



UniCoV Participant Information Sheet

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Name of Study: Multi-Site Study to Develop a SARS-CoV-2 Infection Surveillance System for Third Level Students and Staff in Republic of Ireland (UniCoV)

Site	Trinity College Dublin
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Data Privacy Notice	https://www.tcd.ie/ttmi/unicov/unicovprivacy.pdf

Part 1 – The Study

Invitation to join the study

We invite you to join the UniCoV COVID-19 research study. This leaflet gives information about the research study, so it is important to read it carefully. You should understand the study before making an informed decision about taking part or not. This process is known as informed consent.

Thank you for taking the time to consider taking part. If you wish to join the study after reading and reflecting on the information provided, we ask you to consent on the UniCov app.

What is COVID-19 (coronavirus)? COVID-19, caused by SARS-CoV2 virus, is a new infectious disease. Most people who get infected only have either no symptoms or have mild illness. However, it can cause a more severe illness, predominantly affecting the lungs but in some cases cause death, particularly in people who are older or have other underlying illnesses.

Why is this research being done?

The latest COVID-19 modelling indicates that recurring waves of infection are likely to occur everywhere, requiring several measures to control the spread of the infection. It is important that we use all available tools to control the spread of the infection such as testing and tracing and quarantining, masking, physical distancing and vaccination so that our health service, our economy and society can function safely and sustainably.

Our research project is to develop a surveillance system for SARS-Cov-2 infection based on rapid testing methods. Rapid testing is an additional tool that can quickly identify those that are infectious. If a rapid test is done at least two times each week, it increases the sensitivity of the test i.e. the likelihood of the test being truly positive. Any person with a positive test will have this confirmed by the HSE PCR testing system. Early identification of infection is important for containment of the infection in the University. It also provides monitoring and support for those who are infected by our health service.

The output of this project will be a surveillance system for SARS-Cov-2 infection based on rapid saliva and anterior nasal swab sampling.

Who is sponsoring and funding it? The research project is co-funded by the Science Foundation Ireland (SFI) Strategic Partnership Programme and the participating HEIs.

How will we study this using rapid tests?

We will ask each volunteer amongst the universities' students and staff to perform a self-administered nasal swab and sample of saliva. Volunteers will be provided with clear instructions via an educational video on how to provide high quality samples.

Sample Collection

Who can provide nasal and saliva samples to this study? Please make sure you are eligible to take part. Further information is available at <https://unicov.org/join-the-study/>.

Process Flow Please see Page 7 for a Process Flow diagram for study participants.

Nasal Swab Participants will self-swab their nose and place the swab tip in the extraction tube. The nasal swab will be analysed by a lateral flow device which is similar to a pregnancy test - a positive result is represented by the appearance of a line.

Once the result is available, you will be asked to take a photo of the results on your phone and upload it to the UniCov app. This helps you to accurately confirm your result with the help of the research support team.

Saliva sample For the saliva sample, first you need to place a printed label on the tube. Remember- it is very important that you do NOT eat, drink, smoke, chew gum or brush your teeth for 30 mins before collecting your sample. Wash your hands or use hand sanitiser before collecting the sample.

Uncap the tube. Allow saliva to pool in your mouth and drool it into the tube. Try to collect saliva so that it reached the first mark on the tube. Recap the tube, scan the saliva tube barcode via the UniCoV app and place the tube into a specimen bag and seal it. Wash your hands or use sanitiser after collecting the sample. Drop your specimen bag into one of the designated drop-off points.

Do I have to provide samples to this research study? Participation in this research study is entirely voluntary. As a volunteer, it is completely up to you to decide whether or not you wish to provide samples to this research study. You can change your mind and withdraw from the research at any point without giving a reason, simply by contacting us.

What happens next if I agree to join this study? If you decide to join as a volunteer, you will be asked to consent to the study on the UniCov website. The informed consent process will require you to answer a series of questions and agree to participate in the study. You will be asked to provide personal data when providing your consent. You will also be asked to accept terms and conditions aligned with the UniCoV study once you have downloaded the UniCoV app.

Next, we will indicate to you where to drop off your sample(s). We may ask you to donate repeat biological samples, at regular intervals (e.g. twice per week).

In addition, you will be invited to participate in an initial demographic data questionnaire, followed by a weekly participant questionnaire for the research purposes of developing low-cost high-throughput rapid surveillance systems for SARS-CoV-2. Participation in both is completely voluntary and does not affect the data collection and research carried out elsewhere in the study.

Will my details be kept confidential? Yes. Best ethical and legal practice will be followed to ensure that all your information will be handled in confidence.

Your samples will be labelled with a unique sample study number. Access to your personal details will only be available to the research team in Trinity College Dublin and Student Health. We will also request that your HSE test result be shared with the research team in Trinity College Dublin.

Non-identifiable, data about your sample will be stored in a secure electronic archive (hard-drive).

You will not be identified personally in any report or publication arising from the analysis of your samples and/or data. Only aggregate metrics will be shared with our partner universities (no. of participants, positivity rate, etc.).

What are the risks and disadvantages of joining the research study? You will encounter no significant risks or disadvantages from contributing saliva or swab samples to this research study. However, there is a risk it may generate a positive result. If that happens qualified medical staff will contact, you and ensure you get any follow up necessary.

Researchers have taken steps to minimize the data protection risks of this study. A numeric code will be attached to your sample, so even if the data from the study were accessed it cannot be traced back to you, without the coding system held securely and confidentially by the research team in TTMI and the medical team in Student Health.

What are the benefits of joining the research study? The study may identify asymptomatic infection which would not have otherwise been identified, you will be making a contribution to science, and there may be a benefit to the future development of surveillance system for SARS-CoV-2 infection for third-level institutions. It also may result in the safe and sustainable return to campus for many of our students, staff and faculty so there is a Collegewide benefit to having lots of us taking part.

Can I know the results obtained from my study samples? Your samples will be taken for research purposes and you will receive feedback through the UniCoV app if your sample yields a negative result. In the event that your sample yields a positive indication for SARS-CoV-2, You will be contacted by a qualified medical team member from College Health. Your details will be shared with the HSE and you will be offered an appointment for an official SARS-CoV-2 test conducted in an official clinical HSE testing centre (where this is available under the latest Guidelines) and advised to follow the latest HSE Guidelines. You will also be given current Government advice on what you should do to keep yourself and others safe.

Are there any payments and what happens if an invention is made using my sample/data? Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions, even in the event of your incapacity or death.

What if I no longer want to be in the research study? You are free to withdraw from participation in the research study at any time without giving a reason. If you choose to withdraw, you can either (1) ask us to stop further contact with you, but allow us to continue accessing your existing samples for the COVID-19 research study, or (2) you can ask us to also stop further use of your data and destroy your remaining samples. Any research already done with your data and samples cannot be undone.

Part Two – Data Protection

What will happen to my Samples and Data?

- Your name and/or student ID will be taken to verify that you are participating in the UnicoV Study on collection of the sample kits.
- Once you've provided your sample, it will be transported to a laboratory within Trinity Translation Medicine Institute (TTMI) and kept in a secure location. Samples will be identified by your student no/staff ID only.
- The saliva sample will be tested for the presence of COVID-19 fragments using a technique called RT-LAMP.
- The saliva samples will be destroyed if they yield a negative result.

- We would like to collect a nasopharyngeal swab sample from you on one occasion. It will be used for comparisons between different testing methods. Nasopharyngeal swab samples will be taken by trained personnel using HSE protocols.

- Whole genome sequencing of SARS-CoV-2 will be carried out on all positive samples by the National WGS consortium. This will help to identify any variants of concern and of interest in the University population. This analysis is of the virus only.

- Your personal details that link to that code will be stored securely and only accessible by restricted personnel in the research team in Trinity College Dublin, and the College Health Service.
- The aggregate test result data (rates of positive/negative etc) will be incorporated into a dashboard that will allow participants to see what positivity rates are present in Trinity. This aggregated data will not identify any individual.
- The aggregate test results will be kept and shared with our research partners. This is to allow us work out how many positives/negatives we have in Trinity and to see if there are particular areas of groups that are more likely to be positive and, in that way, help us plan to keep Trinity open.
- No one outside of the laboratory team in TTMI or medical team in the College Health Service will link your barcode ID, staff or student ID, to your contact details, and this will only happen if your result comes back positive, in order to contact you to discuss a positive result and next steps.
- Data processed by reading your barcode label will be collected on the UniCov app and shared with the Trinity research team.
- We will also keep the aggregate data (non-identifiable) indefinitely for further research in the post-pandemic phase.

What is the lawful basis to use my personal data?

This research study is scientific research which is in the public interest. It is conducted by Trinity under its official authority as a university, under the Universities Act 1997.

What are my rights under Data Protection Law ?

You have the following rights in relation to any identifiable information that we collect about you during this research study. These rights do not exist once we have removed any identifiers for analysis of the data.

- *The right to access to your data and receive a copy of it;*
- *The right to restrict or object to processing of your data;*
- *The right to object to any further processing of the information we hold about you (except where it is de-identified);*
- *The right to have inaccurate information about you corrected or deleted (unless this information relates to a positive COVID result, as this is a notifiable disease under the Infectious Diseases Regulations; and*
- *The right to receive your data in a portable format and to have it transferred to another data controller.*

It is important that you know that all persons carrying out the research or otherwise having access to your personal data are **bound by a professional code of secrecy** (like doctors) or a **contractual code of secrecy** (that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data). This is to keep your personal information safe and secure.

Everyone involved in this project has had **training in data protection law** and practice.

This study has had a **Data Protection Impact Assessment** carried out to identify any risks and to ensure they are minimised.

The aggregate data from this study may be used to inform national discussion on how to manage COVID-19 in society and may be published in a scientific journal- but at no time will your personal identity be disclosed.

Who do I contact for further information? If you would like more information or have any queries, contact the Research Study Leader from your institution.

Research Study Leaders:

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