

# C.O.L.D Study

Cough in **O**ccupational **L**ung **D**isease  
 Chief Investigator: Dr Huda Badri

## Participant Information Sheet Version 1.1, 17<sup>th</sup> April 2023

Contents	Page	You are invited to take part in a research study
Why we are doing this research	2	<p>This study is being carried out by a team of trained doctors, nurses and researchers under the supervision of Dr Huda Badri</p> <ul style="list-style-type: none"> <li>Before you decide if you would like to take part, it is important for you to understand why this research is being done and what taking part would involve for you.</li> <li>Please take your time to read the information carefully. Discuss it with your friends, relatives, or GP if you wish to. Take time to consider whether or not you wish to take part.</li> <li>Your participation is entirely voluntary so you do not have to take part if you do not want to.</li> <li>Please ask a member of the research team if there is anything that is not clear, or if you would like more information before considering taking part.</li> <li>Thank you for reading this information. We hope this research will be of interest to you.</li> </ul>
Why have I been asked to take part?	2	
What happens if I agree to take part?	2	
Do I have to take part?	4	
What happens if I change my mind?	4	
Are there any benefits from taking part?	4	
Are there any risks from taking part?	4	
What happens if something goes wrong?	4	
Additional information	5	
How to contact us		Important things that you need to know
<p>If you have any questions about this study please talk to Dr Huda Badri at:            Manchester Clinical Research Facility,            Charles Blackley Ward            Wythenshawe Hospital            Southmoor Road            Manchester M23 9LT</p> <p>Tel: 0161 291 5031</p>		<ul style="list-style-type: none"> <li>This research study involves asking you to complete some questionnaires at your normal clinic visit.</li> <li>You can opt out of the study without giving a reason, even if you have agreed to take part.</li> </ul>



## Why we are doing this research

Cough is an important reflex which is used to clear the airways of irritating material or phlegm. However, a cough can become very troublesome and an early sign of certain respiratory diseases, some of which can be related to work or working conditions. Some people with lung disease report having a persistent cough which disrupts their daily life. The reasons that some people may develop a cough are poorly understood, especially when the lung disease is related to work.

## Why have I been asked to take part?

You have been invited to take part in this research because you are a patient with occupational lung disease attending the clinic at North Manchester General Hospital or Wythenshawe Hospital.

## What happens if I agree to take part?

If you agree to take part after reading this information sheet, an experienced researcher will speak to you about taking part in the study. If you are interested and would like to take part, you can do so at your clinic visit. If you would like time to think about taking part, the researcher will arrange a time to contact you for a call about the study.

## Visit 1

A researcher will talk through the study again with you and answer any questions you may have. If you are still happy to take part, you will be asked to sign a **consent form**. You will then be asked questions about your medical history, lifestyle and details of any medications you are taking. If you do take

medications, it may be helpful to bring a prescription with you to allow us to accurately record your medications and the doses you take. You will then be asked to fill in two questionnaires about cough and whether cough affects your daily life.

## Do I have to take part?

You do not have to take part if you do not wish to. Your decision will not affect the standard of care you receive at Manchester University NHS Foundation Trust, North Manchester General Hospital or Wythenshawe Hospital.

## What happens if I change my mind?

It is okay if you agree to take part in the study but later change your mind. You do not need to give a reason and your decision will not stop you from taking part in other studies in the future if you want to. The study doctor may also withdraw you from the study early if it is necessary for your health.

## Are there any benefits from taking part?

Taking part in this study will not benefit you directly. However, we hope that the results of this study will help us to understand more about cough and improve treatments in the future.

## Are there any risks from taking part?

There are no risks from any of the study tests.

## What happens if something goes wrong?



If you have a concern about any aspect of the study, please speak to the researcher in the first instance. If you remain unhappy and wish to complain formally, you can do so through the NHS complaints procedure. Details can be obtained from the **Patient Experience Team** on **0161 624 0420**.

The hospital is insured to carry out clinical research through the NHS Indemnity scheme, however the normal National Health Service complaints procedures should be available to you. In the 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 NHS Foundation Trust but you may have to pay your legal costs.

NHS indemnity does not offer compensation for non-negligent harm. Non-negligent harm arises where an individual has been harmed during research, through no fault of an individual or institution involved, even though all the correct policies and procedures have been followed.

## How will my information be used?

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

This information will include the following:

- Initials
- NHS number
- Name
- Contact details
- Medical History including test results

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.

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

You can find out more about how we use your information

- at <https://research.cmft.nhs.uk/getting-involved/gdpr-and-research>
- by asking one of the research team
- by sending an email to [cough.research@manchester.ac.uk](mailto:cough.research@manchester.ac.uk), or
- by ringing us on 0161 291 5031.

## Additional information about the study

## Will my details be kept confidential?



We follow strict ethical and legal guidance regarding patient confidentiality. Any information we have about you will be handled in confidence. All data collected will be coded and your name will remain anonymous. When taking part in research it is occasionally necessary for your details to be made available to authoritative research staff who are bound by the same duty of confidentiality. This may include people who conduct quality checks to confirm that the research was done correctly. These people may include research ethics committees, inspectors, monitors and auditors.

### **Who has reviewed this study?**

This study is being sponsored by Manchester University NHS Foundation Trust (MFT) and funded by **The NIHR Biomedical Centre**.

All research in the NHS is approved by the Health Research Authority (HRA) and reviewed by an independent group of people called a Research Ethics Committee (REC). The Research Ethics Committee is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times.

This study has been reviewed and given favourable opinion by HRA and HRCW Cambridge South.

### **What will happen to the study results?**

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain our research results to the medical community. Your name will *never* appear in any report or publication arising from this study.

We will also write about the research findings in the chronic cough newsletter, which is sent to every participant who takes part in our research studies.

### **Who is organising and funding the research?**

This research is being carried out by experienced research staff at NMGH and Wythenshawe Hospital. It is being funded by the North West Lung Centre Charity and the Biomedical Research Council.

**Thank you for reading this information sheet.**