



NOTE: each household will receive one letter referring to one organisation taking responsibility for fieldwork (IQVIA or NatCen). IQVIA letters will go to all households randomly selected for blood draws and either IQVIA or NatCen letters to households not randomly selected for blood draws. Each household will be assigned to only one organisation. Participant Information sheets will be personalised with the specific contacts for the relevant organisation, and whether or not they are being invited for blood draws, indicated by "[DELETE AS APPROPRIATE]"

Study contact: [DELETE AS APPROPRIATE] [IQVIA TO ADD]
[NatCen TO ADD]

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 [DELETE AS APPROPRIATE] [IQVIA TO ADD] [NatCen TO ADD].

What is the purpose of the study?

The coronavirus (COVID-19) pandemic has had a major impact across the [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland. This study aims to find out how many people are still getting COVID-19, or are likely to have had it even if they haven't realised it at the time.

One way to find out whether a person has COVID-19 infection is to directly look for the virus. The main test we are using to diagnose COVID-19 at the moment uses a swab taken from someone's nose and throat. Once someone has completely recovered from the infection, the virus cannot be found any longer in their nose and throat. 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 – with other infections, this is what helps them avoid getting the same infection again, although we do not yet know whether the same is true for COVID-19. 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 find out how many people of different ages across the [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland are still getting COVID-19 as people start going back to work or school, and how many have had COVID-19 in the past. We will do this by testing for the virus in the nose and throat. In some people we will also measure levels of antibodies in their blood. We want to find out how many people have COVID-19 over the coming months – 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 [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland – so a range of ages and places where people live, and not just people with symptoms.

The information we get from people like you taking part will help scientists and the government work out how to deal with the coronavirus outbreak better over the next year and protect the NHS. Thank you for thinking about helping us.

Why have I been invited?

Someone in your home recently took part in a study run by the Office of National Statistics (ONS). For this previous 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 [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland. When they finished that study, they agreed that they could be contacted about possibly taking part in future studies. You can find more details about the use of your home’s contact details by calling **TO ADD** for free or by emailing surveyfeedback@ons.gov.uk.

The letter telling you about this study was addressed to the person in your home who took part in the previous study. However, in this study we are asking for all adults, teenagers and children in your home aged 2 years or older to take part.

Over the next year we plan to include around 150,000 homes from across the [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern

Ireland.

Do I have to take part?

The simple answer is No. Taking part is entirely your choice. Everyone in your home can make a different choice to take part or not to take part – it is not necessary for everyone to do the same. Anyone who takes part may withdraw from the study at any time without giving a reason and without any consequences. 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 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 in your area (called [DELETE AS APPROPRIATE] IQVIA) by phoning **TO ADD**, and the telephone adviser will then be able to book you in for an appointment at a time that works for you, including at evenings or on the weekend. NatCen) by phoning **TO ADD** and registering for the study. A study worker will then contact you to arrange an appointment at a time that works for you including at evenings or on the weekend. 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. The study worker will bring all necessary equipment, including PPE (personal protective equipment) with them to your home for the visit.

When the study worker visits your home, they will first check that you still want to join the study. They will ask you to sign a consent form. If an older child or teenager (10-15 years) in your home 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 worker will then ask everyone who wants to join the study some questions about any symptoms they may have now or in the past, contacts with someone who had COVID-19, and what kind of contacts outside the home they

have. They will also ask about gender, ethnicity, date of birth and occupation, and who their GP is. The study worker will also show everyone how to take a swab from their nose and throat. This swab will tell us whether you currently have the COVID-19 virus. Taking the swab 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 workers in case people have COVID-19 and don't know it.

[If selected for invite for blood – DELETE for swab only] From **those aged 16 years or older**, we would also like to take a 5ml blood sample (about 1 teaspoon) from a vein to measure levels of antibodies. This is no different to having a blood test at your local GP. You do not have to do this part of the study if you do not want to. And 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 worker for the first visit. The study worker will use all the recommended precautions to protect you and other people in your home from getting the virus.

[If selected for swab only – DELETE if selected for blood] In particular, the study worker will not enter your home, and will pass you the self-swabbing kits whilst staying at least 2m away from everyone in the home. They will ask questions from this distance. If you prefer, they can also call you from their car to ask you the questions.

