PROMINENT: Smoking Cessation Study

Participant Information Sheet (PIS)

You are being invited to take part in a research study which seeks to understand the impact of stopping smoking and e-cigarettes on the body over time. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

Who is carrying out this research study?

Professor Philip Crosbie, who is a researcher in Respiratory Medicine within the Division of Immunology, Immunity to Infection and Respiratory Medicine/ School of Biological Sciences at the University of Manchester, is leading the study in collaboration with other scientists in the UK and abroad.

What is the purpose of the study?

We want to look at changes in the body before and after giving up smoking to understand why some people develop lung problems and others do not. We hope this leads to increased understanding of the development of lung disease and whether we can prevent problems occurring or detect them earlier. We also want to look at the effects of e-cigarettes on the body.

Who is able to take part?

People attending the Manchester Lung Health Check service or attending hospital (Manchester University NHS Foundation Trust), who smoke but are thinking about stopping are suitable for the study.

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 your interests. This study has been reviewed and given favourable opinion by xxxxxx Research Ethics Committee and the Health Research Authority (HRA).

Who is funding the study?

The study is funded by a charity called Cancer Research UK and National Cancer Institute (NCI), USA. The study is sponsored by the University of Manchester.

Will the outcomes of the research be published?

We intend to publish and communicate results through publications (in peer reviewed scientific journals), presentations at scientific meetings and conferences and reports to funding bodies. You will not be identified in any report or publication.

We will prepare a lay summary of the results, which will be shared with participants. The study team at Manchester University NHS Foundation Trust (MFT) will coordinate the communication of the lay summary.

What would my involvement be?

Do I have to take part?

It is up to you to decide whether or not you wish to take part. If you decide not to take part, this will not affect the care you receive from your clinical care team in any way.

What will I be asked to do if I take part?

The study will be discussed with you in person by a member of the research team, who will answer any questions you may have. If you would like to take part, we will take you through the consent process and ask you to sign a consent form. This will all be done on the day of your study visit, when all the samples will be collected from you.

Alternatively, you may wish to take this information sheet away with you and take some time to read it through. Following this, if you decide to take part, you can contact the research team using the contact details at the end of the information sheet. Taking part in the study will not change the medical care you receive. The study will include:

- Asking **questions** about your health, involving the completion of questionnaires. Questions on other topics such as your education and occupation history, as well as alcohol use and smoking history will also be covered. This will take approximately 20 minutes to complete.

- Collecting personal information about you (including your name and contact details) – this is so that we can get in touch with you after your first visit in order to arrange telephone calls and a follow-up, track the result of your Low-Dose Computed Tomography (LDCT) scan and confirm any inconsistencies with your medical records.

- Taking your breath carbon monoxide measurement

- Donating mouth, nose and blood samples. The blood sample is optional, the amount of blood will be up to a maximum of 50mL (or 10 teaspoons). Samples will be taken at the following times:

- **Visit 1**
    - At the same time as your Lung Health Check or hospital visit, or on a different day if this is more convenient for you.
- **Visit 2**
    - Several months after visit 1 – usually 9 to 12 months later
    - This will take place either on the Lung Health Check truck or at an alternative location (for example Wythenshawe Hospital or your home depending on your preference).

- Collecting the nose and mouth samples involves the following:
    - **Nose samples** (1) Tissue: a small tissue is placed in a nostril for 1 minute before it is removed. (2) Brush: a soft brush is rubbed on the inside of the nose for 20 seconds. The nose samples are optional.
    - **Mouth samples** (1) Mouth swab: a small swab is gently rubbed on the inside of your cheek for a few seconds then removed. (2) Mouth wash: we will ask you to swill a mouth wash around your mouth for 30 seconds before collecting it in a small pot.

- We will ask your permission for a member of the research team based in Wythenshawe Hospital to be able to review your medical records where relevant to the study for up to 10 years after the study has ended. This will include information from the Lung Health Check and the outcome of screening (result of the LDCT scan). In-between the two visits, you will be contacted by telephone by a member of the research team, approximately once every 3 months, to find out if you have stopped smoking or continue to do so.

What kind of research will be done with my samples?

Analysis of samples may include examining cells, genetic material (RNA, DNA) and proteins. Results of the analysis will not be available to you or your doctor and the care you receive from your clinical care team will not be affected.

Will any genetic tests be done?

The genetic material from your samples (DNA) may undergo genomic analyses. This could determine many or all of the features of your DNA. We are interested only in results that are relevant to health research. No tests will be done for known inherited diseases and care will be taken to minimise the chances of your data and samples being combined in such a way that you could be identified.

The laboratories where your samples will be analysed will not have any information regarding your identity, and biological samples obtained will be used for research purposes only to help with our understanding of the impact of smoking cessation in cancer prevention. Any material not immediately used will continue to be stored for use in future studies to help scientists learn more about environment, genetic changes, and health. The research results are not suitable for use as clinical tests for your medical care.

What are the possible disadvantages and risks of taking part?

The results of this study are unlikely to be of direct benefit to you as it may take several years to analyse the data.

Blood samples: The risks involved in donating a blood sample are the same as for routine blood tests. There may be discomfort or pain in the skin and tissue around the vein where the blood is taken. There may be bruising over the vein after the procedure. Blood will be taken by trained professionals who are experienced in the procedure.

We do not anticipate any significant problems or risks. The collection of the nasal brush sample may cause minor irritation.

What are the possible benefits of taking part?

We cannot promise the study will help you directly, but we hope the information we get from this study will improve our understanding of lung disease for future patients.

What will happen to any samples I gift?

