

SIREN

SARS-CoV2 Immunity & Reinfection Evaluation

INFORMATION LEAFLET FOR PARTICIPANTS

TRUST NAME: BELFAST HEALTH AND SOCIAL CARE TRUST

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We would like you to invite you to take part in this study to understand whether prior infection with SARS-CoV2 (the virus that causes COVID-19) protects against future infection with the same virus.

Before you decide to join this study, 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. Please ask the research team at your organisation if there is anything that is not clear.

This study is being delivered across the UK in collaboration with Public Health Agencies in the devolved health administrations (Northern Ireland, Scotland and Wales).

Why are we doing this study?

The novel coronavirus (COVID-19) pandemic is having a major impact across the UK.

COVID-19 is caused by a virus, called SARS-CoV2, and the main way we diagnose infection with this virus is to take a swab from a person's nose (and sometimes throat too) and look for presence of genetic material from the virus. Once someone has recovered from the infection, the live virus should no longer be present in the nose or throat. One way the body fights infections like COVID-19 is by producing small particles in the blood called "antibodies", which can be detected using a blood test. It takes days or weeks for the body to make enough of these antibodies to fight the infection. When someone gets better, these antibodies can remain in their blood at low levels, and may help protect against future infections with the same virus.

By doing both swab and blood tests together, regularly over time we will be able to assess whether prior infection (measured through an antibody test) protects against future infection (measured through detection of virus on a swab test).

We will also improve our understanding of other important areas:

- The blood tests will allow us to understand the number of healthcare workers infected by COVID in the last few months and allow us to understand whether there are differences related to age, ethnicity and other factors.
- By taking regular samples (both swabs and blood), we can measure what proportion of frontline NHS staff are exposed to SARS-CoV2 and improve our understanding of how quickly it spreads over the coming months.
- By taking blood samples we will understand how an individual's antibody levels change over time and the different types of antibodies that may be present.
- We will also investigate how viruses from different individuals relate to each other by comparing the genetic make-up of the viruses.
- Where participants are swab positive several times we will seek to understand how infectious they might be through attempting to grow (culture) the virus from their samples and explore the changes in the virus genetic material.
- If individuals are admitted to hospital, we will explore how individual characteristics and virus factors may impact on their illness.

Why have I been asked to take part?

Your organisation's research team have invited you to take part because you work in a healthcare setting. We know that individuals who work in healthcare settings have higher rates of infection with SARS-COV2 than the general population, and therefore are a good group in which to look for re-infections. Taking part is voluntary and you should not be placed under any pressure to do so. It is completely up to you to decide whether or not to take part.

What do you want me to do now?

Read this information leaflet carefully to help you decide whether you want to participate in this study. If you have any questions, then discuss them with your organisation's research team.

If you decide to take part, you will be asked to do the following:

a. Enrolment into the study

- Online enrolment consent and questionnaire (around 15 minutes)
- Nose +/- throat swab looking for the presence of coronavirus
- Blood test for antibodies

The aim will be to collect initial samples within 48 hours of enrolment questionnaire completion. This study will also involve us collecting details about your working and medical history, as well as potential exposures to and symptoms of COVID-19, which will allow us to understand the results of your tests in context.

b. Follow-up

- Follow-up questionnaires (2-3 minutes): this will be sent straight to the phone number and/or email address that you provide
- Blood and swab tests

Follow-up will last for 12 months, and the blood and swab tests will happen regularly. For most people the questionnaires, blood and swab tests will be every two weeks initially, although the frequency may change later on.

What if I develop COVID-19 symptoms or become a contact of a confirmed case?

If at any time during the study you develop symptoms consistent with COVID-19, or you become a contact of a confirmed case of COVID-19 and are therefore asked to self-isolate at home, then please report your symptoms and access swabbing as you would normally within your organisation in these circumstances. If that is the case, please reschedule any planned SIREN testing appointments for a later date when you are well and back at work.

What will happen to my samples?

Your samples will be tested at the laboratory used by your organisation.

If your swab is positive, then it will be sent for genetic sequencing of the virus to the COVID-19 Genomics UK Consortium. If you test positive more than once, your swab material may also be sent for further specialised testing by Public Health England for the presence of live virus; you may be asked to provide a second swab sample in order for us to do this, and in rare instances we may ask you to provide further blood samples.

Your blood samples will be tested for antibodies against SARS-CoV2 in your local laboratory. Part of your serum sample will also be sent to Public Health England to undergo further specialised testing for antibodies.

At the end of the study, any remaining serum sample will be anonymised and incorporated into the Public Health England serology biobank. Samples stored at this biobank will be used to perform a range of different national antibody surveys in the future. If you do not want us to transfer your sample to this biobank, you can indicate this on your consent form, and your sample will be destroyed after the SIREN study is completed. Selecting this option will not prevent your participation in the SIREN study. The donated samples will be treated as a gift, which means that we will not be able to return them to you.

During your participation in the SIREN study you may be invited to join other linked studies; participation in these supplementary studies is entirely voluntary.

What will happen to my results?

You will receive your results from your healthcare organisation; depending on your organisation's procedures you will either be informed of your results automatically or you can request your results. Your research team will inform you of this process. You will be informed immediately when a nose or throat swab shows evidence of COVID-19.

