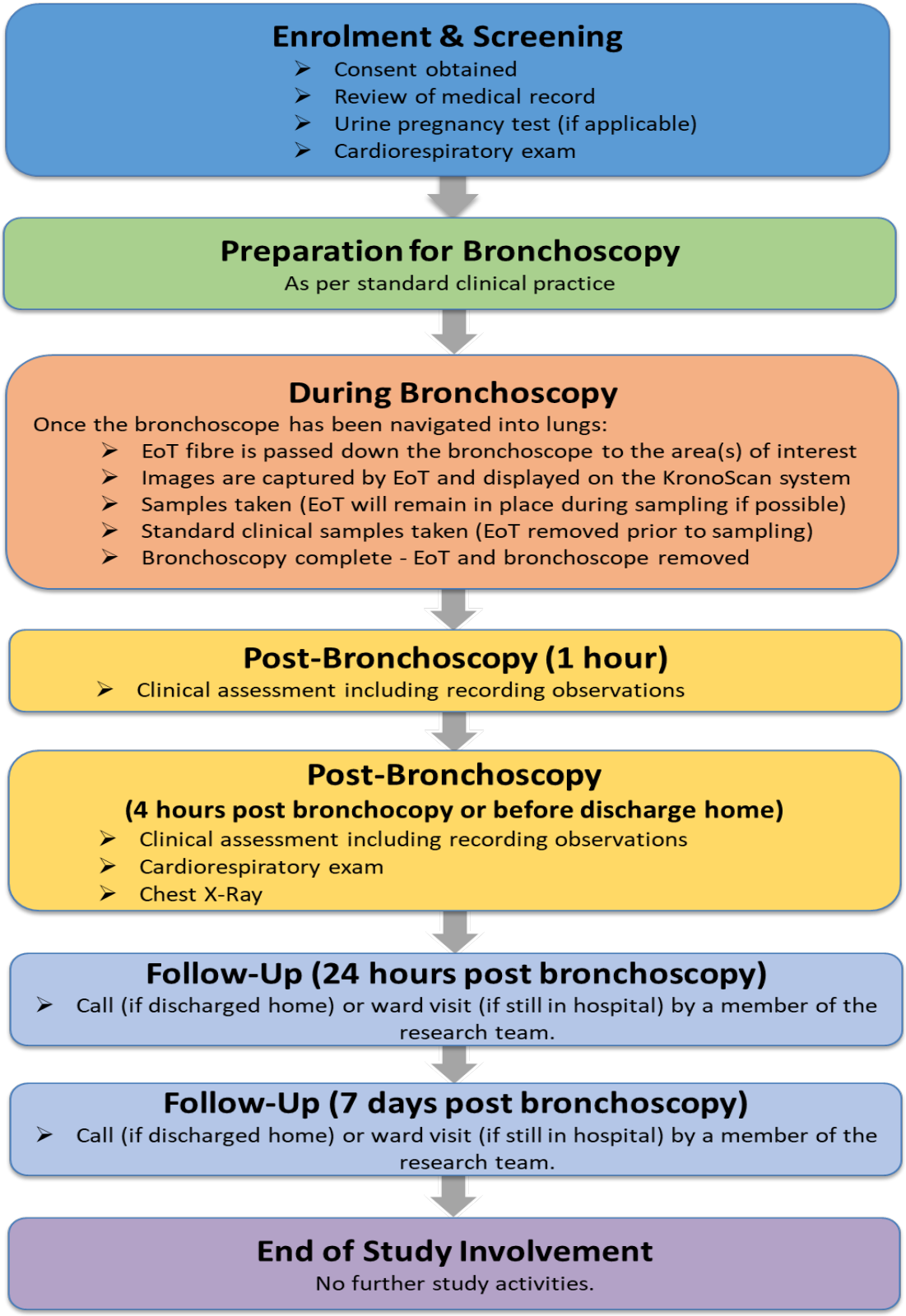

Figure 4: Summary of Research Involvement

Alt text: *Flow diagram showing the different visits (study time points) for participants, and summarises the activities that will be undertaken at each.*

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 before or after the bronchoscopy procedure.

What are the possible benefits of taking part?

While there are no direct benefits to you taking part, we are testing these new imaging technologies to see if they can help doctors distinguish between healthy and diseased lung tissue in order to take a more accurate tissue sample (biopsy) in the future. It is hoped that these technologies will accelerate the time taken to reach an accurate diagnosis, thereby informing treatment plans and transforming patient management and care.

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 commercial development of this test.

What are the possible disadvantages of taking part?

This is the first time that the EoT imaging fibre (camera) has been used in humans but it has undergone extensive pre-clinical testing. EoT has not been used in a clinical setting, therefore no adverse events have been reported.

