



For workers recruited from
active sites

Take part in a COVID-19 workplace research study

We are inviting you to take part in an important research study about COVID-19. The study is being conducted by the Health & Safety Executive (HSE), UK Health Security Agency (UKHSA) (replacing Public Health England on 1 October 2021), University of Manchester and the London School of Hygiene & Tropical Medicine.

This study involves completing a questionnaire and having two blood tests, six weeks apart, for antibodies against COVID-19. This **will help the Government understand how the virus which causes COVID-19 spreads in workplaces**. We have chosen you because your workplace has recently experienced cases of COVID-19. Participation is completely voluntary.

You can find more information about the study in this Participant Information Sheet.

**To take part in the study please follow this link:
and give your consent to take part today**

If you do not have access to the internet, you can call **XXXXXXXXXX** to take part by phone.

You do NOT have to take part in this study. It is voluntary.

If you agree, there will be an online questionnaire to complete, including questions about the timing of any recent illness and what symptoms you may have had, and some questions about your current health status and exposures. We will then invite you to an appointment for a blood test for antibodies against COVID-19.

Thank you in advance for your help.

Professor Andrew Curran
Chief Scientific Adviser.
Director of Research and
Head of GSE Profession.

Dr Petra Manley
Consultant Epidemiologist.
Field Services, Health
Protection Operations

Professor Neil Pearce
Department of Medical
Statistics.

**Professor Martie van
Tongeren**
Centre for Occupational and
Environmental Health.
Division of Population
Health, Health Services
Research and Primary Care.

**Health and Safety
Executive**

**UK Health Security
Agency**

**London School of Hygiene
& Tropical Medicine**

**The University of
Manchester**

Participant Information Sheet for Workers

The COVID-OUT Study

COVID-19 Outbreak investigation to Understand Transmission

We'd like to invite you to take part in our research study. It is funded by the UK Government as part of a larger research programme called the PROTECT COVID-19 National Core Study on transmission and environment. The research will be carried out by the Health & Safety Executive (HSE), UK Health Security Agency (UKHSA) (replacing Public Health England on 1 October 2021), University of Manchester and the London School of Hygiene & Tropical Medicine.

COVID-OUT webpage <https://sites.manchester.ac.uk/covid19-national-project/rapid-investigation-of-outbreaks-and-evidence-synthesis/>

You do NOT have to take part in this study. It is voluntary.

However, we hope that you will agree to take part, as the information you provide will help us to understand more about COVID-19 infection and how it can spread in the workplace. Before you decide, please read this information sheet, because it describes what we want to do, and what we will ask you to do if you volunteer.

What is the purpose of the study?

This study will help us understand how the virus spreads in workplaces and will help us to make them safe. To do this, we need to collect information from you and your workplace to see if this can help us to know how and why "outbreaks" happen at work, and what we could do to reduce the risk of the virus being transmitted.

How will we carry out this study?

We will carry out this study at your workplace. Your workplace has been chosen because it has experienced an increased number of COVID-19 cases. The local Health Protection Team (HPT) and UK Health Security Agency (UKHSA) may have already collected information as part of their outbreak investigations. For our research study, we would like to collect some additional information from you, and to seek your agreement for us to have access to your previous COVID virus test results. The extra information we would like you to volunteer to provide will include your health and the nature of your work. We will also ask you to have a blood test so we can see if you have any antibodies to the virus. This additional information will be collected by the UKHSA/HSE field study team. The blood tests we are asking you to do are voluntary, you do not have to take part in all tests, and you can withdraw from the study at any time.

What would I need to do if I volunteered for this study?

During an approximately six-week study period, you will be asked to do the following:

Week 1	<ul style="list-style-type: none">○ Complete an online questionnaire. This includes questions about your living and working conditions, method of travel to work, the contact you have had with other people, if you've used any face covering, and infection control practices○ Provide your consent for the study to obtain your COVID virus test results and the virus genomic analysis results, where available, from the national COVID test databases.○ Take a blood test for antibodies to find out if you have had COVID-19 in the past. This test will be carried out at your workplace or, if it is not possible, a home test can be arranged with your agreement. It requires taking a 5ml blood sample (about 1 teaspoon) from a vein by a phlebotomist. This is no different to having a blood test at your local GP. This is voluntary. You do not have to do this.
week 4 -6	<ul style="list-style-type: none">○ Take a second blood test for antibodies using the same method as the first one in week 1. Before taking the test, you will be asked if you have had COVID-19 symptoms since the first test in week 1.

The antibody (blood) tests outlined in the study may not be carried out at every outbreak site.

We will never use your test results in a way that identifies you personally.

We will visit your workplace and may need to take photographs of the workplace while we are there. You may be in some of these photographs. If you are in any of these photos, we will cover and blur your face in these photographs so that you cannot be recognised.

Why have I been invited?

We are asking you to help us in this research because there may be a cluster/outbreak of COVID-19 at your workplace. We are asking all workers at your workplace to take part. This includes workers that are now self-isolating or are off sick because of COVID-19.