Your test results will be shared with Public Health England and appropriate Devolved Administrations who are conducting the study and who also monitor the number of infections in each country. The SIREN team may wish to find out more detailed information about you and your results; we may discuss your results with appropriate individuals within your organisation, including the local research team, the occupational health team or the microbiology/virology team.

As part of this study we may also look at blood or swab test results for SARS-CoV2, which you have submitted in the past or those which you may submit for another reason during the study period (e.g. if you have symptoms or are the contact of a case). This may include samples which you have submitted elsewhere (e.g. your GP or local community testing). If you have had SARS-CoV2 testing in the past where your personal details are not recorded on the sample (usually through your occupational health department or through a previous Public Health England study), we may request these details or test results from your organisation's occupational health or research teams.

What if I have a positive swab test result as part of SIREN?

A positive swab test result will be managed by your organisation's team in line with national and local guidelines. This includes reporting to NHS Test and Trace, or the relevant contact tracing service in the Devolved Administrations. Necessary precautions such as self-isolation may also extend to your household as per current national guidelines.

If you have SARS-COV2 antibody detected in your blood test, you should remember that this does not necessarily protect you against future infection, and you should not change your behaviour. You should take all usual precautions against COVID-19 at home and at work.

What are the benefits to me?

The study will not benefit you directly, but your participation will help provide important information about SARS-CoV2 re-infection among staff working in healthcare organisations and provide a stronger evidence base to inform national guidance and policy. At the end of the study, the overall results will be published in national reports.

What are the disadvantages?

For some, blood sampling may cause momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of lightheadedness when the blood is drawn, and rarely, an infection at the site of blood draw. Some individuals additionally find the swab tests uncomfortable.

As the study Sponsor, Public Health England has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

What if I change my mind?

If you no longer want to be involved, you can withdraw from the study at any time by visiting the SIREN website and following the link to withdraw from the study: <https://snapsurvey.phe.org.uk/siren/>. Withdrawal is not complete until you have completed the form at this link.

How will my data be stored, processed and shared and who will have access to it?

Your personal data will be stored and processed in accordance with the [General Data Protection Regulations](#) (GDPR) and the [Data Protection Act 2018](#). Your identifiable data and individual survey responses will be collected and analysed by Public Health England and by the relevant Devolved Administration Public Health organisation if you live in Northern Ireland, Scotland or Wales. Your identifiable data and results will be also accessed and collected by the team working on the SIREN study at the site where you work. Your data will be transferred securely between these organisations. The COVID-19 Genomics UK Consortium who process positive swab samples will also need access to your personal information. Organisations will also follow local and national requirements such as informing NHS Test and Trace, or the relevant contact tracing service in the Devolved Administrations, where there is a positive swab, and in some cases informing your GP.

Researchers will link your questionnaire responses and testing results using your personal identifiable details which you have provided us and those which we hold centrally e.g. NHS number. In order to improve understanding of the information you provide, Public Health England and the relevant devolved Public Health Authority may also look at records about your health and care which are held centrally, for example the National Immunisation Management System.

Access to this identifiable dataset will be controlled so that only members of the study team who need to see this are able to do so. Non-identifiable data will be used in reports and scientific publications. Non-identifiable information may be collected, analysed, reported and shared with others within Europe to contribute to research. More information can be reviewed in the SIREN Privacy Statement, available here <https://snapsurvey.phe.org.uk/siren/>.

Am I eligible to participate in COVID-19 vaccine or prophylaxis trials?

Yes, you are eligible to join and continue in this study even if you are currently enrolled in, or subsequently join, a COVID-19 vaccine or prophylaxis interventional trial. However, we know that some trials do not allow you to be enrolled in other studies, particularly studies where you will be told your antibody test result such as in SIREN. If you are enrolled in another study, please check with the research team managing the other study whether they are happy for you to enter SIREN. However, as we do not know the future enrolment criteria of vaccine studies we are very happy for you to enrol into SIREN and this can be a discussion area for the future.

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 Berkshire Research Ethics Committee.

How have healthcare workers been involved in the study?

This study has been reviewed by healthcare workers who have participated in other Public Health England studies (including swab and blood test studies for COVID-19).

What should I do if I have any complaints?

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 the chief investigator Dr Susan Hopkins via the phe.siren.participants@phe.gov.uk. If you are still unhappy, you can contact the Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG or email: complaints@phe.gov.uk.

Who is funding the study?

The Department of Health and Social Care is funding the study through the COVID-19 grant to Public Health England, and study costs borne by devolved administration Public Health Agencies is funded by the governments in Northern Ireland, Scotland and Wales.

What should I do now?

If you would like to join, please contact your organisation's research team, who will take your details. You will then be provided with your unique **study number** and **passcode**. You will need to use these to access the online consent form and questionnaire, via <https://snapsurvey.phe.org.uk/siren/>. Your research team will discuss with you how to arrange your blood and swab tests. If you have any questions about enrolment or the running of the study at your organisation, please contact your organisation's research team in the first instance on the phone number or email address at the top of this form.

Thank you for reading this information and considering taking part.