PARTICIPANT INFORMATION SHEET

FINE Study

Fibrosis Imaging in lu**N**g canc**E**r

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

What is the purpose of the study?

You will recently have had a diagnosis of lung cancer (presence of a tumour from the lung). During the diagnostic journey you may have had to undergo multiple imaging tests and scans which tell us information about the location and extent of the tumour. However, some more information about the biological activity of the tumour (the way the tumour works) could be useful. In many tumours there is a reaction called fibrosis which is a type of scarring and thickening of the tissue. There is growing evidence that the level of fibrosis in and around tumours may relate to how well the cancer responds to treatment.

Recently a new type of 'tracer' (a dye that is injected before a scan) called FAPI has been developed and in some patient groups with cancers has been shown to 'light up' areas of fibrosis on scans called PET scans so that the person taking the image can see them better. This helps to understand the degree of fibrosis in the tumour and the distribution of fibrosis in the body because of the tumour. However, we do not currently know if this related to the response to treatment in patients.

This study aims to investigate whether a FAPI-PET scan before treatment could help to indicate how effective the cancer treatment they received has been on the tumour. This would allow us in the future to decide which patients may need additional treatments targeting the fibrosis as well as the tumour itself by using this new scan.

Why have I been invited to take part?

At the present time you are on a pathway for the management of lung cancer and will either be scheduled for consideration of surgery OR for anti-cancer treatment against the cancer. We are asking permission to include you in this study where we would perform an additional PET scan before your treatment using the fibrosis tracer.

Do I have to take part?

No. It is up to you to decide whether you would like to take part in this research. If you would like to be involved, you will be given this information sheet to keep and asked to sign a consent form. The procedure (described below) is in addition to your standard care. All research related procedures, tests and follow ups will be performed by a member of the research team. If you decide to take part you are free to change your

mind at any time and without giving a reason. It is very important to note that if you think you do not want to be involved, then we shall fully understand and **this will not in any way alter your care, now or at any stage in the future.**

What will happen if I decide to take part?

If you agree to take part, you will be invited to discuss the details of the study with a member of the research team who will make sure you understand everything. We will review your clinical records including medical history, and investigations so far to confirm your eligibility for the study. If you are either pregnant or breastfeeding then you will not be able to take part in this study. You may be asked to take a pregnancy test if the possibility of pregnancy cannot be excluded. After consent is taken, we schedule you for a research PET scan.

The research involves a procedure called a PET scan (figure 1), which detects radioactivity from a tracer. As part of your diagnostic investigations, you may have had one of these already. However, here we are using a different 'radiotracer' which will tell us about the level of fibrosis activity in the body because of the tumour. You will have a small amount of the radiotracer (called 68Ga-FAPI) injected into your arm, which takes 60-120 minutes to travel and remain in the areas of interest. During this time, you will be asked to rest and will be monitored in our clinical research facility. When you are ready for your scan, you will be taken to the scanning room by a member of the research team. The PET-CT scanner is a large machine with a round, donut shaped hole in the middle and this machine will detect areas of activity in the body in 3 dimensions as well as a CT scan to allow us to define where those areas of activity are. You will be asked to lie on the scanner bed as the images are acquired. This usually takes 20-30 minutes but may vary at the time. If you need to speak to the doctor or radiographer during the scan you will be able to attract attention by pushing the patient buzzer. They will then speak to you over the intercom or come into the scanner room to speak to you.

Figure 1 PET CT scanner

Following the scan, you will return to the research facility. As the level of radiation exposure is very low you will not feel any effects and should be able to go home soon afterwards. We ask that you avoid close contact with other people for 8 hours after the injection of the radioactive tracer. In particular during this time you must avoid any contact with children and pregnant women. Please note that being at a distance of 1 metre away from them is fine.
We will also ask permission to take additional blood tests for research at the time of consent and/or your scan. The total amount of blood taken as part of this study will be approximately 20ml, which is equivalent to 4 teaspoons.

If you are undergoing surgery, then once the lung sample is removed from the body we will ask for a small part of this for research purposes.

We will ask for your permission to review your clinical record for up to a year following consent. This is to see how you are getting on and if you have had any further treatment and a review of your CT scans to assess the response to treatment. This will not require any further visits or contact on your part.

What are the possible disadvantages and risks of taking part?

As the PET scan is an additional scan to your routine care there is a small increase in the amount of radiation exposure (from CT scans and the use of radiotracers) that you would be exposed to compared to not taking part.

There is a small chance that the scan of your lungs will pick up an abnormality that we were not expecting to find. If this was to happen, we would explain the abnormal findings to the care team looking after you so they can speak to you about this and factor this into the treatment decisions.

If you take part in this study you will have a PET-CT scan. This exposure will be extra to those that you would have if you did not take part in the trial. This procedure uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. In patients with your current clinical condition, the chance of this happening to you is small.

