



ST. JAMES'S
HOSPITAL



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

PRECISE PLUS STUDY

**Identifying the Evolving Patterns of COVID-19,
Influenza and Respiratory Syncytial Virus infection
and Vaccine-Related Immunity in HealthCare
Workers**



**PRECISE Plus: Observational study of the Evolving Patterns of COVID-19,
Influenza, Respiratory Syncytial Virus Infections and Vaccine-Related
Immunity in Healthcare Workers**

Participant information leaflet Version 1.5 29/09/2023

We are asking you to take part in this important study looking at the immune response to COVID-19, Influenza and RSV infections as well as COVID-19 vaccinations in healthcare workers. This study is a national study which has been funded by Health Protection Surveillance Centre (HPSC). St James's Hospital (SJH) and Galway University Hospital (GUH) are the selected hospital sites.

Participation in the study is voluntary, meaning that you only need to take part if you want to. This study follows on from previous PRECISE Studies within the hospital and involves the same study team. This leaflet provides information about the study.

What is COVID-19 (coronavirus)?

COVID-19 infection caused by SARS-CoV-2 virus is a relatively new infection that can affect your lungs and general health and is still causing illness in Ireland and 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. We also have an incomplete understanding of the impact of other seasonal viral infections such as Influenza and RSV on healthcare workers.

What is the study and why is it being done?

SARS-CoV-2 is a relatively new virus and there are still many things we don't know about it. Our study is specifically aimed at healthcare workers. When a person becomes infected with a new virus, their body produces a response through our immune system. This response is called antibody. We will look to see if there are any differences in this response, depending on whether or not you have had a COVID-19 infection before. We will also look to see if there are any differences in this response depending on whether you had your COVID-19 infection before or after your vaccination. This may help us to better understand why some people have only a mild infection, whereas some people become unwell. It will also help identify the risks associated with Influenza and RSV infection in healthcare workers.

How will the study results be used?

The results will give us very useful information about the immune response to COVID-19 infection and vaccination. Anonymised results (that is, without the possibility of identifying anyone) will be shared with the Health Protection and Surveillance Centre and the HSE to help inform decisions about how to control the spread of the virus, including how best to utilise booster vaccinations. A report with the overall results of the study will be made public on the HSE 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.

Who is doing this study?

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

All health research must have ethical approval to ensure that it is fair and safe. The plan for the study has been approved by an Ethics Committees at each hospital.

How will it be done?

All staff members working in St James's Hospital, Dublin, and Galway University Hospital, 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. Participation in this study is voluntary and if you would like to take part, we will ask you to indicate your consent. We will also ask your consent to link your results with any of the previous PRECISE Studies (Phases 1 to 4) if you took part in them. If you previously participated and gave a blood sample in any earlier phase of the PRECISE Study at either St James's Hospital or Galway University Hospital, we will ask in your Consent Form if you are happy for us to continue to store those samples.

We will ask your permission to invite you to provide a blood samples in the future. This is not mandatory. We will also ask your permission to look at the dates and types of COVID-19 vaccine and Influenza vaccine you have received through CoVax (this is the HSE's national vaccination database). If you are working at St. James's Hospital, we may use Occupational Health records, again to look at the types of COVID-19 and Influenza vaccinations you have had, and the dates that you received them. We will link this information, with your permission, to the results of this study, and with your consent to the other PRECISE studies previously performed in GUH and SJH.

We will email you monthly to fill in short online questionnaires. These questionnaires will ask if you have had a confirmed COVID-19 PCR or COVID-19 Antigen test, Influenza PCR test or RSV PCR test in the preceding month.

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 may ask you at a later date.

Can everyone take part in the blood testing?

If you have any symptoms of COVID-19, Flu or RSV at the time of your blood test appointment, we will ask you to reschedule. This is because travelling to the testing centre may be a risk to your health or the health of others. You can still contribute to the questionnaire part of the study.

What am I being asked to do?