Samples taken as part of this study will be analysed in scientific laboratories globally, including at the University of Manchester. The scientific work will be co-ordinated by the International Agency for Research on Cancer (IARC) which is based in Lyon, France.

As a gift, you understand that if this research leads to the development of a new treatment or medical test that you will not benefit financially. In the future, we would like to keep your samples for possible use in future studies/diagnostic test development that cannot yet be specified.

We may share samples with scientists at other organisations located within the UK, Europe or further abroad. The use of data or tissue samples in future studies will only be carried out if further review and approval is given by an independent committee.

The institutions that your data and/ or samples will be shared with will be publicly-owned organisations such as academic institutions, charities and research laboratories/ organisations. They will not be shared with private sector companies. All transfers will be carried out under the appropriate contracts or agreements.

Your personal identifiable information will not be released to other researchers.

Will I be compensated for taking part?

You will not receive a payment for taking part in this study and it is completely voluntary.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. Please inform the member of the research team who approaches you of your decision to take part or otherwise. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form.

You are free to withdraw from the study at any time without your current and future medical care being affected. If you withdraw entirely from the study, we would like to keep all your samples and data generated from samples. However, if you wish, any stored samples already collected and data will be destroyed.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research study we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Your name
- Contact details
- Gender
- Ethnicity
- Date of birth
- NHS number
- GP details
- Medical history
- LDCT scan images
- Demographics data

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (https://documents.manchester.ac.uk/display.aspx?DocID=37095)

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- You will be assigned a unique study ID number. Questionnaires and data collection forms will only contain this unique study ID. Your samples will be labelled with this unique number before being transferred to the laboratories for analysis and storage. Researchers / scientists using the samples will not be able to identify you as the donor.
- All study data will be collected by the research team based at MFT and will be stored securely at MFT and/ or University of Manchester. CT images and reports will be held securely on NHS Trust servers, as is standard practice.
- Data about you (e.g. personal details and health information) will be stored in a secure electronic database at MFT. Any information from sample or data analyses will be stored separately from your personal details. Data from remote medical case record review (for a period of 10 years after the end of the study) will also be recorded on the study database. Paper copies of your original signed consent form, personal data collection form and study questionnaire will be kept in separate locked filing cabinets at MFT.
- Data collected about you as part of this research will be held in two locations, as follows:
    - Study Database (REDCap) held on University of Manchester secure network - this database will only have pseudonymised data in it. This means that data identifying you (such as your name, NHS number or date of birth) is replaced with non-identifiable data (a unique study ID) so that you cannot be identified.
    - Study Database held on NHS Trust servers – this database will have your personal data in it. It will only be accessible to the research team based at MFT, at the authorisation of the Chief Investigator. Your personal data will never be transferred outside the NHS Trust or shared with external organisations.
- The link between your identifiable data and the unique study ID will be stored securely in a different location at Manchester University NHS Foundation Trust (MFT) and only the Chief Investigator of the study (Professor Philip Crosbie) and personnel authorised by him will have access to break the study codes and identify you, if necessary. We will keep identifiable information about you for 10 years.

- Access to your personal details during and after the study will only be available to authorised members of the research team based at MFT, namely the Chief Investigator, study researchers, research nurses and the site research administrators. Only those directly involved with the study and your care will be able to view this data; this will require a username and password.
- We will ask for your consent to access your primary and secondary care health records so that any inconsistencies or missing data identified can be cross-checked. This will include information from the Lung Health Check and the outcome of screening (result of the LDCT scan). If diagnosed with cancer, details of the type, stage and treatment will be recorded.
- Individuals from the University of Manchester, the site where the research is taking place (MFT) and regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.
- With your consent, we will share information collected about you as part of the Manchester Lung Health Check service with scientists / researchers in other organisations working on the samples you provide. These organisations may be universities, NHS, charitable organisations in this country or abroad. This will be done in accordance with UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/)
- Information shared with other researchers will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.
- We will ask for your permission to share your involvement in this study with your GP.
- Findings from the study will be shared through publications and reports to the funding body. Under no circumstances will information that identifies you personally be disclosed in any of these documents.
- All study data/ documents will be retained for a period of 10 years following conclusion of the study. This is so that we can find out if you develop cancer in the future and if so, if there is a link with the findings from this research. Following the end of the retention period all study documents (except consent forms) will be destroyed.
- If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

The research team on 0161 291 5888. Alternatively, you can speak to:

Professor Philip Crosbie, Professor of Respiratory Medicine and Honorary Consultant, North West Lung Centre, Wythenshawe Hospital, Manchester University NHS Foundation Trust, Southmoor Road, Manchester, M23 9LT. Tel: 0161 291 2116.

If you remain unhappy and wish to complain formally, you can do this by contacting patient liaison at Wythenshawe Hospital main outpatients (0161 291 5600). Details can be obtained by writing to: Patient Liaison Office, Wythenshawe Hospital, Southmoor Road, Manchester, M23 9LT or from the hospital website:

https://mft.nhs.uk/wythenshawe/patients-visitors/patient-experience/pals/

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints

In the unlikely event that something does go 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 Manchester University Hospital NHS Foundation Trust or The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researchers:

Professor Phil Crosbie

Professor of Respiratory Medicine

North West Lung Centre, Wythenshawe Hospital

Manchester University NHS Foundation Trust, Southmoor Road,

Manchester M23 9LT

Tel: 0161 291 2116

Or

The TORCH Research Team

1st Floor NIHR Building, Wythenshawe Hospital,

Manchester University NHS Foundation Trust, Southmoor Road,

Greater Manchester, M23 9QZ

Tel: 0161 291 5888