

Participant Information Leaflet

Name of Study: [Trini-Screen Covid - Screening of Staff and Students for SARS-CoV-2 in Trinity College Dublin]

Site	Trinity College Dublin
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Part 1 – The Study

Why is this study being done?

We are asking you to take part in this research study looking at the effectiveness of the LAMP method of screening for COVID-19 infections in staff and students. LAMP is a relatively new technique and is different from the diagnostic test used in HSE laboratories to detect COVID-19. However, it is technically simple and easy to perform, and it will not deplete laboratory reagents that the HSE critically needs to perform its testing. There is emerging evidence that LAMP is a useful alternative and many research laboratories and diagnostic companies are currently performing clinical trials to support it. This study aims to contribute to this research.

This study is also intended to assist us in being safe as possible while at College during the current pandemic. It is co-ordinated through the Faculty of Health Sciences as part of Trinity's response to COVID-19 and to support a safe environment for each of us to work and study in.

Participation is recommended but is voluntary meaning that you only need to take part if you want to. This leaflet provides information about what taking part in this study entails.

What is COVID-19 (coronavirus)?

COVID-19 infection caused by SARS-CoV2 virus is a new pandemic infection that can affect your lungs and general health and is causing illness in Ireland and is spreading rapidly 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 underlying illnesses.

What is the proposed programme and why is it being done?

SARS-CoV-2 is a new virus and there are many things we don't know about it. Currently, the majority of people being tested are those who are ill or have some symptoms of COVID-19. However, it seems that a proportion of people do not develop any symptoms. While this is good news for them, it means there is a risk they could still transmit the virus to others. This is called asymptomatic transmission.

This programme of screening people who are well on a regular basis, aims to identify those people who may have contracted the virus but who don't know they have it. This means they could be referred for a diagnostic test and isolate themselves until they have cleared the virus.

The idea is that this will prevent transmission of the virus to others who may become ill and minimise the number of clusters of infection that might develop in Trinity.

Description of study

The study aims to find out how widely COVID-19 infection exists among staff and students in Trinity College Dublin, by inviting all to undergo regular COVID-19 antigen testing.

This will help to make decisions about how to control the spread of the infection and how to make College a safer environment, help us understand if other factors contribute to infection acquisition and help us understand why some staff and students become infected while others do not.

The study involves providing a saliva sample which you will collect yourself to check if you have particles from the virus that causes COVID-19 (a sign that you may have been infected with the virus). We are inviting you to take part in the study, as set out in this information leaflet.

What do I need to do or what will happen?

We propose to do this using a simple saliva test. Each person will be asked to provide a sample of saliva into a special tube and to leave it at a designated depot/ collection point around College. Each person will be asked to repeat this process once a week on a designated weekday (Mon-Fri). Once collected the samples will be transferred to some of our laboratories in TTMI and TBSI where researchers will perform a rapid test to identify characteristic viral components in the samples. If the test is negative, you will hear nothing more. If it comes back positive, the result will be sent to the College Health Team who will contact you and arrange for a diagnostic test if necessary.

Who is doing this study?

This programme is being co-ordinated through the Faculty of Health Sciences as part of Trinity's plan to resume activity on campus in as safe a manner as possible.

Will I get the result of my saliva test?

Typically – no.

You will only be contacted if the screen detects a positive sample.

What if I do not want to take part?

Participation in this study is voluntary. If you do not wish to take part, neither your ability to study nor your work will be affected by this decision in any way now or in the future. If you agree to take part in the study, you have the right to withdraw your consent at any time, by contacting the local lead at your study site listed below.

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

Information is available on this website www.tcd.ie/ttmi/triniscreen. We are happy to answer your questions. You may send an email to triniscreen@tcd.ie

We hope you will agree to take part in this important research study! Study website www.tcd.ie/ttmi/triniscreen

Why have I been invited to take part?

- We are trying to recruit as many people as possible to try to minimise clusters of infection emerging around Trinity. We want to work together to keep each other as safe as possible.
- There is evidence that people who feel well and healthy may still have COVID-19. These people are called asymptomatic. If we can identify these people, we will be able to reduce the risk of clusters forming and help to keep Trinity open.
- We are starting with a targeted programme aimed at Staff and students in College Accommodation. Over the next months we plan to expand the study to all staff and students who are on campus and who want to be part of the programme.

Do I have to take part? Can I withdraw?

- It is important that you know that participation in this programme is **voluntary**;
- If you decide not to participate there will be **no adverse consequences for you**;
- It is absolutely fine to withdraw from the programme at any time. If you want to stop being involved – simply don't show up for the next scheduled sample.
- If you want to have details of previous screens erased, just let us know and we will ensure all of your data is deleted. You simply need to *contact Frank Mangan on 01-8964331*
- No samples will be stored. This means they will all be destroyed after testing as a matter of routine.

How will the study be carried out?

Below is a general overview of the study.

How will the test be done?

In the laboratory we will use a technique called LAMP. It is a relatively new technique and is different from the one used in HSE laboratories to detect COVID-19. However, it is technically simple and easy to perform, it will not deplete laboratory reagents that the HSE needs to perform its testing. There is emerging evidence that LAMP is a useful alternative and many research laboratories and diagnostic companies are currently performing clinical trials to support it.

