



ST. JAMES'S
HOSPITAL



University Hospital Galway
Ospidéal na h-Ollscoile, Gaillimh
GALWAY UNIVERSITY HOSPITALS



Seirbhís Sláinte
Níos Fearr
á Forbairt

Building a
Better Health
Service

Participant information leaflet Version 3, 11/02/2021

Prevalence of COVID-19 Antibodies in Irish Healthcare Workers (PRECISE Study)

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We are asking you to take part in this important study looking at rates of COVID infections in Health care workers. This study is a national study which has been advocated for by the National Public Health Emergency Team (NPHE), Department of Health, and coordinated by the Health Service Executive (HSE) as part of the national response to the COVID-19 pandemic. St. James' Hospital and University Hospital Galway have been selected as the testing sites. Participation in the study is voluntary meaning that you only need to take part if you want to. This leaflet provides information about the study.

What is COVID-19 (coronavirus)?

COVID-19 infection caused by SARS-CoV2 virus is a new pandemic infection that can affect your lungs and general health and is causing illness in Ireland and spreading rapidly around the world. It is

caused by a virus called coronavirus. Most people who get infected only have a mild illness. However, it can cause a more severe illness and death, particularly in people who are older or have other illnesses.

What is the study and why is it being done?

SARS-CoV2 is a new virus and there are many things we don't know about it. Up to now, we have been testing people in Ireland who are ill and we have been counting the number of cases of infection. The results of the SCOP1 study (Study to Investigate COVID-19 Infection in People Living in Ireland) have shown coronavirus antibodies among the population of Dublin to be estimated at 3.1% and among the population of Sligo to be estimated at 0.6%. Our study is specifically aimed at healthcare workers; we want to find out how widely COVID-19 has spread in healthcare workers living in Ireland. This study aims to find out how widely COVID-19 has spread in healthcare workers living in Ireland. When a person becomes infected with a new virus, their body produces a response – called antibodies - to the virus. These antibodies can usually be detected in the blood, usually a week or two after the illness started. By doing a blood test for these antibodies it is possible to say, in most cases, if the person has been infected at some stage with the virus that causes COVID-19 infection. The study will help in making decisions about how to control the spread of the infection, how to understand the risks of acquiring infection either in work or outside of work and how to make the hospital a safer working environment. It may also be valuable for informing us how to evaluate vaccine responsiveness when a vaccine for COVID-19 becomes available.

Who is doing this study?

This study is being coordinated by the HSE, and undertaken by St. James' Hospital and Galway University Hospital. The study will be coordinated by a research team from all three centres.

How will it be done?

All staff members working in St. James' Hospital, Dublin, and University Hospital Galway are being invited to participate in the study. Participants are invited from all departments in the hospitals. People who are taking part in the study will be asked to answer a short online questionnaire and to give a blood sample in their hospital. Participation in this study is voluntary and if you would like to take part, we will ask you to indicate your consent.

We did the same study 6 months ago. We are repeating it to see if the amount of healthcare workers with antibodies has changed a lot. If you took part in the previous study, we will ask your permission to link your results, so that we can see if your result has changed. If you took part in the last study but do not want us to link your results you can still take part again. If you did not participate in the last study, you can still participate in this study.

How does vaccination affect the study?

The roll-out of vaccination has added an extra component to this study. We will also be able to measure antibody response to vaccination in this study. You are invited to participate whether you have been vaccinated or not.

If you have already had COVID-19 infection can you still take part?

Yes. If you have already had COVID-19 infection, we would still like you to take part in the study. If you are still isolating because of your illness, we will not ask you for a blood test but would still ask you to answer the questionnaire.

Can everyone who is asked, take part in the blood testing part of the study?

Unfortunately, anyone who has been advised to 'cocoon', anyone who has suspected or confirmed COVID-19 at the moment, and anyone who is restricting their movements because they are a close contact of a COVID-19 case, will be excluded from the blood testing part of the study. This is because travelling to the testing centre may be a risk to their health or the health of others. They can still contribute to the questionnaire part of the study.

Any healthcare worker who has symptoms should not come to work and should contact the Occupational health department at their hospital site.

What am I being asked to do?

The study involves filling out a short questionnaire and taking a blood test. If you agree to take part in the study, we will ask you to do the following:

1. Indicate that you wish to take part. You can do this by signing up with your email address at the link at the bottom of this information leaflet. If you do not have an email address feel free to contact us and we will arrange for you still to take part.
2. The link will bring you to an online consent form
3. Following completion of the consent form you will be brought to a brief online questionnaire (5-10 minutes)
4. You will then be asked to book your blood sample via an online system called Swiftqueue. There will be testing all day over 7-10 days in April so you can choose a slot that suits your work schedule. The testing will be carried out in the hospital in which you work. We will make sure that physical distancing is in place at this location, and face-masks will be obligatory. The blood sample will be taken by trained personnel.
5. On the day of your blood test, you may be asked if you wish to take part in a separate study that is measuring a different type of antibody to COVID-19, called IgA. The PRECISE study is focused on IgG antibodies to the virus. It is now thought that levels of virus-specific IgA antibodies found in the saliva may be more informative. It is also possible to measure viral proteins and viral RNA in saliva. If you are interested in partaking in this study we will refer you to the study team to take a saliva sample. They will explain more about it to you at the time.

You do not have to participate in anything extra if you do not wish to and can continue to participate in the PRECISE Study.

What information will you collect?

We will record the following information about you: Name, contact details, date of birth, sex, occupation, country of birth, and who shares your household. We will ask you questions about COVID-19 illness, like whether you have been diagnosed with the condition, have had a swab taken (whether positive or negative) or have had symptoms that might have been COVID-19 illness, or if you had contact with a known or suspected case of COVID-19. We will also collect information about whether you have been vaccinated, with which vaccine, and how many doses you have received.

