University College Cork, Ireland
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UniCoV UCC Antigen Study Information Sheet

(*for University College Cork participants*)

(Version 5.1 dated 15 September 2022)

We invite you to join the UCC UniCoV Antigen research study. This form gives information about the research study, so it is important to read it carefully.

Why is this research being done? This study is an extension of the UniCoV SARS-CoV-2 surveillance study here in UCC. The aim of our research study is to continue to refine a surveillance system for SARS-Cov-2 and other seasonal viral infections based on rapid testing methods. Rapid Covid 19 antigen testing can quickly identify those that are infectious with Covid 19. Symptomatic individuals, who test negative for Covid 19 will be offered further testing for seasonal flu, RSV and Adenovirus using a clinician administered Point of Care Test (POCT). Any person with a positive test will be requested to provide a saliva sample for confirmatory Covid 19 PCR testing and genome analysis which will be carried out in the UCC Microbiology Department

What is COVID-19 (coronavirus)? COVID-19, caused by SARS-CoV-2 virus, is a new infectious disease. Most people who get infected have either no symptoms or have a mild illness. However, it can cause a more severe illness predominantly affecting the lungs and, in some cases, can cause death, particularly in people who are older or have other underlying illnesses.

Who is doing this study and who is sponsoring and funding it? This study is led by Dr John MacSharry, Dr Michael Byrne, Prof Mary Horgan. The research project is co-funded by the Science Foundation Ireland (SFI) Strategic Partnership Programme and the participating Universities.

How will I be recruited to this study? You will be asked to provide an expression of interest along with your UCC email address and following this you will be contacted by email, from unicov@ucc.ie, and asked to download the UniCoV-UCC Power App. Any data you submit to the UniCoV-UCC app will be stored in a secured SharePoint file within UCC's Microsoft Office 365 architecture.

What type of tests will be used? We will ask you as part of the study to download the UCC UniCoV-Antigen Power App which involves performing a COVID-19 symptom checker, a self-administered nasal swab and providing a sample of saliva. The nasal swab will be analysed by a lateral flow device which is similar to a pregnancy test (i.e., a bar will appear indicating the test works at C and a bar at T will indicate positive result). An instructional video on how to do this will be provided to you via the UniCoV App. We will ask you to drop off the saliva test at a designated location in UCC and it will be processed in the Microbiology laboratory in UCC. If you are symptomatic and have tested negative for Covid 19 we will offer you further testing using a different antigen test which tests for influenza A and B, Adenovirus and RSV. The sample for this test will be taken via a nasopharyngeal swab (similar to HSE PCR test) by a Student Health Department Clinician.

Who can provide nasal and saliva samples to this study? You can participate in this study if you are a student or staff member of UCC.

What happens next if I agree to join this study? If you decide to join as a volunteer, you will be asked to read and sign an informed consent form and will then be asked to download the UCC UniCoV Antigen App. Next, we will explain to you how to use the app, perform the antigen tests, and provide the saliva sample. This will include using the symptom checker and how to upload your antigen test and obtaining a red or a green status. The Green status shows that you have no symptoms or detectable virus and are considered safe to be on campus. The Red status will be issued if you have symptoms on the symptom checker and/or have a positive antigen test. If you do obtain a red status, UCC Student Health will contact you to advise on the next steps to take in the event you are infectious.

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 barcode linked to a unique sample study number. Access to your personal details will only be available to necessary clinical researchers on this project in the UCC Student Health Department. This will be accessed for the purposes of clinical assessments relating to your symptoms.

The UCC Student Health Department and UniCoV UCC project team will use the data collected via the UCC UniCoV Antigen App to generate reports and will export pseudonymised (non-identifiable) outputs from these reports. No personal data or identifiable data will be shared outside of UCC.

You will not be identified personally in any report or publication arising from the analysis of your samples and/or data. Your data will be stored securely within the UCC data security structure via Microsoft 365 and your data will be processed in line with UCC's Data Protection Policy. **Full details of how your personal data will be processed is set out in the Data Protection Notice (below).**

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 minimise 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 confidential by the data controller.

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 contributing to science, and there may be a benefit to the future development of surveillance system for SARS-CoV-2 infection and other seasonal viruses or third level institutions. You will be contributing to the ongoing body of knowledge on the benefits of the use of self-tests and Point of care Tests in the management of infectious diseases.

Can I know the results obtained from my study samples? The result of the Covid 19 antigen test will be interpreted by you. Results from Point of Care Tests will be immediately available during the consultation. Results from laboratory analysis of saliva samples will be sent to you by email. If you do have a positive SARS-CoV-2 test, we will sequence the genomic data to look for variants of concern. We may also send the samples to the UCD BSL 3 facility for infectivity characterisation. All these samples will be de-identified and will be assigned a random lab associated number with no personal identifiers.

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 UniCoV Antigen research study, or (2) ask us to also stop further use of your data and destroy your remaining samples.

Who do I contact for further information? If you would like more information or have any queries, contact the Research Study Leaders (see below).

Research Study Leaders

Prof Mary Horgan, University College Cork, College Rd, Cork and Royal College of Physicians of Ireland. m.horgan@ucc.ie

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