[If selected for invite for blood – DELETE for swab only] The study worker will need to come into your home in order to take blood. They will bring all necessary equipment, including PPE (personal protective equipment) to come into your home for the visit. If anyone in your home is currently experiencing symptoms of COVID-19, self-isolating or shielding, we would still like to make this visit but using social distancing. 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. In this case, the study worker will not enter your home, and will pass you the self-swabbing kits whilst staying at least 2m away from everyone in the home. They will ask the few short questions from this distance. If you prefer, they can also call you from their car to ask you the questions.

We will also ask whether you or anyone in your home would be interested in further visits so that we can see how infection with COVID-19 changes over time. 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 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 selected for invite for blood – DELETE for swab only] 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 health data from the NHS, Public Health England and ONS, or the equivalent national bodies in Wales and Northern Ireland, 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. We will use your address, date of birth and sex to do this.

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 worker visit your home. [If selected for invite for blood – delete for swab only] When blood is taken there is a possibility of bruising and/or fainting – the study workers are trained to reduce this risk.

The study has been designed to make the risk of catching COVID-19 as small as possible – that is why study workers will use the recommended precautions and PPE [If selected for invite for swab only – DELETE for blood] and avoid entering your home. However, even with this, it is possible that there is still a small risk of getting COVID-19 from the study worker (or a study worker getting it from someone in the study).

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 to both of the organisations running the study (both the one leading in your area, [DELETE AS APPROPRIATE] IQVIA NatCen, and another company called [DELETE AS APPROPRIATE] NatCen IQVIA). These organisations are sharing responsibility for sending results back. At the moment, they will send the test results onto your GP, who will be able to discuss them with you if you have questions. We are working hard on being able to text you your results - if you are happy to give us your mobile number, they can text you the results directly as soon as this service is ready. 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 self-isolation on <https://www.nhs.uk/conditions/coronavirus-covid-19/symptoms-and-what-to-do/>¹ – do not wait for the results of the tests done in this study. Like all tests, this test is not perfect, so both “false positives” (the test result is positive but you don’t have the infection) and “false negatives” (the test result is negative but you do have the infection) are possible. Whatever the results, it is also essential to keep following government guidance.

What should I do if my swab test result is positive?

If your nose and throat swab is positive, then you and everyone in your home should follow the guidance above and isolate even if you don’t have any symptoms. Please also contact the NHS Test and Trace system to let them know that you have tested positive (<https://contact-tracing.phe.gov.uk/>).

[If selected for swab only – DELETE for blood] If anyone in your home tests positive for COVID-19, we would like to ask you whether you and any other adult aged 16 years or older in your home would be happy to give a 5ml blood sample (about 1 teaspoon) from a vein to measure levels of antibodies at your study visits. This is no different to having a blood test at your local GP. You do not have to do this part of the study if you do not want to, and neither does anyone in your home. The only difference would be that the study worker would need to come into your home to take the blood; everything else about the visits would be the same. When blood is taken there is a possibility of bruising and/or fainting – the study workers are trained to reduce this risk.

Other studies in the [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland are also trying to include people who test positive for COVID-19 outside of hospitals. If you test positive in this study and would be happy for us to do so, we would send you information about other studies that have been approved by a Research Ethics Committee so that you could contact

¹ An electronic version of this information sheet which you can just click on the hyperlinks is on <https://www.ndm.ox.ac.uk/covid-19-infection-survey> (under information sheets on list on the right hand side).

them if you would be interested in taking part in their research too. You do not have to agree to this to be part of this study, and you do not have to take part in other research you may be told about. For example, a study led by Genomics England, is trying to find out whether there are genetic factors that mean that some people experience severe symptoms whilst others experience only mild symptoms. If you have a positive test, you can register for this yourself on <https://www.genomicsengland.co.uk/covid-19/>. [If selected for invite for blood - delete for swab only] You can also join this study if your blood test is positive for antibodies to COVID-19.

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

Yes, if you are registered with a GP, after your first visit, IQVIA or NatCen will tell them that you are in this study. We will also send all the results from study tests to your GP. Your GP may also contact the Test and Trace system.

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 other healthcare 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 home 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, NatCen and IQVIA and specific other providers listed under "What will happen to my data" 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, [If selected for invite for blood - DELETE for swab only] and blood if you agree to this, every person within your home (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 the 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 you would not receive compensation for visits that don't happen. If you are happy to give us your email address, we can get vouchers to you quickly, or we can post them if you prefer.