How will my information be used and stored?

The only people who will be able to see your information will be members of the research team at the site where you work. These will be the principal investigator, the lead investigator and the data manager. Your data will always be managed confidentially. Your data and questionnaire answers will be held in a secure online database. Only personal data necessary to carry out the study will be processed and stored in the database. Your personal data will not be disclosed outside of the study group and will not be linked to your name on the hospital laboratory system. Your records in the study will not be linked with any other records that may be held in other databases or registers. Data will be only be collected and used in this study to the extent needed to achieve the aims. Data will be processed for the purposes of public interest, in the area of public health, for scientific research, in accordance with applicable data protection legislation. All groups involved in the study operate in compliance with the General Data Protection Regulation (EU) 2016/679 and with the Data Protection Act 2018 and are accredited for information security ISO 27001. All staff and researchers involved in the study have had data protection training. It will not be possible for any participant in the study to be identified in reports that are produced from the study. Your personal data will only be held for as long as it is needed for this study and for not more than five years. After that time, your name, address, and anything else that could identify you will be deleted. The plan for the study has been approved by the National Research Ethics Committee set up by the government to approve research on COVID-19. For further information on this, please see the website: <https://www.hrb.ie/news/covid-19-coronavirus/coronavirus-news/article/new-nationalethics-committee-for-covid-19-research/>

What are my rights?

All participants have the following rights in relation to data:

- Right to access data held
- Right to restrict the use of the data held
- Right to correct inaccuracies
- Right to have information deleted
- Right to object to profiling
- Right to complain to the supervisory authority (Data Protection Commission)

You can exercise these rights by contacting the PI or DPO, contacts listed in this leaflet.

What will happen to my blood sample?

Your blood sample will be tested on site at the hospital where you work for the antibodies to COVID-19 virus. We will test for two types of antibodies, one that is produced in response to infection with COVID-19 as we did in October, and another that is produced in response to vaccination. Your blood

sample will be stored for a period of two years after completion of the study and will then be destroyed. During this time, if you agreed to it on the consent form, we might contact you about using your sample for other closely related studies that will help us to continue to improve our understanding of this virus. Any additional studies will undergo ethics review and approval.

Will I get the result of my blood test?

When signing the consent form, you will be asked whether or not you wish to receive the result of your blood test. If you wish to receive it, we will text you your result, and a brief explanation of what the result may mean. As this is a new disease the tests for it are also new. It is still not clear exactly what the results mean for people themselves. This test is not a test to diagnose current COVID-19 infection in an individual – it is designed to help us to estimate the number of infections at population level. If antibodies to the COVID-19 virus are not found in your blood, it may mean that:

- You may have never been infected with COVID-19 – this is the most likely explanation
- You have been infected but had a mild infection and have a level of antibody in your blood that the test we are using is not able to detect. If antibodies to the COVID-19 virus are found in your blood, it may be a sign that you were infected with the COVID-19 virus at some time. However, we do not know now whether this will give you protection against getting the infection again. The reason we do not know is because this is a new disease and the tests for it are also new. **So, your result cannot be taken to mean that you are immune to COVID-19. It is very important that you continue to follow all the physical distancing and hygiene measures recommended by the government, and supported by your local Infection Prevention and Control team, and follow all advice in relation to PPE use.**

Sometimes the test can show a positive result even though you do not actually have the antibody. This may be more likely to happen if you have recently had infection with another virus or if you are pregnant or in certain other situations. This possibility will be discussed with you if you are phoned with a positive test result.

Sometimes, the test result can be inconclusive, meaning that the laboratory is unable to give a clear result one way or the other. You may be offered another test to try to see if that gives a clear result. We will phone you if this is the case.

If you have been vaccinated against COVID-19 we may be able to see this in your antibody result.

If you have been vaccinated against COVID-19 but the test indicates that antibody is not detected, this does not necessarily mean that the vaccine is not working the way it should. There are other mechanisms of immunity that we are not testing for in this study.

Will anyone else get the result of my blood test?

Only you will receive the result of your individual blood test. The study team will not inform your GP or Occupational Health of your result. Your result will not be attached to any of your records in the hospital, either in HR or your medical records.

How will the results of the study be used?

Even though we can't be sure of the meaning of the results for each person, the results will give us (1) very useful information about the transmission of the virus in the hospital setting, (2) will allow us to assess the risk of acquisition of infection over time (3) will inform our understanding of measurable sustained immune response over time and (4) will inform you and us about the response to the vaccine. Anonymised results (that is, without the possibility of identifying anyone) will be shared with the Department of Health COVID-19 team and HSE to help with making decisions about how to control the spread of the virus. A report with the overall results of the study will be made public on the HPSC website once we have analysed all the information. Results will also be published in a scientific peer-reviewed journal. These results will not identify any individuals.

What if I do not want to take part?

Participation in this study is voluntary. If you do not wish to take part, neither your care nor your work will be affected by this decision in any way now or in the future. If you agree to take part in the study, you have the right to withdraw your consent at any time, by contacting the local lead at your study site listed below.

I'm still not sure. Where can I get more information?

Information is available on this website precise.castorconsent.com. We are happy to answer your questions. You may phone the helpline or email us:

St. James's – 087 3611790 precise@stjames.ie

Galway – 087-3232614 seropstudy.guh@hse.ie

Study website precise.castorconsent.com

St. James' Hospital www.Sjames.ie

Dr. Niamh Allen, Specialist Registrar in infectious Diseases and Principal Investigator xxx@stjames.ie

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Data Protection Officer, GUH – contact details to be added