During the development of the device, identified risks have been addressed with measures put in place to remove or minimise the likelihood of these risks happening. Collapsed lung (pneumothorax) is when air becomes trapped next to the lung. Pneumothorax has been assessed as an unlikely/rare risk from use of the EoT device during a bronchoscopy. This has been highlighted as a risk from the bronchoscopy procedure itself (occurring in less than 1-2% of patients) and is not limited to the use of the EoT device. To minimise this risk, the EoT The imaging fibre will only be operated used by an appropriately trained qualified doctor who is a clinical member of the research team.

The KronoScan imaging system (video equipment) will not come into direct contact with you. This system has been used previously in a research study (LungSpy MHRA Ref: CI/2021/0061/GB) without raising any concerns and has undergone all the required testing to ensure that it is safe for use. It will only be operated by qualified members of the research team.

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. We will rule this out by scanning your chest before and after the procedure.

Following a bronchoscopy, it is quite common to have a sore throat. Before the procedure starts, you will be given sedation as well as anaesthetic being sprayed to the back of your throat to numb it, this will help to reduce any potential discomfort you may experience afterwards. These details are explained in greater detail in the bronchoscopy information sheet provided to you by the NHS.

In addition, people can commonly experience cough, and fever, within 24 hours following bronchoscopy. You will be advised by your clinical team how to manage these symptoms if they arise, but may advise taking simple analgesia such as paracetamol.

What if there are any problems?

If you have a concern about any aspect of this study, please contact 0131 651 8294 or THT-Clinical@ed.ac.uk and we will do our best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal NHS Complaints 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 any treatment you receive now or in the future.**

If you decide to withdraw from the study, we will complete a withdrawal form as part of the study management process. As part of this process, we will ask for a reason for withdrawal, you do not have to provide this, but it may be useful for the research team to understand your reasons for withdrawing.

Once you have joined the study (provided consent), you will have the following withdrawal options:

1. If you request to withdraw from the research study, for any reason, including in the unlikely event that you lose of capacity, **prior to the bronchoscopy** we will withdraw you from the study and you will receive no further contact from the research team. No further data will be collected.
2. If you request to withdraw from the research study **after you have undergone your bronchoscopy**, you will have the following withdrawal options:
    a. No further contact from the study team (no follow up visits) but we would like to continue to collect relevant clinical and safety data from your NHS Lothian electronic health record. In the unlikely event that you lose capacity following the bronchoscopy, but before completion of all follow up visits, you will be withdrawn from the study in accordance with this option.
    b. Withdrawal from **all** aspects of the study including review of electronic health records for clinical and safety data relevant to this clinical investigation.

Following all requests to withdraw, use of the data already collected will be discussed and your decision documented as part of the withdrawal process. We may not be able to delete or remove the data already collected, and ability to do so would, in part, depend on how soon after the data was collected that the withdrawal request is made. For example, if your deidentified data has already been included in any analysis or we have already reported the results of the clinical investigation. Where data cannot be removed from the data set, a full explanation will be provided to you.

What happens when the study is finished?

Following completion of the 7-day follow-up with the research team, your involvement in the study will end.

The research team will compare the findings obtained from the research samples and images with the results from the routine clinical samples. However, all samples (including those collected using or guided by the imaging fibre) will be analysed by the Pathology team at the Royal Infirmary of Edinburgh and used to support your clinical diagnosis.

The research team will not be able to provide individual research results. A summary of the results will be published on our website when available (https://psh.ac.uk/). Should you wish to find out more about the overall results of the study, please contact the research team by email (THT-Clinical@ed.ac.uk) or by telephone on 0131 651 8294 referencing **Precision Lung**. You can request this information is shared by telephone, email, or in person.

Study data, including date of birth and sex assigned at birth, will be stored on a database under a participant number and retained at the University of Edinburgh's Institute for Regeneration and Repair (IRR). All study data will be archived securely in accordance with Sponsor requirements for a minimum of 10 years. When the minimum retention period has elapsed, study documentation will not be destroyed without prior permission from the Sponsor.

Your personal data (including initials, name, telephone number, and consent form) will be securely stored by the research team for a period of 3 years. Personal identifiable 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.

With your consent, we may use your de-identified data and/or tissue collected from this study for future studies that have been reviewed by ethics and received a favourable opinion. We will not do so without your consent.

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.

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

How will we use information about you?

We will need to use information from your medical records for this research project.

We will collect your Community Health Index (CHI) number or NHS number. Note that the CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number or NHS number is being collected to allow us to check your clinical results from the bronchoscopy procedure and will be used for administration of the study, including follow up visits as detailed above.

Other personal identifiable information collected will include your name, telephone number, sex assigned at birth, date of birth, and health information. 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 assigned instead.

We will keep all information about you safe and secure in the Chief Investigator's Research Office in the Royal Infirmary of Edinburgh, or on a secure, University of Edinburgh server (electronic data). In addition, we will hold your name, telephone number, and CHI number on a password protected electronic file held on the NHS server. This is to allow the research team to carry out follow-up phone calls. Access to the file will be restricted to the team members responsible for carrying out these visits. This file will be deleted at end of the study.

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). Images obtained will be stored on University of Edinburgh systems and labelled by participant number and image number only.

The optical images obtained will be reviewed using specific image viewer software. Image analysis will be carried out by appropriately trained personnel. Individuals performing image analysis will be blinded to clinical results (e.g. pathology results).

Where samples have been collected by your clinical care team, we ask your permission to retain any surplus quantities of these samples for storage and analysis within the Institute for Regeneration and Repair at the University of Edinburgh. All samples will be de-identified and stored according to your study participant number.

On completion of the analysis of any samples by the research team, any tissue remaining will be returned to NHS Lothian for storage in the NHS Biorepository, as per standard practice for samples collected during a bronchoscopy.

We may send your de-identified samples and images (linked to a unique identification number only) to external institutions as part of data analysis. None of your identifiable information will be sent to other parties. Where data is being shared with a third party, there will be an appropriate data sharing agreement between organisations to ensure your information is safe.

INTERNATIONAL TRANSFERS

Your data will not be shared outside the UK.

Once the study is finished, 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.

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 diagnosis from hospital records. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. You have the right to ask us to remove, change, or delete data we hold about you for the purposes of the study. 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.

If you agree to take part in this study, we will store your personal data including your contact details (name and telephone number) at the research office at the Royal Infirmary of Edinburgh,

NHS Lothian for administration of the study. Identifiable personal data, including your contact details, will be retained for 3 years.

The study database, as detailed above in the section *What happens when the study is finished?* will be held on the University of Edinburgh's secure server for a minimum of 10 years. After this period, the study data will be fully anonymised and archived in a secure University of Edinburgh research data archive or destroyed, subject to permission from the sponsor.

If you agree to take part in this study, you will have the option for your deidentified data saved from this study, to be used in future research that has been reviewed by ethics and received a favourable opinion.

You will also be given the option to allow the research team (within the sponsoring organisation) to use your saved contact details to contact you about participation in other d research studies that have been reviewed by ethics and received a favourable opinion. This is optional and you will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

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

You can find out more about how we use your information

- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to THT-Clinical@ed.ac.uk
- by sending an email or calling one of the co-sponsor data protection officers.

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

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.

Following this study, if the decision is made to commercially advance the technology, the commercial company funding this study (Prothea Technologies Ltd) may be given ownership of the results to allow this to happen.

You will not be identifiable from any published results.

Who is organising and funding the research?

This study has been developed by the Translational Healthcare Technologies (THT) Group, part of the University of Edinburgh.

The study is co-sponsored by the University of Edinburgh and NHS Lothian, they have responsibility for organising and managing the study, and ensuring that it is done so in an ethical and legal way.

The study is funded by Prothea Technologies Ltd. Prothea is responsible for developing the imaging fibres and systems.

One of the clinical investigators involved in this study (Dr Ahsan Akram) has a potential perceived conflict of interest as a shareholder and consultant for Prothea. Any potential perceived conflicts of interest have been considered and a conflict-of-interest management plan in place.

Who has reviewed the study?

The study proposal has been reviewed by a number of the THT team, as well as independent clinicians, and relevant members of the Prothea Technologies Team. Participant-facing documents have been reviewed by a patient representative.

We have had this information sheet (this document) reviewed by a patient representative, and changes were made based on their feedback. We also plan to include patient representatives in membership of study committees where appropriate.

For a previous study (LungSpy, MHRA Ref: CI/2021/0061/GB) where the same imaging device was used, alongside an earlier version of the imaging fibre (Panoptes) we worked closely with members of the Breath Takers Support Group who fed into the design of the LungSpy study. Breath Takers is a peer support group for individuals with bronchiectasis and their carers. It aims to aid rehabilitation, improve quality of life, and promote awareness of bronchiectasis. This study follows the same design principles that were agreed for LungSpy.

Furthermore, we have another investigation planned that will use the same devices and recruit in the Intensive Care Unit (BAC2BAC Clinical Investigation – not yet approved). Patient representatives are involved in numerous ways for this BAC2BAC study including the study design and review of participant facing documents. Feedback from the BAC2BAC study have also been taken into consideration when developing the Precision Lung Clinical Investigation.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from **South East Scotland REC 02**. NHS Management Approval has also been given. 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 Dr Nik Hirani and he can be contacted at N.Hirani@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact **Dr Tom Craven, Consultant in Critical Care, Royal Infirmary of Edinburgh at** thomas.craven@nhs.scot.

Additionally, you can also contact the Patient Advice and Support Service (PASS) which is an independent service, giving free, confidential information, advice and support to anyone who uses the NHS in Scotland. It aims to support patients, their carers and families in their dealings with the NHS and in other matters affecting their health. Visit https://www.cas.org.uk/pass to find your local office or phone 0800 917 2127.

Complaints

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

Patient Experience Team – NHS Lothian
Mainpoint
102 Westport
Edinburgh
EH3 9DN

By telephone
0131 536 3370 (open Mon-Fri, 9am to 2pm)

By email
LOTH.Feedback@nhs.scot

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/.