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 survey. 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 TELEPHONE.

What is the purpose of the survey?

The coronavirus (COVID-19) pandemic has had a major impact [DELETE AS APPROPRIATE BASED ON REGION] across the UK/ [WALES] across the UK and Wales/ [NORTHERN IRELAND] at both a UK-wide and individual country level/ [SCOTLAND] across the UK and Scotland. This survey 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 throat and nose. Once someone has completely recovered from the infection, the virus can no longer be found in their throat and nose. 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 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 survey we want to find out how many people of different ages [DELETE AS APPROPRIATE BASED ON REGION] across the UK/ [WALES] across the UK and Wales/ [NORTHERN IRELAND] UK-wide and at an individual country level [SCOTLAND] across the UK and Scotland/ are still getting COVID-19, particularly with many people now returning 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 throat and nose. 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/ [WALES] UK and Wales/ [NORTHERN IRELAND] UK overall and its individual countries /[SCOTLAND] UK and Scotland/ – so in 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 in the survey, will help scientists and the government work out how to deal with the coronavirus outbreak better over the next year. Thank you for thinking about helping us.

Why have I been invited?

[ENGLAND, WALES, SCOTLAND] For either this survey, or a previous survey run by the Office for National Statistics, your address was randomly selected from a database called AddressBase, which is maintained by the Ordnance Survey [NAME SOURCE DATABASE AS APPROPRIATE BASED ON REGION]. It contains details for 40 million residential and business addresses in the [DELETE AS APPROPRIATE BASED ON REGION] UK/ [WALES] UK and Wales/ [SCOTLAND] UK and Scotland.

[NORTHERN IRELAND] For either this survey, or a previous survey run by the Northern Ireland Statistics and Research Agency (NISRA), such as the NISRA COVID Opinions Survey, your address was randomly selected from the NISRA Address Register primarily based on the Land and Property Services POINTER database.

In this survey 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 240,000 homes [DELETE AS APPROPRIATE BASED ON REGION] from across the UK/ [WALES] from across the UK and Wales/[NORTHERN IRELAND] UK-wide and within individual countries/ [SCOTLAND] from across the UK and Scotland.

Do I have to take part?
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 survey at any time without giving a reason and without any consequences. Parents/carers may also withdraw their child from the survey 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 survey, then we will arrange for a member of the survey team to make an appointment to visit your home.

- By ‘currently resident’, we mean a person who typically stays overnight in the household address at least four nights out of seven.
- 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.

To register to take part in the survey, please call TELEPHONE. Once you have registered, an appointment will be confirmed by a member of the survey team in the next 7 days. You will be able to let them know a time that works for you, including at evenings or on the weekend. The reason for sending someone from the survey team to your home is so that you do not have to travel to a health centre. Everyone working for the survey has received appropriate training. The survey team member will bring all necessary equipment, including PPE (personal protective equipment) with them to your home for the visit.

When the survey team visits your home, they will first check that you still want to take part. 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 survey, we will ask both them and their parent or carer to sign to say they are happy to be in the survey. 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 survey team will then ask everyone who wants to join the survey 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, religion, date of birth and occupation. The survey team will also show everyone how to use a self-swabbing kit to take a swab from their throat and nose. This swab will tell us whether you currently have the COVID-19 virus. Taking the swab is easy; it is the same swab test that is being used 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 the survey team 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 survey 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 20 minutes with the survey team member for the first visit. The survey team will use all the recommended precautions that protect against the virus.

[If selected for swab only – DELETE if selected for blood] In particular, the survey team 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 survey team member 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 survey team 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. Alternatively we can change the visit to a different date when no one is self-isolating or has symptoms.

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: the first visit only
- B: the first visit and a visit every week for one month (5 visits in total)
C: the first visit, a visit every week for one month, and then 11 monthly visits
(16 visits in total over 1 year)

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 each involves the same questions, and throat and nose 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 survey to health data from the NHS, Public Health England and ONS, or the equivalent national bodies in Wales, Northern Ireland and Scotland, 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 [REPLACE WITH EQUIVALENT IN WALES AND NI AND SCOTLAND] going during this pandemic. We will do this for one year after your last visit. We will use your name, address, date of birth and sex to do this.

What should I consider?

Anyone aged 2 years or older can take part in this survey. 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 or surveys.

What are the possible benefits of taking part?

