



Office for
National Statistics



Study contact: 0800 0856 807

Participant information sheet for Adults (Including parents and carers) and Adolescents 16 years and older

COVID-19 Infection Survey

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please call 0800 0856 807.

What is the purpose of the study?

The coronavirus (COVID-19) pandemic is having a major impact across the UK. This study aims to find out how many people have the infection, or are likely to have had the infection even if they haven't realised it at the time.

One way to find out whether a person has an infection is to directly look for the microbe in their nose and throat. COVID-19 is caused by a virus, and the main test we are using to diagnose it at the moment is a test to find this virus. Once someone has recovered from the infection, the virus is no longer present. But one way the body fights infections like COVID-19 is by producing small particles in the blood called "antibodies". It takes 2-3 weeks for the body to make enough of these antibodies to fight the infection. When someone gets better, these antibodies still stay in their blood at low levels – this is what helps them not get the same infection again. So scientists try to measure levels of both the virus and these antibodies to

work out who has COVID-19 now (with or without symptoms) and who has had it in the past.

In this study we want to work out how many people of different ages across the UK have COVID-19 now and how many have had COVID-19 in the past. We will do this by testing for the virus in the nose and throat and by measuring levels of antibodies in their blood. We also want to find out how many people have COVID-19 over time – either with symptoms or without knowing they have the infection because they don't have any symptoms. We want to do this in a group of people that reflect the population of the UK – so a range of ages and places where people live. This information will help scientists and the government work out how to manage the pandemic better moving forwards and protect the NHS from being overwhelmed.

Why have I been invited?

You recently took part in a study run by the Office of National Statistics (ONS). For this study, your address was randomly selected from a commercially available source called AddressBase, which is maintained by the Ordnance Survey. It contains details for 40 million residential and business addresses in the UK.

When you finished that study, you gave the ONS your contact details and agreed that you could be contacted about possibly taking part in future studies. You can find more details about the use of your contact details by calling **0800 085 7376** for free or by emailing **surveyfeedback@ons.gov.uk**.

The letter you have received will have been addressed to the household member who took part in the previous study. However, in this study we are asking for all adults, teenagers and children in your household aged 2 years or older to take part.

In the first phase of this study, we are planning to include around 11,000 households from England. Over the next year we plan to include around 132,000 households from across the UK.

Do I have to take part?

It is entirely your choice whether you take part or not. Everyone in the household can make a different choice – it is not necessary for everyone to do the same. If you do take part, you may withdraw from the study at any time without giving a reason and without penalty. Parents/carers may also withdraw their child from the study at any time without giving a reason.

What will happen if I decide to take part?

If you or anyone currently resident in your household would like to take part in the study, then we will arrange for a study health worker to visit your home. By currently resident, we mean a person who typically stays overnight in the household address at least 4 nights out of 7. A 'household' is defined as one person living alone; or a group of people (not necessarily related) living at the same address who share cooking facilities and share a living room or sitting room or dining area.

Please call the company running the study (called IQVIA) by phoning **0800 0856 807**, and the telephone adviser will then be able to book you in for an appointment at a time that works for you. The reason for sending someone from the study to your home is so that you do not have to travel to a health centre. Everyone working for the study has received appropriate training.

When the study health worker visits your home, they will first check that you still want to join the study. We will ask you to sign a consent form. If an older child or teenager (10-15 years) in your household wants to join the study, we will ask both them and their parent or carer to sign to say they are happy to be in the study. For younger children aged 2-9 years, we will just ask their parent or carer to sign, although it is important that the child is also happy about this.

The study health worker will then ask everyone who wants to join the study some questions about any symptoms they may have, or contact with someone who had COVID-19. They will also ask about gender, ethnicity, date of birth and occupation, and who their GP is. The study health worker will also show everyone how to take a swab from their nose and throat. This is easy and is being done in the drive through testing centres. Anyone aged 12 years or older can take the swab themselves. We will ask the parent/carer to take the swab from children aged 2-11 years, after they have tried it themselves. The swabs are the same size as used normally for children. The reason for asking people to swab themselves is to protect study health workers in case people have COVID-19 and don't know it.

In your invitation letter, you may have been told about an optional part of the study for **people aged 16 years or older**. If not, do not worry, please just move onto the next section. This part of the study needs a 5ml blood sample (about 1 teaspoon) to be taken from a vein to measure levels of antibodies. This is no different to having a blood test at your local GP. If you were offered this part of the study, and you or anyone in your household is interested in this part of the study,

please tell us when you book your appointment so we send someone who is trained to take blood. You can always change your mind after booking the appointment, including on the day.

Each person will need to spend around 15-30 minutes with the study health worker for the first visit. The study health worker will use all the recommended precautions to protect you and other people in your home from getting the virus. The study health worker will bring all necessary equipment, including PPE (personal protective equipment) with them to your home for the visit.

If anyone in your household is currently experiencing symptoms of COVID-19, self-isolating or shielding, we would still like to make this visit. This is because it is really important to find out how many people with symptoms or who are self-isolating or shielding are infected or exposed to the virus. The only difference is that we will not take blood from anyone. The study health worker will not enter the household, and will pass you the self-swabbing kits whilst staying at least 2m away from everyone in the household. They will ask the few short questions from this distance.

We will also ask you whether you would be interested in repeating this visit. This is for researchers to see how infection with COVID-19 changes over time. You do not have to agree to be part of this study. You could agree to

- A: no further visits
- B: further visits every week for one month (5 visits in total)
- C: further visits every week for one month, and then every month through the year after your first study visit (16 visits in total)

You do not have to agree to more home visits, even if you agree to the first visit. These repeat visits should only take around 15 minutes, because it is the same questions, and nose and throat swab every time. If you agree to give blood the first time, we would like to take blood again every month, but not at weeks 1, 2 or 3.

We will link information from you in this study to data from the NHS and ONS to check your health status, whether you have visited hospital or a GP, or had another test for COVID-19 somewhere else. This is to try to work out what we need to do to keep the NHS going through this pandemic. We will do this for one year after your last visit.

What should I consider?

Anyone aged 2 years or older can take part in this study. The only exception is adults who are not able to consent for themselves. Taking part will not affect the

medical care you receive and there is no effect on any regular medication or other prescribed or over-the-counter medicines you might be taking. It is also fine to take part if you are involved in other research studies.

Are there any possible disadvantages or risks from taking part?

The main disadvantage to taking part is the time and inconvenience of having a study health worker visit your household. When blood is taken there is a possibility of bruising and/or fainting – the study healthcare workers who will do this are trained to take blood to reduce this risk.

What are the possible benefits of taking part?

The samples that you take from your nose and throat will be tested at a national testing centre for the COVID-19 virus. The testing centre will send the results of these tests back to ONS and IQVIA. IQVIA will send the test results onto your GP, who will be able to discuss them with you. You would not usually get these tests done. However, it is very important that if you develop symptoms of COVID-19 you follow the usual NHS guidance on **[nhs.uk/conditions/coronavirus-covid-19/symptoms-and-what-to-do](https://www.nhs.uk/conditions/coronavirus-covid-19/symptoms-and-what-to-do)** – do not wait for the results of the tests done in this study. Whatever the results, it is also essential to keep following government guidance.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Yes, we will tell your GP that you are in this study, and we will send all the results from tests on your and nose and throat swabs to them. Please do not call your GP: they will be able to call you to discuss results when they have arrived.

Will my taking part in the study be kept confidential?

Yes. We will only use names and date of birth where this is absolutely necessary to link to your NHS and ONS records. We will use your postcode to try to work out how COVID-19 is spreading around the country. All samples and study records will be identified only by a code for your household and each person in it joining the study, together with month and year of birth (not actual date). Information which can identify you will only be held by ONS and IQVIA for the purposes of the study.

Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

To reflect their time, inconvenience and having to donate nose and throat swabs (and blood if you agree to this), every person within your household (regardless of how old they are) who joins the study will be compensated with a £50 voucher for the first home visit they complete. For every further visit that they complete, they will be compensated with a £25 voucher. So someone who completes all 5 visits in the first month would get £150 in vouchers, and someone who completes all 16 visits over a year would get £425. These will just be for visits that are completed; for example, if the study is stopped participants would not receive compensation for visits that don't happen.

What will happen to the samples I give?

Your nose and throat swabs will be tested at the National Biosample Centre using the standard test to find out if someone currently has COVID-19. The nose and throat swabs will be destroyed once the test is done.

