Imperial College
London

Participant Information Sheet (PIS)

Part 1

Study Title: The UK Interstitial Lung Disease Post-COVID Study (UKILD-Post COVID)

Invitation to participate in the above study:

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully and discuss it with others if you wish. **We will go through the information sheet with you and answer any questions you have.**

Part 1 of the PIS tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of this study is to help us with our research into pulmonary fibrosis that develops following COVID-19. We are looking at the long-term effects of SARS-CoV-2 infection across a wide range of disease sufferers, from mild non-hospitalised patients up to hospitalized patients that needed intensive care support. We aim to understand why some people who had COVID-19 developed scarring of the lungs and why some people recover more quickly than others. As there are very large number of patients who have suffered a COVID 19 infection 2, it is very important to understand the how may patients may suffer from lung scarring and if it is a short or long term consequence of the disease.

Why have I been invited?

You have been invited to take part in this study because the clinical team looking after you suspects that you may have some residual changes in the lungs following COVID-19. We aim to recruit a total of approximately 2000 patients for the study.

Do I have to take part?

It is up to you to decide whether or not to take part. We will describe the study and go through this information sheet. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or not to take part will not affect the standard of care you receive.

What will happen to me if I take part? What do I have to do?

The clinical team who are caring for you will ask if you wish to be part of this study. Once you have had time to make a decision and agreded to take part with a signed concent the

clinical team will look at your medical record ans ask some questions about your health to asses if you are eligible to continue in the study. To participate in the study you will be required to participate in up to three clinic visits over a 12 month period; at 3 months post covid, 6 months and 12 months. The proceedures and time required for each visit are given in detail below;-

The clinical and research team will asses your recent medical history and take some measurments of height weight BMI unless such information is available in your current medical record, this will provide a baseline against which we can measure the rate of your recovery.

Visit 1 (~3 months) (Post COVID-19 infection patients)

1. Review of eligibility with participant
2. Obtain written informed consent
3. History and anthropometric measurements, e.g. height, weight, body mass index (BMI)
4. Blood sample (6-10 ml) collection
5. Pulmonary function test (20 minutes)
6. *Optional* 6-minute walk test (6MWT) (10 minutes)
7. Quality of Life questionnaire (SF-36) (10 minutes)
8. Clinical Frailty Scale (CFS) (5 minutes)
9. Personal health questionnaire (PHQ) (10 minutes)
10. Montreal Cognitive Assessment MOCA (10 minutes)
11. Dyspnea 12 score (10 minutes)
12. FACIT-F questionnaire (10 minutes)
13. EQ5D-5L (10 minutes)

Visit 2 (~6 months) (Post COVID-19 infection patients and matched controls)

All visit 1 assessments will be repeated.

Optional Visit 3 (~12 months) (Post COVID-19 infection patients)

All visit 1 assessments will be repeated.

Visits will be scheduled to take place over 1 day. Visit 2 is optional, visits 1 and 3 are obligatory.

The information from these proceedures including, but not limted to, CT scan, lung function and a walk test which are performed as part of routine NHS care, will be used as part of the study. This includes tests you may have as part of your ongoing clinical care held on national databases before, during participation and for the duration of the study can be shared with the study team where relevant. If you agree to participate in the research then we will also record

details of the results in a research database. Any details that we keep about you will be held confidentially. Your samples will be stored pseudonymously using a code.

The information we collect may be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. If the information we collect could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for health and care research, or if you have agreed, it can be used to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

What will happen to the samples that I donate for research?

You have a choice as to whether or not to consent to donate samples (e.g. blood) that will be treated as a gift to the University. These will be stored pseudonymously using a code which will be kept confidential.
Samples and pseudonymous data may be shared with other organisations, including hospitals, academic and commercial organisations outside of the EEA to undertake this work.

It is planned that the samples we collect from you will be used for a number of separate analyses focused on scarring lung diseases. These include;

1) Looking for proteins, cells or metabolites (biomarkers) in the blood, that predict how lung fibrosis changes over time.

2) Looking for genetic changes in the blood (in RNA and DNA) that explain why only certain individuals develop pulmonary fibrosis and to see if any of these changes predict how pulmonary fibrosis progresses. This will include looking at specific genes and also undertaking whole genome and exome analysis in the future. The purpose of these analyses is not to provide a diagnosis for you. Results from the genetic analyses will not be used to prove any disease-causing genes which may carry any risk of disease for you or your close relatives. The aim is to determine if there are genetic associations related to pulmonary fibrosis.

With you consent, stored samples may be used in future ethically approved studies to assess new biomarkers for the risk of developing lung fibrosis and the prognosis of this condition.

To try and better understand the processes that lead to the development of fibrosis we work in collaboration with researchers in a number of universities around the world and with members of the pharmaceutical industry. For some research, we will send your samples to these researchers. If we do this, all samples will be pseudoanonymised – i.e. nobody working with the samples will be able to identify you. No company involved in this research will know the identity of individual participants.