The samples that you take from your throat and nose will be tested at a national testing laboratory for the COVID-19 virus. The laboratory will send the results of these tests back to ONS and its partner organisation IQVIA, which shares the responsibility of informing you of your test results. 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 guidance on self-isolation on [DELETE AS APPROPRIATE BASED ON COUNTRY] https://www.nhs.uk/conditions/coronavirus-covid-19/symptoms-and-what-to-do/1 www.gov.wales/symptoms-and-self-isolation-contact-tracing [REPLACE WITH WEBSITE WITH EQUIVALENT GUIDANCE FOR NORTHERN IRELAND/SCOTLAND]. Even if you have had a recent test done in this survey and have developed symptoms, do not wait for its results before self-

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/covid-19-infection-survey/protocol-and-information-sheets
isolating. If you have not had a recent test in the survey, please follow the guidance on getting a test [AMEND AS NECESSARY WITH EQUIVALENT GUIDANCE FOR WALES/NORTHERN IRELAND/SCOTLAND]. 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 throat and nose 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. As required by law, we will share your positive swab test result and personal data (including your name, contact details, postcode and ethnicity) with [AMEND AS APPROPRIATE BASED ON COUNTRY] Public Health England for referral to the NHS Test and Trace system/Public Health Wales for referral to the NHS Wales Test, Trace, Protect system/the Public Health Agency for referral to the HSC Northern Ireland’s Test and Contact Tracing programme/ NHS Inform for referral to the Test and Protect system ([DELETE AS APPROPRIATE BASED ON COUNTRY] https://contact-tracing.phe.gov.uk/ https://gov.wales/contact-tracing-if-you-have-tested-positive/ https://www.publichealth.hscni.net/covid-19-coronavirus/testing-and-tracing-covid-19 https://www.nhsinform.scot/campaigns/test-and-protect). By taking part in this survey you agree to this disclosure taking place.

[If selected for swab only – DELETE for blood] If anyone in your home tests positive for COVID-19 on a throat and nose swab, 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 survey visits. This is no different to having a blood test at your local GP. You do not have to do this part of the survey if you do not want to, and neither does anyone in your home. The only difference would be that the survey team would need to come into your home to take the blood, and would do so using appropriate PPE; everything else about the visits would be the same. When blood is taken there is a small risk of bruising and/or fainting – the survey team members are qualified to reduce this risk.

Other studies in the [DELETE AS APPROPRIATE BASED ON REGION] UK/ [WALES] UK and Wales/ [NORTHERN IRELAND] UK and its individual countries/[SCOTLAND] UK and Scotland are also trying to include people who test positive for COVID-19 outside of hospitals. If you test positive in this survey 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 them if you
would be interested in taking part in their research too. You do not have to agree to take part in this survey, and you do not have to take part in any other studies or surveys about which we send you information. 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 swab 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.

Are there any possible disadvantages or risks from taking part?

The main disadvantage to taking part is the time and inconvenience of having a member of the survey team visit your home. However they will try to make appointments for a convenient time and the appointments can even be in the evening or weekend. When blood is taken there is a possibility of bruising and/or fainting – the survey team are qualified to reduce this risk.

The survey has been designed to make the risk of catching COVID-19 as low as possible – that is why the survey team will use the recommended precautions and PPE 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 survey team member (or a survey team member getting it from someone in the survey).

What do I get for taking part?

To reflect their time, inconvenience and having to donate throat and nose swabs, and blood if you agree to this, every person in your home (regardless of how old they are) who joins the survey 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. These will just be for visits that are completed; for example, if the survey 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. We will also email you updates on results and news about the study.

Will I be told my results?

Yes, you will be told your results. At first this will be by letter. We are working hard
on being able to text or email you your results - if you are happy to give us your mobile number or email address, we can text you the results directly as soon as this service is ready.

[If selected for invite for blood – DELETE for swab only] It is important to remember that the throat and nose swab is a test for whether you currently have coronavirus infection now. Whereas a positive antibody test means that you have been exposed to COVID-19 at some point in the past - it does not mean you are infected with the virus now.

**Will my taking part in the survey be kept confidential?**

Yes. We will only use name, address, date of birth and sex 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, and in your local area. All samples and survey records will be identified only by a code for your home and for each person in it joining the survey, together with month and year of birth (not actual date). Information which can identify you will only be held by ONS and IQVIA and specific other providers listed under “What will happen to my data” for the purposes of the survey.

If you have a positive swab test result, as required by law, we will share your result and personal data (including your name, contact details, postcode and ethnicity) with [AMEND AS APPROPRIATE BASED ON COUNTRY] Public Health England for referral to the NHS Test and Trace system/Public Health Wales for referral to the NHS Wales Test, Trace, Protect system/the Public Health Agency for referral to the HSC Northern Ireland’s Test, Trace and Protect programme/NHS Inform for referral to the Test and Protect system.

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

**What will happen to the samples I give?**

Your throat and nose swabs will be tested at one of the national Lighthouse laboratories, either at the National Biosample Centre, Milton Keynes, Glasgow, or Alderley Park, Liverpool, using the standard test to find out if someone currently has COVID-19. The throat and nose 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 –
we will still 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 survey. 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. IQVIA will organise the survey visits and will work in partnership with survey workers from other select partner organisations. The companies involved in running the survey will only use information about you for this survey – they will not pass it on to anyone not involved in the survey.