The study involves filling in 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. Go to precise.studyenrollment.com
2. This will bring you to an online information leaflet
3. You can then register with the portal. You will then be sent an online consent form
4. Once you have read the consent form you can sign it if you are happy to do so
5. Complete the brief questionnaire
7. You may be contacted again by the study team in the future for a further donation of blood to look at immune studies if you consent to this
8. We will contact you monthly via email to complete short online questionnaires. These monthly e-mails will continue until the end of the study.
9. You can withdraw from the study at any time without needing to provide an explanation

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

Participants will be asked to complete a monthly online questionnaire that will ask about any diagnosed COVID-19, Flu or RSV infection or symptoms that could suggest undiagnosed infection in the last month. They will also be asked at that point to confirm the date of any positive test. Alternatively, the participant can contact the study team via a dedicated email, and the study member can complete their questionnaire on their behalf. The questionnaire will collect information on:

1. Symptom duration (days of symptoms)
2. Symptom severity

3. Number of days of absence from work as a result of the incident infection.

Participants' vaccination history will be sought from the HSE's centralised vaccination database CoVax as well as from Occupational Health.

If the participant has previously participated in a PRECISE study they are asked to self-identify at the time of enrolment and consent requested for current study data to be linked to previous study data. The data will be used to link to any results, questionnaire data or to PRECISE 1, 2, 3 and 4.

What will happen my personal data?

The data collection for enrolment will be via a questionnaire on an online platform called Castor EDC. This third party provide the platform for data collection, but the data will not be shared with them.

In order to minimise the data collected, questionnaires have been specified to ask only for information related to COVID-19, Flu and RSV infections and related risk factors

The non-blinded data will be retained for up to 5 years from completion of the study, this will be retained by the data controller.

Who will access and use my personal data as part of this study?

The confidentiality of this data is ensured through a single person (the data controller) having access to the non-blinded data. The non-blinded data will be stored on a single password protected file, that is stored on a secure server that cannot be accessed except by the data controller. Only blinded data or summaries of the data will be shared.

St. James's Hospital and Galway University Hospital are joint data controllers as each hospital will determine their own data processing activities and prospectively approve the governance arrangements thereof. A data sharing agreement is in place between the two sites.

The data collection for enrolment and incident infections will be via a questionnaire on an online platform called Castor EDC. This third party provide the platform for data collection, but the data will not be shared with them.

Will my personal data be kept confidential? How will my data be kept safe?

The data will be held on a password protected file, on a secure server hosted by GUH and SJH. It can only be accessed by use of an authorised computer, on the GUH or SJH network.

Serum samples will be retained for 5 years after the end of the study for the purposes of performing assays on the samples as new variants of concern are identified and our understanding of immunity to COVID-19 increases. We will apply for ethics in a separate application should we wish to proceed with additional testing on the samples in the future.

Your GP or other healthcare providers will not be notified of the results.

Anonymised results (that is, without the possibility of identifying anyone) will be shared with the Health Protection and Surveillance Centre and the HSE to help with making decisions about how to control the spread of the virus, including booster vaccinations.

What is the lawful basis to use my personal data?

The lawful basis for processing of the data for this study comes from GDPR Article 6(1)(e) and article 9 (2)(j).

What are my rights?

You have the right to:

- Access your data held and a copy of the data
- To restrict *or object to processing data*
- *To have any information about them corrected or deleted*
- Data portability, meaning they have a right to move their data from one controller to another in a readable format.
- To withdraw consent
- To lodge a complaint with the Data Protection Commissioner

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

We are more than happy to answer your questions. You may phone the helpline or email us:

Galway – seropstudy.guh@hse.ie

St James's Hospital - PRECISE@Stjames.ie

Data Protection officer, SJH dataprotection@stjames.ie

Galway University Hospital www.saolta.ie

St James's Hospital www.stjames.ie

Data Protection Officer, GUH – Liam.quirke@hse.ie