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.

Any blood samples will be tested by scientists at the University of Oxford. They will look for the levels of antibodies against COVID-19 using a newly developed research test. This test is currently in the process of getting regulatory approval – when it is approved, we will send you your results. However, it is very important to understand that we do not know yet what it means to have antibodies in the blood in terms of whether you can get COVID-19 again: that is one of the reasons 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. [NatCen - DELETE FOR IQVIA] NatCen will organise the study visits and will work in partnership with study workers from some other organisations called Ipsos-MORI, Kantar Public and NISRA (the Northern Ireland Statistics and Research Agency). The companies involved in running the study will only use information about you for this study – they will not pass it on to anyone not involved in the study.

To do this study, we will be using information from you and NHS Digital, Public Health England and ONS, and equivalent national databases in Wales and Northern Ireland (such as the Health and Social Care Board). We will use the minimum personally-identifiable information possible. NatCen, IQVIA and ONS will keep identifiable information about you from this study for up to 5 years after the study has finished.

ONS, NatCen and IQVIA sometimes share selected information with their service providers to help run very large studies like this one. 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: further information on <https://www.sodexo.com/home/legal--privacy/online-data-protection-policy.html>
- helping us get in touch: our service providers for this are HH Global, GovDelivery and Serco: further information on <https://www.hhglobal.com/uk/privacy-policy>, <https://granicus.com/privacy-policy/>, and <https://www.serco.com/privacy-policy>.
- helping us organise household visits by region: UK Geographic: further information on <https://www.ukgeographics.co.uk/>

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 <https://compliance.web.ox.ac.uk/individual-rights>. The information we find out from this study may be useful for others. The study is funded by the UK government, and so the data that we collect may be shared with researchers and organisations, inside or outside the UK. We would only share information that could not identify you (no names or addresses or full postcodes 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

<https://www.ons.gov.uk/aboutus/transparencyandgovernance/dataprotection>.

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 consequences. This includes after you have arranged an appointment for a study 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 [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland. 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, ONS or Public Health England or other equivalent databases in Wales and Northern Ireland 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 are already being used to help the government work out the best way to manage the COVID-19 pandemic in the [DELETE AS APPROPRIATE BASED ON REGION] UK/UK and Wales/UK and Northern Ireland over the next year – you can find a summary on <https://www.ndm.ox.ac.uk/results>. The results of this study may also be presented at academic meetings and may be published in medical journals. Any data presented will not identify any individuals.

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, please contact our dedicated team on COVID-19@ons.gov.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. Members of the public have looked at this information sheet, and teenagers

have also looked at the shorter version. We are grateful for their helpful feedback which has been included.

Who is organising and funding the study?

This study is funded by the Department of Health and Social Care, with in-kind contributions from the Welsh Government and the Northern Ireland Assembly. The research is being undertaken by ONS, NatCen, IQVIA and the University of Oxford. It is sponsored by the University of Oxford.

- IQVIA are responsible for arranging appointments, managing participants taking their own nose and throat swabs, and taking blood samples in some households, and sending results to GPs and participants.
- NatCen are responsible for arranging appointments, managing participants taking their own nose and throat swabs, and sending test results to GPs and participants.
- 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 [DELETE AS APPROPRIATE] IQVIA NatCen) by phoning TO ADD TO ADD. The telephone adviser will then be able to book you in for an appointment for a study worker to visit your home to complete the study. A contact email is available for those unable to telephone (e.g. due to hearing or speech impairment) [DELETE AS APPROPRIATE] IQVIA TO ADD NatCen TO ADD.

[IQVIA only] 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

[NatCen only] NatCen 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, please contact ONS on **TO ADD**. ONS opening times 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.

If you are affected by any of the issues raised in this information sheet or are looking for information on COVID-19 (coronavirus) please visit:

- Coronavirus explained: <https://coronavirusexplained.ukri.org/en/>
- Government guidelines: www.gov.uk/coronavirus
- NHS advice: <https://www.nhs.uk/conditions/coronavirus-covid-19/>
- Samaritans - Emotional support for everyone: www.samaritans.org
- Mind - Advice and support for anyone with a mental health problem
www.mind.org.uk

<https://www.ndm.ox.ac.uk/covid-19-infection-survey>