The most important potential risk is of an allergic reaction to the tracer, which is very rare (serious allergic reactions occur in approximately 1 in 10,000 patients) and we have clear procedures for managing such reactions. There is also a small risk of bleeding, bruising and infection from the cannula insertion but we will follow a sterile procedure.

What are the potential benefits to me of taking part?

There will be no direct benefit to you, however, we believe the results of our work may bring potential benefits for patients diagnosed with lung cancer in the future.

Is there any reimbursement for taking part?

Any extra travel required to take part in this study will be fully reimbursed.

What happens if I change my mind?

You can change your mind at any point during the study. If you subsequently decide that you do not want to take part/continue in the study we would remove you from the study and destroy the data at your request.

What if something goes wrong?

We do not anticipate any adverse events or effects from being a part of this study. However, as for all clinical studies we are obliged to mention that unseen risks can accompany any procedure or agent. 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).

If you or your family wish to complain formally, this can be done through the NHS Complaints Procedure. Details can be obtained from the Patient Experience Team at Waverly Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, Tel: 0131 536 3370, Email: feedback@nhslothian.scot.nhs.uk.

What happens when the study is finished?

At the end of the research we will analyse all of the data collected, which will be anonymised. There is no follow up required from the study, your usual medical care will not change as part of the study and you will continue your routine care as part of the cancer pathway. If you agree, your anonymised data and images such as the PET-CT scans may be used for future lung cancer approved studies. You will not be identifiable in these data.

What will happen to any samples taken?

Blood samples taken at different time points (consent and/or day of scan) during the study will be stored with only an ID number. These blood samples will be used to compare the level of signal seen in the scan to various measurements in the blood to assess if there is any relationship present. On occasion we undertake gene testing of the samples to assess the specific cell types of their various gene levels. The results from the gene testing will not produce any clinically significant findings (any findings that could impact your care) and no feedback from results will be given.

Pictures and images will be kept for analysis and presentation. You will not be recognised from these images. With your permission we will use your data and blood/lung sample for future studies. As before, we will ensure that your identifiable information is removed from your data and samples.

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.

How will we use information about you?

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

This information will include your initials and CHI number. 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. We will keep all information about you safe and secure.
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.

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 NHS systems. 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. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team or
- by sending an email to dpo@ed.ac.uk

Can I access the results of the research?

Yes. Should you wish to know the overall results of the study please contact Dr Ahsan Akram, his contact details can be found at the end of this information sheet.

What will happen to the results of the research 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 identified in any published results.

Who is organising and funding this study?

This study has been co-sponsored by the University of Edinburgh and NHS Lothian and is being funded by Cancer Research UK. Neither the hospital nor the University receive payment if you are enrolled.

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 given a favourable opinion by the West of Scotland Research Ethics Committee 5.

Is there an independent doctor you can approach for further information?

Further information is available from Dr Gourab Choudhury, Consultant and Clinical Lead for Respiratory Medicine, Royal Infirmary of Edinburgh, Tel: 0131 536 1000. This person is not directly involved in this study so can give you independent advice if you need it.

Contact for further information

If you would like further information now or at any stage in the future, please do not hesitate to contact Dr Ahsan Akram by mail or telephone at:

Dr Ahsan Akram
CRUK Clinician Scientist and Honorary Consultant in Respiratory Medicine
Centre for Inflammation Research, Queen's Medical Research Institute, University of Edinburgh, Edinburgh,EH16 4TJ. Phone no. 0131 242 9810

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

PARTICIPANT CONSENT FORM

PARTICIPANT NUMBER: | | | | | | |

TO BE COMPLETED BY THE PARTICIPANT:	INITIALS
I confirm I have read the Information Sheet version _____ dated _____ for the above study. I have been given the opportunity to consider the information and ask questions. I have had these questions answered satisfactorily and have been given a copy of the information sheet to keep.	☐
I understand that taking part is entirely voluntary and I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
I understand that relevant sections of my medical records and data collected during the study may be looked at by individuals from the Sponsor (The University of Edinburgh and NHS Lothian), from the NHS Organisation or other authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
I give permission for my electronic patient records to be collected by the research team, without further visits in the future for the purpose of the study, including the results and images from any routinely undertaken follow up scans.	☐
I agree to my anonymised blood or lung sample and/or data being used in future studies	☐
I understand that the results of this study may be used for future commercial development of products/tests/treatments and that I will not benefit financially from this.	☐
I understand that there is a chance of finding an unexpected abnormality on the PET-CT scan and that I will be informed of this and appropriate further investigations will be arranged with my permission.	☐
I agree to take part in the above study	☐
I agree to my blood tests undergoing gene assessment (circle answer)	Yes No

Participant's signature:			
PRINT NAME:		Date :	
Name of person taking consent:			
PRINT NAME:		Date :	

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical records