Appendix 2

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Science Foundation Ireland For what's next

OÉ Gaillimh NUI Galway
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UniCoV UCC Information Sheet
(*for University College Cork participants*)

(version 3.2 dated 27 July 2021)

We invite you to join the UniCoV COVID-19 research study. This form gives information about the research study so it is important to read it carefully.

Why is this research being done? The return to on-campus teaching activity is constrained by risks to university staff and students arising from face-to-face education of large cohorts of unvaccinated students. The aim of our research study is to develop a surveillance system for SARS-Cov-2 infection based on rapid testing methods. The development of a surveillance system for third-level institutions would aid in the return to on-campus learning by providing a safer environment for students and staff and increasing their confidence and providing assurance that working and studying on University campuses poses a low risk in terms of contracting COVID-19. 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.

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 investigators across each of the participating university sites – National University of Ireland Galway (NUIG), Trinity College Dublin (TCD), University College Dublin (UCD), and University College Cork (UCC). 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 UniCoV-UCC 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.

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. You can only join the study at the University in which you are a student or staff member. Samples will not be accepted from individuals who have been diagnosed with COVID-19 within the previous 6 months of study onset.

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 UniCoV-UCC 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, scan your barcoded saliva tube, 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. We may also ask you to perform surveys to assess your experience of social gatherings, using the App and using the antigen kits and saliva tubes. We will contact you by email and provide a web link to the survey.

As part of the Study you will be asked either to provide samples for 2 weeks (4 samplings) or for 8 weeks (16 samplings). This will be selected by a computer-based randomisation process. These different timings are termed surveillance (2 week) and serial (8 week) testing. See Figure 1 below for an illustration of the process.

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 symptoms of COVID-19 or for referring you for a HSE COVID-19 test. We will also request that your HSE test result be shared with the study.

The UCC Student Health Department and UniCoV UCC project team will use the data collected via the UniCoV-UCC App to generate reports and will export pseudoymised (non-identifiable) outputs from these reports to the UniCoV data portal. The UniCoV data portal is owned and operated by NUI Galway. 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 O365 and your data will be processed in line with UCC's Data Protection Policy. Anonymised aggregated metrics will be visible on the UniCoV website dashboard (for example, positivity rate, incidence rate etc.). **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 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.

Can I know the results obtained from my study samples? In the event that your sample yields a positive indication for SARS-CoV-2, you will be asked to contact the UCC Student Health Centre 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. We will also ask that you agree to the result of your HSE test being made available to the study. If your HSE test is negative, you may be asked to self-isolate as a precaution to prevent spread of other respiratory disease. If you do have a positive SARS-CoV-2 test we will sequence the genomic data in Teagasc Fermoy, Co. Cork 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 COVID-19 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 Leader from your institution (see below). There will also be a FAQs section available on the UniCoV website (https://unicov.org/).

Research Study Leaders

UCC
Prof. Mary Horgan, Royal College of Physicians of Ireland & University College Cork, College Road, Cork. m.horgan@ucc.ie
Dr. John MacSharry, School of Medicine & School of Microbiology, University College Cork, College Road, Cork. j.macsharry@ucc.ie
Dr Michael Byrne, Student Health Department. University College Cork, College Road, Cork m.byrne@ucc.ie

NUIG
Dr. Breda Smyth, Director of Public Health, HSE West, Merlin Park, Galway. smythb@nuigalway.ie
Prof. Charles Spillane, Genetics & Biotechnology Lab, Ryan Institute, National University of Ireland Galway, University Road, Galway. charles.spillane@nuigalway.ie

TCD
Prof. Kingston Mills, Trinity Biomedical Science Institute, Trinity College Dublin, College Green, Dublin 2. kingston.mills@tcd.ie
Prof. Orla Sheils, Faculty of Health Sciences, Trinity College Dublin, College Green, Dublin 2. osheils@tcd.ie

UCD
Prof. Patrick Mallon, School of Medicine, University College Dublin, Belfield, Dublin 4. paddy.mallon@ucd.ie
Prof. Grace Mulcahy, School of Veterinary Medicine, University College Dublin, Belfield, Dublin 4. grace.mulcahy@ucd.ie

Figure 1 Flow diagram of process for volunteer participants