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Participant Information Sheet

The UK Silicosis Registry

Principal investigator: Dr Johanna Feary

You are being invited to take part in a research study. Before you decide 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 and discuss it with others if you wish.

Ask 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.

Thank you for reading this.

Do I have to take part?

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 a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you are receiving, now or in the future.

What is the purpose of the study?

A patient registry is like a survey that collects health information about people with a specific medical condition. In our Registry these are people with silicosis who have developed the condition from exposure to silica dust in their jobs.

Silicosis is not very common and is a complex condition. Bringing together information on people across the UK means we can better understand silicosis and how best to treat it. We can also compare patients with silicosis in the UK with those in other countries. Doctors can learn from this and provide better care for people with silicosis in the future.

The Registry information is held on a secure and confidential computer database.

Why have I been chosen?

You have been invited to take part because you have a diagnosis of silicosis. We are inviting everyone in the UK who has a diagnosis of silicosis and who attends a specialist occupational lung disease clinic to take part in this study

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What will happen to me if I take part?

This is an observational study which means we are not testing any new treatments in this study.

We will collect information recorded during your usual clinic visits from your normal clinical team. This may include:

- Height and weight
- Breathing tests
- CT scan results
- Other test results (for example, blood and urine tests)
- A list of companies you have worked for
- What you did in each of those jobs
- Your symptoms
- What treatment you take
- Any other medical conditions you have
- If you have ever smoked

We will also ask you to complete a questionnaire which should take around 15 minutes to complete about your health and how you are feeling when you attend your usual clinic appointments. This will be on paper or online. Your usual clinical team will then enter this information, and your clinical information into the Registry after your clinic visits on an annual basis.

You will not need to attend any extra hospital appointments. If you decide not to take part it will not affect your clinical care. You are free to withdraw from the Registry at any time and should contact your usual clinical team if you would like to do so. If you decide to withdraw from the study, no further information about you will be entered into the Registry.

Will my information be confidential?

Yes - all the information in the Registry is held confidentially.

The Registry holds information which can be used to identify you (such as name and date of birth, etc.). These 'identifiers' are **only** collected to allow your usual clinical team (the staff treating you at hospital) to know which record is yours. Information which could identify you is **never** shown to anyone outside your usual clinical team unless a numerical identifier is shared for the purpose of data linkage. We call this pseudo-anonymised.

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To keep your information safe and secure:

- Information which can be used to identify you (such as your name and date of birth) will only be visible to your usual clinical team.
- The research team cannot identify you, we only see an anonymous patient identification number.
- When researchers use the Registry they are not even given your anonymous patient identifier. They only see a random one-time identifier which they cannot use to identify you in any database.

A very small number of experienced staff are responsible for protecting your identifiers. They encrypt them on the database, which means the information is converted into a highly complex code which nobody is able to read. Only the staff at your usual hospital have access to read it through their secure accounts. These staff maintain the system, in accordance with Data Protection legislation.

What are the possible disadvantages and risks of taking part?

The main disadvantage to taking part is you will be asked to complete an additional questionnaire when you come to clinic which will take up to 15 minutes.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get might help improve the treatment of people with silicosis and improve our understanding of how silicosis may be prevented.
Analysing Registry information from hospitals across the UK should help to improve patient care by supporting us and the NHS in understanding:

- How many people are living with silicosis and if this changes over time.
- How well people's lungs work once they have silicosis, if their disease is getting worse and how it is being treated.
- National trends in silicosis (which might not be obvious in just one hospital)
- If there are differences in how people are treated (for example depending on where in the country they live)
- Where more support is needed for services like your clinic.
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What happens when the research study stops?

When the research study stops, we will keep your information for 10 years.

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What if something goes wrong?

We are collecting the information already part of your clinical records and your answers to a questionnaire. We do not expect anything to go wrong with this.

'If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Principle Investigator (Dr Johanna Feary: j.feary@imperial.ac.uk). The normal NHS complaints mechanisms are also available to you.'

HOW WILL WE USE INFORMATION ABOUT YOU?

Research Study Title: The UK Silicosis Registry
Imperial College London is the sponsor for this study and will act as the Data Controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. 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.

The study data will then be fully anonymised and securely archived or destroyed.

The study will close on 31 December 2030 after recruiting eligible patients for a period of five years.

For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you and from your medical records for this research project. This information will include your name, date of birth, NHS number, postcode, and contact details. This information will only be seen by your usual clinical team.

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.

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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.
Imperial College London is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Data management plans have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing and storage of the data.
- Data to be stored in a dedicated secure environment which underpins security measures.
- Data will be stored in ISO 27001 certified and/or Cyber Essentials accredited environment
- Robust pseudonymisation has been implemented to prevent identification
- Access controls have been implemented to ensure only key personnel can access the data.

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. 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. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"; 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

Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London rely on "scientific or historical research purposes or statistical purposes

INTERNATIONAL TRANSFERS

We may share data about you outside the UK for research related purposes.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible

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under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with other universities.

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

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner's Office (ICO) website - www.ico.org.uk
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London 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.

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POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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.

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

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WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to j.feary@imperial.ac.uk or
- by ringing us on 020 7594 7968.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to j.feary@imperial.ac.uk, or by ringing us on 020 7594 7968.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk or 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 remain unsatisfied 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)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the Data Controller (us) first before involving them.

What will happen to the results of the research study?

The Registry results will be reviewed on a regular basis and published on a regular basis in scientific journals and reports. Your data is confidential so you will not be identified in any way. We will also update the website with the Registry results on a regular basis [www.lungsatwork.org.uk/UKsilicosisregistry]

Who is organising and funding the research?

The Registry is being funded by the Royal Brompton Hospital Charity for the first year. If the Registry needs ongoing funding to run, then we will apply for this separately. If further funding applications are needed but not obtained then the Registry may need to close early.

Your doctor will not be paid for including you in this study.

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Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by York Research and Ethics Committee.

Contact for Further Information

Thank you for reading this information sheet and for considering taking part in the UK Silicosis Registry. If you have any questions then you can contact your local consultant or Dr Johanna Feary (j.feary@imperial.ac.uk) or call 020 7594 7968.

A copy of the written information and signed Informed Consent form will be given to the participant to keep.