Your blood sample will be tested by scientists at the University of Oxford. They will look for the levels of antibodies against COVID-19 in your blood. Because the blood samples will be tested for antibodies using a research test, we will not tell you the results of these tests. We do not know what these test results mean yet: that is the reason that we are doing the research. We would like to keep any blood that is not used for the antibody test for future research, including for future tests related to COVID-19 that may be better. Your de-identified samples will be used mainly by researchers in the UK, but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. We will ask your permission for this – you do not have to agree to this to be part of the study. Your blood samples will either be used up or destroyed after 5 years.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford and the ONS are Joint Data Controllers and are responsible for looking after your information and using it properly.

We will be using information from you and NHS Digital (the NHS body who looks after all NHS data) to do this study and will use the minimum personally-identifiable information possible. IQVIA and ONS will keep identifiable information about you from this study for up to 5 years after the study has finished.

ONS sometimes shares selected information with their service providers to help run studies. They only share the personal details that are needed for the study, and they are not used by service providers for any other purpose. To find out more about each service provider's commitment while they are handling your information, please visit their websites. In this study, we work with other organisations to provide the following services:

- sending a thank you gift: our service provider for this is Sodexo
- helping us get in touch: our service providers for this are, APS and GovDelivery.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at **compliance.web.ox.ac.uk/individual-rights**

The information we find out from this study may be useful for other countries.

After the study has ended, the data that we collect may be shared outside the UK. We would only share information that could not identify you (no names or addresses or date of birth).

If you have a question about how the ONS processes your personal data or want to find out more about your rights under data protection legislation, please see the ONS's data protection page. ONS takes their responsibilities to keep your personal information secure very seriously. As such, they take every reasonable precaution to ensure your information is protected from loss, theft or misuse. These precautions include appropriate physical security of our offices, controlled access to computer systems, and use of secure, encrypted internet connections when collecting personal information.

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

You can choose to withdraw from the study at any time if you change your mind, without giving a reason and without penalty. This includes after you have arranged an appointment for a study health worker to visit your home and if you have already given a swab from your nose and throat or a blood sample. If the tests have already been done when you change your mind, we will still use the data from them because it is very important for our study to get a good picture of who has had COVID-19 across the UK. But if you no longer wish for any leftover blood to be stored, we will destroy it. You can also decide that you do not want us to get any more information about you from the NHS or ONS if you leave the study. We will use the data collected up to the time you leave the study.

What happens at the end of the study?

The results from this study will be used to help the government work out the best way to manage the COVID-19 pandemic in the UK over the next year. The results of this study may be presented at academic meetings and may be published in medical journals. If this is the case, any data presented will not identify any individuals. ONS will write to you at the end of the study to tell you what the study has found.

What if we find something unexpected?

None of the tests done in this study are likely to find anything unexpected. They are only looking very specifically for the COVID-19 virus, or for antibodies to it.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Professor Sarah Walker on **sarah.walker@ndm.ox.ac.uk** or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on **01865 616480**, or the head of CTRG, email **ctr@admin.ox.ac.uk**.

How have patients and the public been involved in this study?

This study follows government and WHO advice, and its conduct is based on best practice, which has been informed by patients, service users and members of the public.

Who is organising and funding the study?

This study is funded by the Department of Health and Social Care. The research is being undertaken by ONS, IQVIA and the University of Oxford. It is sponsored by the University of Oxford.

- IQVIA will be responsible for arranging appointments, managing participants taking their own nose and throat swabs, and taking the blood samples.
- The National Biosample Centre are responsible for storing and testing the throat and nose swabs.

- Scientists at the University of Oxford are responsible for storing and testing the blood samples.
- ONS will analyse the data provided by the University of Oxford and The National Biosample Centre, in collaboration with the University of Oxford.

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 participants' interests. This study has been reviewed and given favourable opinion by the Berkshire B Research Ethics Committee.

Further information and contact details

To take part you will need to register with the company running the study for the government (called IQVIA) by phoning **0800 0856 807**. The telephone adviser will then be able to book you in for an appointment for a study health worker to visit your home to complete the study.

IQVIA opening times are:

- Monday to Thursday - 9:00am to 9:00pm
- Friday - 9:00am to 8:00pm
- Saturday - 9:00am to 5:00pm
- Sunday - 9:00 to 5:00pm

If you have any queries having taken part in the study, please contact us on **+44 (0)800 298 5313**. The opening times for the phone line are:

- Monday to Thursday - 9:00am to 9:00pm
- Friday - 9:00am to 8:00pm
- Saturday - 9:00am to 1:00pm

Thank you for considering taking part.