What do I have to do?

There are no restrictions to your diet or lifestyle, you should continue to take your medications as directed by your usual clinical care.

What are the possible disadvantages and risks of taking part?

All of the things that we are asking you to do as part of this research are very safe and happen in the hospital on a daily basis. However, There are also very small potential risks to participants during blood sampling regarding potential infection, some mild discomfort and the possibility of bruising in the days following. However, all venepuncture and blood sampling will be conducted by a fully phlebotomy trained member of the clinical research team.

What are the possible benefits of taking part?

These procedures are purely for research and there will be no direct benefit to you. However, it is to be hoped that our research will lead to an improved understanding of the causes of lung fibrosis following COVID-19 and the mechanisms by which it occurs.

Will I be paid?

You will not receive payment for participating in the study.

What happens when the research study stops?

It is intended that results from this research will be reported in international scientific journals and conferences. No information that would enable you to be identified will be published. Results from this research may contribute to future research projects and development of new treatments for pulmonary fibrosis.

What if there is a problem?

Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. This is a complex study and involves many research and delivery partners, such as universities, hospitals, laboratories, data processing and logistic operators. To deliver the study we will need to share your personal information with some of these partners. We will only share the minimum information with these partners to undertake the task they are performing. They are bound by the same rules as us to keep your information confidential and safe. 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 access other research and public data, we will use your information along with that data to answer some of our research questions. Your primary care doctor will be informed that you are taking part in this study. Some of your information may be sent to our partners outside of the European Economic Area (EEA), where data rules are different, however they must follow our rules about keeping your information confidential and safe.

Can I take part if I am already taking part in another research study?

We appreciate there are many studies of patients whom have had COVID-19. If you are already enrolled in another research study, this will not affect your ability to take part in this study. Similarly, if you wish to take part in another research study you can remain in this one. We will ask your permission to link your information from other studies to the information collected for this study.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the treatments being studied. If this happens your research doctor will tell you and discuss whether you should continue in the study. If you decide to continue in the study he/she may ask you to sign an agreement outlining the discussion. A summary of research findings will be provided to participants on request.

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

If you withdraw from the study, we will destroy all your identifiable samples, but we will still need to use the data collected up to your withdrawal. This data will be banked and may be used for future research. If you do not wish for us to do this, there is an option to opt out on the consent form. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital and your GP. If you do not want this to happen, tell us and we will stop.

In the unlikely event you lose capacity to consent during the study, Identifiable data or tissue already collected with consent will be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to you.

How will we use the information about you?

Imperial College London is the sponsor for 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. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from your medical records for this research project. This information will include your initials/ NHS number/ name/ contact details. 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.

Legal basis

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.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). If we do this, all samples will be anonymised – i.e. nobody working with the samples will be able to identify you. Imperial College London will ensure that all data is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

The following Research Collaborators / Partners in the study;

- University of Nottingham
- University of Edinburgh
- University College London
- University of Sheffield
- University of Oxford
- University of Manchester
- University of Leicester
- University of Liverpool
- University of Southampton
- Royal Brompton Healthcare Trust

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 central NHS records, your hospital, and your GP. 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. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. The data will be housed securely in a

REDCAP eCRF hosted by Imperial College London.

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

What if I wish to make a complaint?

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator. Website: www.ico.org.uk/concerns Tel: 0303 123 1113

You may also raise a complaint through the National Health Service Complaints Procedure. The Patient Advice and Liaison Service (PALS) can help you with this Tel: 020 7349 7715.

Your GP will be informed of your participation in the study. Any clinically significant findings will be conveyed to the consultant looking after you or general practitioner, who will inform you of the results.

What will happen to the results of the research study?

It is intended that results from this research will be reported in international scientific journals and conferences. No information that would enable you to be identified will be published. There will also be an internal report of the initial findings. Results from this research may contribute to future research projects. If you wish to obtain a summary of the research findings, this can be obtained on request to the principal investigator.

Who is organising and funding the research?

This research study is funded by the UKRI Medical Research Council. The doctor conducting the research will not receive payments or benefits as part of this study.

Imperial College
London

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by the XXX Research Ethics Committee (REC).

Further Information and Contact Details

To obtain further general information about our lung disease research or for specific information about this research project please contact the Chief Investigator [Professor Gisli Jenkins] at the address at the bottom of this leaflet.

If you have a concern about any aspect of this study you should ask to speak with the researchers who will do their best to answer your questions.

Thank you for taking the time to consider this study. If you do choose to participate, you will be given a copy of this information sheet to keep and also a copy of the consent form that you will be asked to sign.

Professor Gisli Jenkins
NIHR Research Professor and Margaret Turner Warwick Chair of Thoracic Medicine
Head of Margaret Turner Warwick Centre for Fibrosing Lung Disease,
National Heart and Lung Institute,
Imperial College London,
Guy Scadding Building,
Cale Street,
London, SW3 6LY

Study Email: UKILD consortium ukildcovidstudy@imperial.ac.uk