Do I have to take part?

No, it is your choice to take part. It is voluntary.

Anyone who takes part may withdraw from the study at any time without giving a reason and without any consequences. Any information collected from you before withdrawal will still be used in the analysis and write up of the findings.

Are there any possible disadvantages or risks from taking part?

This study poses minimal risk to you. Giving blood samples may cause mild and short-term discomfort but not any significant long-term risk.

What are the possible benefits of taking part?

You will find out if you have COVID-19 in the past and if you have antibodies against COVID-19 virus. Everyone helping with this research will help us to work out how to stop the spread of the virus, and how to make workplaces more COVID-secure. This will help keep businesses open whilst keeping people healthy and safe.

To thank you for your participation, you will be able to claim a £20 “one4all” voucher once you complete the consent form and the first questionnaire. You will be able to claim two further £15 vouchers for completing the two blood tests and a follow-up questionnaire, for a total of £50 if you complete all parts of the study. The vouchers are redeemable at www.one4alldigital.com.

These are electronic vouchers that can be used online or converted into cards so they can be used on the high street. The electronic or card vouchers are redeemable at most high street retailers ie: Boots, B&Q, Argos, H&M, John Lewis, M&S, ODEON cinema, TK max and many more.

What will happen with my blood sample?

Your blood samples will be processed in a UKHSA laboratory and tested for antibodies to see if you have had COVID-19 in the past. Any remaining serum sample at the end of the study will be anonymised and incorporated in the UKHSA Seroepidemiology Unit (SEU) collection, unless you ask us to destroy your sample as soon as it has been tested. Samples stored at the UKHSA SEU will be used for further research. If you do not want us to transfer your sample to the UKHSA SEU collection, this will not prevent you taking part in this study and you can indicate your preference on the consent form. The donated samples will be treated as a gift meaning that we will not be able to return them to you.

Your antibody blood test results will be sent to you privately after the 2nd antibody test in week 6 and will not be shared with your employer.

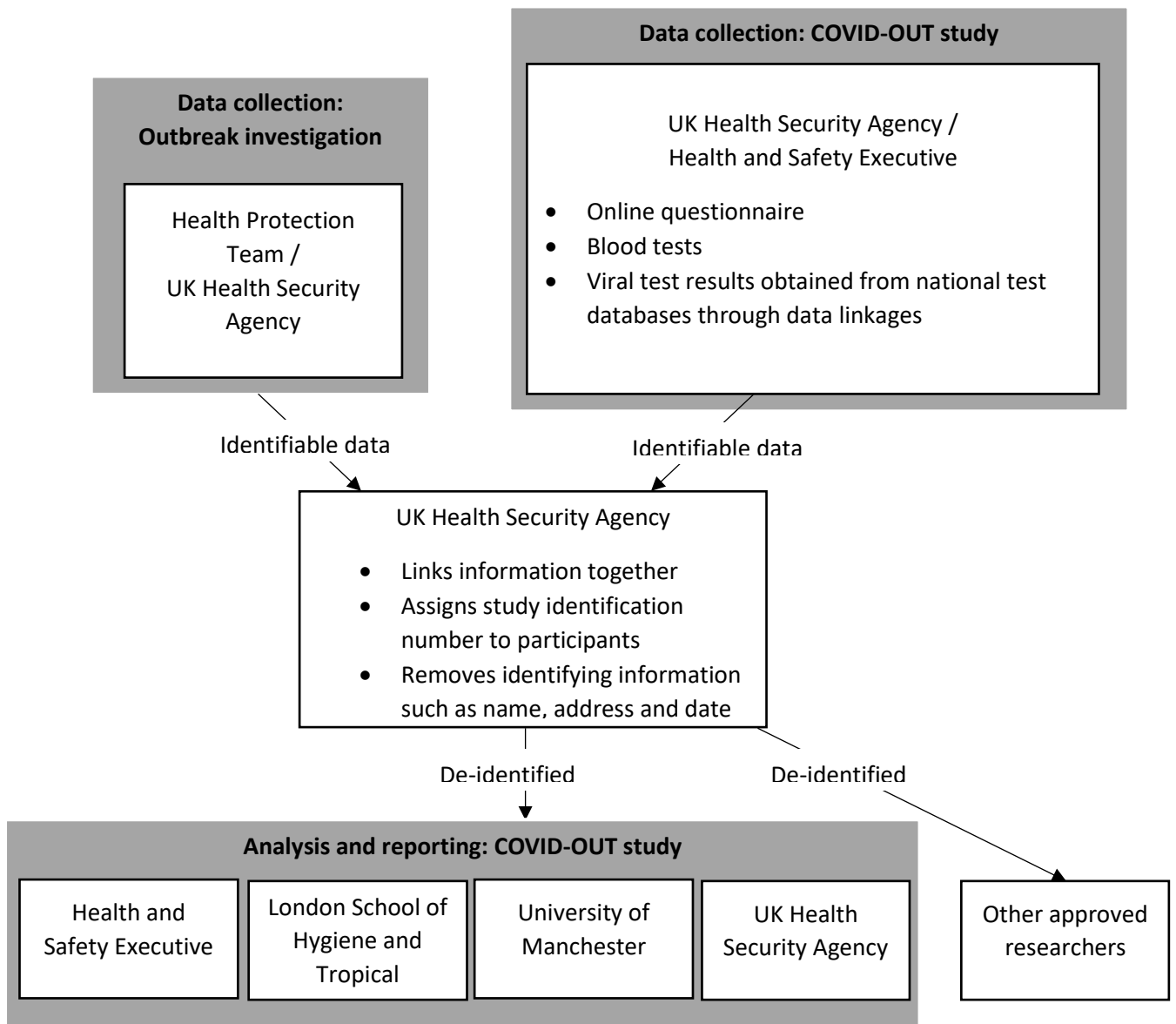
Will my information be kept confidential?

We will treat any information you provide, or any health information sent to the study team as strictly confidential. Your personal data will be protected by the Data Protection Act 2018, and the General Data Protection Regulations. HSE is the sponsor for this study based in Great Britain and will be using information from you to undertake this study.

HSE and UKHSA are joint data controllers for this study, which means that HSE and UKHSA are both responsible for looking after your information and using it properly. The flow of your personal data through the study is summarised in the chart on the next page and is described in more detail below.

Authorised staff of the UKHSA/HSE field study team will have access to personal data during field study data collection to enable them to collect the research data. If your blood sample is taken from home, then the phlebotomist will need your name and home address to undertake the visit. The UKHSA/HSE field team will need to work with an individual from your workplace to organise the site visit. It may be necessary to share your name with this individual to effectively manage the on-site blood tests. This individual will not see any test results or other personal data collected. **No other personal information you provide to us as part of this research study, including test results or the answers to questionnaires will be shared with your employers.**

Members of the UKHSA/HSE team will be able to access your personal information, including your name, date of birth, and contact information during the field study. The team at UKHSA will use this information to link together your test results with data collected as part of the online questionnaires and other information about your workplace. The team at PHE will also use this information to link any test results your employer or national COVID test databases may already hold. Pseudo-anonymised data will be shared with the wider research team for research purposes. Any information about you will have a study identification (ID) number on it instead of your name when shared with the study team. Only UKHSA/HSE field study team will know what your study ID number is and have the system in place to keep this secure. UKHSA will keep identifiable information about you for 1 to 3 years after the study has finished.



Flow of your data through the study

As this study is a component of the National Core Study programme on COVID-19 Transmission and the Environment, we will make the anonymised data from this study available through the Trusted

Research Environments (TREs). This is provided by another National Core Study programme on Data and Connectivity to support COVID-19 research, which will help to answer immediate operational and policy needs.

You cannot be identified from any results of the research. The findings from the study, such as in reports and scientific papers, will be put into the public domain to help others. All published data will be anonymised, and no study participants will be identified from any reports produced as part of this study.

This research is being conducted as a task carried out in the public interest (GDPR Article 6(1)(e)). Health information is a special category of data that we are processing for reasons of public interest in the area of public health (GDPR Article 9(2)(i) and archiving, research and statistical purpose (GDPR Article 9(2)(j)). Your rights to access, change or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. You can find out more about how we use your information by contacting the study team using the details at the end of the sheet, or from HSE's and UKHSA's (managed through NHS England) published Privacy Policy Information:

<https://www.hse.gov.uk/privacy.htm>
[NHS England » NHS England's privacy notice](#)

Can I consent to a part of this study only?

We would ideally like you to take part in all parts of the study. However, if you would prefer not to take part in some parts of this study, then you can indicate this preference on the consent form. You can, of course, discuss any questions or concerns you have with one of the research team before signing the consent form. Signing up is your choice, you can change your mind and withdraw at any time, without giving a reason.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the study team who will do their best to answer your questions (see contact details at the end of the sheet). If you are still unhappy, they will advise you on how to make a formal complaint.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the North East NHS Research Ethics Committee (reference 20/NE/0282). The role of the committee is to protect the interests of study participants.

How do I take part in the study?

If you want to go ahead and take part in the study, please follow the link xxxxxxxx which will take you to a consent form and the study questionnaire.

You do not have to carry on taking part in this study. You can simply change your mind and remove your contact details, or information provided to the study team, at any time.

Please telephone or email the study team if you have any questions or want to talk to someone about this study. The main contact details are at the end of this sheet.

Study Contact details

If there is anything that is not clear, or if you would like more information, please contact the study team as below.

Study links

Dedicated email and phone

COVID-Out@hse.gov.uk

Xxxx

Health Data Research UK COVID-19 National core studies webpage

<https://www.hdr.uk/covid-19/covid-19-national-core-studies/>

COVID-19: Transmission and environment main page

<https://sites.manchester.ac.uk/covid19-national-project/>