What does the test detect?

The LAMP test detects whether or not viral **RNA** is present in samples from a person. It does this by capturing and amplifying regions of the virus' genetic material in a test tube. The laboratory test uses special enzymes to make many copies of the viral target (if it is present). The results of the test are determined based on a colour change in the sample tube.

What does the result mean?

Positive test result: - A positive LAMP result means that the person the sample was taken from is likely to be currently infected by the virus.

Negative test result: - A negative LAMP result could mean that the person is not currently infected by this virus, the virus is not present at the site the sample was taken from, or that it is too early, or too late in the infection cycle to detect replicating virus. This is why when test results are negative, new samples are taken a few days later to reduce the chance of incorrectly missing an infected person. LAMP tests cannot detect if a person has had the virus and then cleared it after the end of the **COVID-19** disease, i.e. whether a person had the disease, as it only detects when active virus is present.

When will the study take place?

The study will take place during Semester One and Two. People who want to be involved will be asked to supply a saliva sample once each week on designated weekdays.

Where will the study will take?

The study will take place at Trinity in the Halls of Residence initially and will be extended to all staff and students. We will work together to try to ensure we can remain open and keep everyone safe. So everyone is part of the research team, including people who will provide samples, staff who will transport the samples to laboratories, admin staff who will prepare coded labels for samples, researchers in our laboratories who will process the tests. We will all be in this project together.

What will happen to me if I decide to take part?

- If you decide to take part, you will be asked to present and provide a saliva (spit) sample on a specified day each week.
- There will be designated collection depots throughout College to collect samples.
- This sample will be labelled with an ID number so your personal name and details will not be visible to any researchers in the laboratories or transporting samples.
- The saliva sample will be tested using the LAMP test to see if there are particles of COVID-19 present.
- You won't hear anything unless your sample tests positive. If that happens staff in College Health will identify your details and contact you. If this happens they will ask if you are experiencing any symptoms. If so they will refer you for a Diagnostic HSE test. **It is important to remember our research project is using a screening tool and a proper diagnostic test will be needed to confirm any positive samples.**
- If you have no symptoms, you will be asked to carry out a repeat saliva test and College Health Staff will advise you of Government Guidelines to keep you and others safe.

What will happen to my Samples?

- Your samples will be transported to a Trinity Laboratory- most likely within TTMI, TBSI. They will not have your name on them- but your Staff ID and for students your Student ID code and room number (for those living on campus accommodation).
- The saliva sample will be tested for the presence of COVID-19 fragments.
- The ID code will only be linked to your contact information should a sample have a positive test. In that event, only properly trained medical staff within the College Health Services facility will link your Staff / Student ID to your contact information in order to contact you to explain the result.
- The saliva samples will be destroyed once they have been tested – whether positive or negative.
- **What will happen to my Data?**
- No one outside of the medical team in the College Health Service will link your staff /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.
- The aggregate test results will be kept by Trinity. 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.

- We will retain the Consent Form in order to provide evidence of consent in accordance with Article 7 of the GDPR requirements, and because this research study is classified as health research under the Health Research Regulations.
- 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.*
- *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 data protection 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.

Are there any benefits to taking part in this research?

- As an individual, it is unlikely you will have an obvious benefit. However, working together as a team we are hoping to keep each other safe and so there is a College-wide benefit to having lots of us taking part.

Are there any risks to me or others if I take part?

- There is no risk for you in providing a sample.

- Every measure will be taken to maintain your confidentiality.
- 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.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

- You will only be contacted if your sample produces a positive result for COVID-19. Otherwise you will not hear from us.
- If you are contacted, it will be by a qualified medical team member. You will be advised on the best course of action and supports will be provided to ensure you can access a diagnostic test if needed. You will also be given current Government advice on what you should do to keep yourself and others safe.
- This is an important research study and we will produce a report that may be published in medical journals or at a conference, or in a report submitted to government. In any publication, the data will be in aggregate, so you will not be identifiable.

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has been approved by the Faculty of Health Research Ethics Committee. Approval was granted on 23rd September 2020 with an amendment granted on 9th November 2020 to extend the pilot to include all students and staff and to extend the pilot to include Semester 2.

Who is organising and funding this study? Will the results be used for commercial purposes?

The study is being done on behalf of Trinity College Dublin. The costs associated with the study have come from Trinity College Dublin as a satellite to an SFI funded project on COVID-19. There is no commercial aspect to this study. We are simply trying to keep the university as safe as possible to allow us remain open during the current pandemic.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

No, we are not paying individuals to take part in the study.

Part 4 – Future Research

Will my personal data and/or biological material be used in future studies?

- Samples will be destroyed once they have been tested and will not be used for any other purpose than testing for the presence of COVID-19.
- Details of the aggregate number of positive cases we detect, and which areas they are from will be kept so we can model patterns over time. You will not be identifiable from this data.
- It is important that you know that participation is voluntary and that you can withdraw your consent to this study at any time.

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- *Principal Investigator: [Prof Orla Sheils].*
- *Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.*

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

You will not be contacted again, as the study is entirely voluntary. If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep.