



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive



Volunteer Consent Form

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

Research Study Leaders:

Prof. Breda Smyth, Director of Public Health, HSE West, Merlin Park, Galway. breda.smyth@hse.ie

Prof. Charles Spillane, Genetics & Biotechnology Lab, Ryan Institute, National University of Ireland Galway, University Road, Galway. charles.spillane@nuigalway.ie

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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

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

Please complete the consent form below, please note if you have had COVID-19 in the last 6 months you will not be able to take part in this research study.

Statements of Understanding	YES	NO
I have been provided with information about this study: I confirm that I have read and understood the UniCoV Information Sheet , version 2.0 dated 09 June 2021. I have had the opportunity to ask questions and these have been answered to my satisfaction. I understand that if I have questions about this research, I can contact any of the Research Study Leaders involved in the study, details of which are provided above.	<input type="checkbox"/>	<input type="checkbox"/>
I fully understand that I am participating in a COVID-19 surveillance research study and that the research project is not providing a COVID-19 screening or diagnostic service to me or my organisation.	<input type="checkbox"/>	<input type="checkbox"/>

I am aware of the potential risks and benefits of this research study as outlined in the UniCov Information Sheet.	<input type="checkbox"/>	<input type="checkbox"/>
I am aware that I may be contacted by researchers as part of this research study and may receive communication via SMS to my mobile telephone number or via email to my student email address.	<input type="checkbox"/>	<input type="checkbox"/>
Voluntary participation: I understand that if I choose not to take part, this will not affect me at work or study in any way. My health care by the HSE will not be affected by this decision in any way now or in the future. I am aware that I can withdraw from volunteering in this research project at any time and without giving a reason. I may change my mind and ask that my saliva and swab sample(s) be destroyed. I fully understand that all of my data can be removed from all datasets on my instruction.	<input type="checkbox"/>	<input type="checkbox"/>
I fully understand that the researchers plan to publish the results of this study and that aggregate data may be analysed as part of a peer reviewed publication but will not include any information that would identify me.	<input type="checkbox"/>	<input type="checkbox"/>
I fully understand that in the event of a positive result, my sample will be sent for Whole Genome Sequencing of the SARS-CoV-2 viral genome, and that no human genes will be sequenced or measured in any way.	<input type="checkbox"/>	<input type="checkbox"/>
I fully understand that in the event of a positive result my sample will be sent for further testing to detect how infectious the positive sample is.	<input type="checkbox"/>	<input type="checkbox"/>

Sample Collection	YES	NO
I understand that I will carry out the collection of my own saliva and anterior nasal swab samples for the study and will be provided with instructions on how to do so. I understand that I will carry out self-testing of my anterior nasal swab samples(s) using a Lateral Flow Antigen Test and will upload a picture of my result with the barcode of the test device to a web based application.	<input type="checkbox"/>	<input type="checkbox"/>
I understand that should any of my saliva or anterior nasal swab samples yield a "Positive" result for SARS-CoV-2 that this is not a clinical diagnostic confirmation of COVID-19, and that my details will be shared with the HSE via Student Health who will arrange follow up for me. I 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.	<input type="checkbox"/>	<input type="checkbox"/>
I understand that should the study tests determine that SARS-CoV-2 virus is "not detected" in my sample, that I should not consider this as an indication that I do not contain the virus, but rather that		

<p>the test did not detect the virus in my sample.</p> <p>I recognise that I could be infected at low levels under the limit of detection of the assay and/or that I could become infected after I provided the sample to the research study.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>In the event of my UniCoV Study tests yielding a 'positive' result and the HSE PCR test yielding a 'not detected' result, I understand that my original samples may be reassessed in the laboratory and I may be offered a repeat HSE PCR test.</p>	<input type="checkbox"/>	<input type="checkbox"/>

Provision of Samples and Data	YES	NO
<p>Provision of samples: I agree to give saliva and anterior nasal swab samples for this "Multi-Site Study to Develop a SARS-CoV-2 Infection Surveillance System", including providing repeat samples for those being serially screened.</p> <p>I understand that my samples will be used to develop a surveillance system for SARS-Cov-2 infection.</p> <p>I understand my samples will be stored in the relevant university research laboratories prior to use for the purposes of this project.</p> <p>I understand that my sample will be destroyed once the process for developing a surveillance system for SARS-Cov-2 infection is completed.</p> <p>If I am identified as a close contact of a case of COVID-19 I will inform the research team via the Student Health Unit and agree to supply further UniCov study samples in addition to the HSE testing which will be carried out</p> <p>I agree to comply with HSE advice if I test positive for COVID-19 or am a close contact of someone with COVID-19</p> <p>I consent to share my HSE test result with the research project.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Provision of data: I agree to provide personal details (e.g. name, date of birth, occupation) and contact details (e.g. address, email, phone number etc.) where only my contact details will be associated with my sample which will have a unique numeric code. My contact details will only be used/decoded in the event that my saliva or swab samples yields an indication for presence of SARS-CoV-2 using the experimental surveillance platform.</p> <p>I understand that I may be invited to be surveyed by the</p>	<input type="checkbox"/>	<input type="checkbox"/>

research project for the research purposes of developing low-cost high-throughput rapid surveillance systems for SARS-CoV-2 based on rapid tests combined with saliva and anterior nasal swab sampling.		
I agree to be part of the research study, and understand that I will be asked to provide each saliva and anterior nasal swab sample, using the protocol/instructions provided by the research team.. I take full responsibility for the Infection Prevention and Control procedures that I should follow as outlined in the guidelines when giving my sample to ensure no communicable diseases can be transmitted via contact with the samples or its containers. Any nasopharyngeal swab samples I provide will be taken by a trained professional using HSE protocols, and will be used for comparisons across different tests and with other sample types (saliva, anterior nasal swab).	<input type="checkbox"/>	<input type="checkbox"/>
I agree to use a web enabled application for the purposes of this study.		

I fully understand that by ticking to agree to participate I am consenting to enter the study. I am agreeing to provide my saliva and anterior nasal swab sample(s) for the purposes of developing a surveillance system for SARS-Cov-2 infection. I understand that participating in this research is completely voluntary. Even if I decide to participate now, I may change my mind and stop at any time.

I agree to participate in the study (please tick box & provide contact details).

I AGREE TO PARTICIPATE

I **DO NOT** AGREE TO PARTICIPATE

PRINTED NAME OF VOLUNTEER:.....

DATE OF VOLUNTEER BIRTH:.....

EMPLOYEE OR STUDENT NUMBER:.....

COMPANY/ORGANISATION:.....

HOME ADDRESS:.....

.....**EIRCODE:**.....

CONTACT MOBILE PHONE:.....

UNIVERSITY EMAIL ADDRESS:

DATE:

Research Volunteer ID Code [ATTACH PERSON ID CODE]

Lead Researcher

Name: Prof. Breda Smyth

Signature:

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NUI Galway Research Ethics Committee

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