To do this survey, we will be using information from you and NHS Digital, Public Heath England and ONS, and equivalent national databases in Wales, Northern Ireland and Scotland. We will use the minimum personally-identifiable information possible. IQVIA will keep identifiable information about you from this survey for up to 5 years after the survey has finished.

The ONS has the statutory objective to promote and safeguard the production of official statistics that serve the public good. In order for us to produce statistics we may link the data we obtain through this survey with other survey and administrative data that we hold. Further information on what we use data for is available at https://www.ons.gov.uk/aboutus/transparencyandgovernance/datastrategy. All our uses of data will comply with UK Statistics Authority's ethical framework. Further information on the ethical framework is available at https://www.statisticsauthority.gov.uk/about-the-authority/committees/nsdec/data-ethics/. The ONS will continue to hold the data collected through this survey for as long as it remains useful for statistical research and production. The ONS may provide access to de-identified data to accredited researchers for accredited research purposes via accredited processing.
environments, where it is lawful and ethical to do so. When making this de-
identified data available we may link the data we obtain through this survey with
other survey and administrative data that we hold. Access will only be provided to
support valuable new research insights about UK society and the economy that are
considered to be in the public good. Further information on how we provide access
to data for research purposes is available at
https://www.statisticsauthority.gov.uk/about-the-authority/better-useofdata-
statistics-and-research/betterdataaccess-research/.

ONS 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 survey, 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 survey, 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,

Some of IQVIA’s offices are located outside the UK, therefore IQVIA will sometimes
need to process your information at a destination outside the European Economic
Area. Such transfers will only take place with appropriate safeguards in place to
ensure the confidentiality and security of your personal information. If you require
any information about these safeguards, you may contact us at TELEPHONE.

If you have a positive swab test result, as required by law, we will share your result
and personal data (including your name, contact details, postcode and ethnicity) with
[AMEND AS APPROPRIATE BASED ON COUNTRY] Public Health England for
referral to the NHS Test and Trace system/Public Health Wales for referral to the
NHS Wales Test, Trace, Protect system/the Public Health Agency for referral to the
HSC Northern Ireland’s Test, Trace and Protect programme/NHS Inform for referral
to the Test and Protect system.

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 survey may be useful for others. The survey 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.

The Data Protection Officer at ONS can be contacted at DPO@Statistics.gov.uk.

What will happen if I don’t want to carry on with the survey?

You can choose to withdraw from the survey 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 member of the survey team to visit your home and if you have already given a swab from your throat and nose 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 survey to get a good picture of who has had COVID-19 [DELETE AS APPROPRIATE BASED ON REGION] across the UK/ [WALES] across the UK and Wales/ [NORTHERN IRELAND] UK-wide and at an individual country level/ [SCOTLAND] UK and Scotland. 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, Northern Ireland and Scotland if you leave the survey. We will use the data collected up to the time you leave the survey. The survey is based on a representative sample of addresses and so if you move house, your participation in the survey will finish.

What happens at the end of the survey?

The results from this survey are already being used to help the government work out the best way to manage the COVID-19 pandemic [DELETE AS APPROPRIATE]
What if we find something unexpected?

None of the tests done in this survey 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 survey.

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 survey, please contact our dedicated team on COVID-19@ons.gov.uk.

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

This survey 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 survey?

This survey is funded by the Department of Health and Social Care, with in-kind contributions from the Welsh Government, the Department of Health on behalf of the Northern Ireland Government, and the Scottish Government. The research is being undertaken by ONS, 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 throat and nose swabs, and taking blood samples in some households, and sending results to participants.
• The Lighthouse Laboratories at the National Biosample Centre, Milton Keynes, Glasgow and Alderley Park, Liverpool, 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 Lighthouse Laboratories at the National Biosample Centre, Milton Keynes, Glasgow and Alderley Park, Liverpool, in collaboration with the University of Oxford.

Who has reviewed the survey?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This survey 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 survey for the government by phoning TELEPHONE. The telephone adviser will register you onto the survey and an appointment will be confirmed in the next 7 days. A contact email is available for those who are unable to telephone, for example due to hearing or speech impairment EMAIL. If you are able to use the telephone, it would help us if you could do so.

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

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/
- NHS advice: [DELETE AS APPROPRIATE BASED ON COUNTRY, REPLACE FOR
NORTHERN IRELAND AS APPROPRIATE

https://www.nhs.uk/conditions/coronavirus-covid-19/
www.gov.wales/coronavirus

- 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/covid-19-infection-survey