

Test-Ed COVID-19 Testing Project Information for University of Edinburgh staff and student participants

Participant Information Sheet

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Chief Investigator- Professor Tim Aitman, University of Edinburgh
Co-Investigator- Professor Linda Bauld, University of Edinburgh
Co-Investigator - Professor Nick Gilbert, University of Edinburgh
Co-Investigator - Dr Alice Street, University of Edinburgh
Co-Investigator- Professor Neil Turok, University of Edinburgh

Introduction

We'd like to invite you to join the University of Edinburgh's COVID-19 Testing Project. The aim of this project is to introduce an easily accessible and efficient system to provide regular COVID-19 screening for University of Edinburgh, and other educational institutions' and organisations' staff and students.

Please take time to read this information carefully. If anything isn't clear, or if you'd like further details, you can email us at TestEd@ed.ac.uk. You can withdraw at any time prior to giving a sample, or at any later time point without giving a reason, by choosing not to collect a kit or provide a sample, or simply informing the study team that you no longer wish to participate (see later section in form).

The project will help University of Edinburgh, and other educational institutions' and organisations' staff and students know if they have COVID-19 infection, even if they don't have symptoms. By finding cases of infection early, we can give staff and students who test positive information and support to self-isolate. This will reduce the risk that people with the infection will pass it onto others at work, study or elsewhere.

Before deciding whether to participate, it is important for you to understand why the research is being done and what it would involve for you.

What the study is about

The aim of the study is to assess whether a robust testing system can be set up at the University of Edinburgh, and other educational institutions and organisations that will detect people who are infected with COVID-19 but are not yet showing any symptoms.

The standard way of testing for COVID-19 is by using a test called RT-PCR which measures genetic material (RNA) produced by the virus. This method is costly. Our study aims to test large numbers of staff and students across the University of Edinburgh, and other educational institutions and organisations in a more cost-effective way. Once infected people are detected early before they show symptoms they will be asked to self-isolate. They will also be provided with information and support to do so, in order to prevent them from infecting others. This will make the University, and other educational institutions and organisations safer places for those who work and study in them.

The test process will use saliva (the clear liquid that is made in your mouth and that you can spit out) to make sample collection as easy as possible. After you give a saliva sample, researchers will conduct RT-PCR analyses on pooled samples (lots of samples at once). If a pool of samples test positive, further tests will be performed that will identify individual positive samples in the pool. Pooling samples will allow a much larger number of people to be tested at a very low cost.

We are also planning to do additional work that involves tagging each sample with a “molecular bar-code”. A molecular bar-code is a synthetic, unique, chemical tag which attaches to the molecules that we will analyse in your saliva. This will allow an infected sample in a group of samples to be identified more efficiently. Combined with the pooling method of analysing samples, this will allow an even larger number of samples to be analysed more quickly.

As a screening test it will detect many but not all cases, and is not designed for those already showing COVID-19 symptoms. **If you have COVID-19 symptoms, you are not eligible to participate in this testing project, which is only for University of Edinburgh staff and students without symptoms of COVID-19.**

What Will Happen If I Take Part In This Study?

You'll be invited to fill in registration and consent forms online. By filling these in, you will be confirming that you are willing to provide saliva samples and be sent links to online surveys to obtain feedback about the testing process after you have been tested. You will also be asked to complete a demographic questionnaire as part of the registration process which will ask a few questions about yourself e.g. age, gender, whether or not you have a disability, ethnicity and if you have received a COVID-19 vaccine. These questions are important as they help us to analyse and interpret test results and to understand how participants are responding to the TestEd scheme. Participation in online surveys is voluntary and each survey will involve about 10 minutes of your time. It will help us improve the testing project as it is rolled out. At the end of the survey you will be asked if you would be happy to take part in a future interview with a researcher. Taking part in an interview will be entirely voluntary and there will be a separate information and consent process for this element.

We will extract DNA and RNA (the building blocks of your genetic make-up) from your saliva sample. This will allow us to test whether your saliva contains genetic material derived from the virus that causes COVID-19, and, if detected, the strain of the COVID-19 virus to be determined. Your sample will be kept for a maximum of 6 weeks following sample collection and measurement before it is destroyed.

Who Is Eligible To Participate In This Study?

Everyone who works or studies at the University of Edinburgh, and at other educational institutions and organisations and who can login through EASE (non-University participants will use a separate registration form) is welcome to take part. The study includes anyone aged 16 years old and over, who does not have symptoms of COVID-19 and who is able and willing to provide a saliva sample. We intend to collect samples from all participants, ideally twice a week for up to 6 months (or as long as you can manage) which is the anticipated remaining duration of the study programme as determined by availability e.g. when available in Edinburgh and the surrounding areas of other educational institutions and organisations. Samples will be collected at designated collection points throughout the University of Edinburgh, and other educational institutions and organisations, in areas (such as at building reception desks) where trained University monitors are available to support the process. We will initiate the study at the Institute of Genetics and Cancer, and will invite other departments to join as we increase testing capacity.

How Will My Privacy Be Protected?

Your data will be processed in accordance with Data Protection Law. Your registration form will include details that can identify you. The data from this form will be stored securely, separate from the lab data. Your data will be referred to by a unique participant number rather than by name. Your data will only be viewed by the research team but may be shared with research regulators on request

for regulation purposes. This will not include any identifiable information about you. Once analysis is complete, both the saliva sample and the RNA from it will be destroyed.

As the sample collection points are located within University of Edinburgh, and other educational institutional and organisations' buildings you should be aware that you may be visible to other members of the University of Edinburgh, or other educational institutions or organisations when you collect your sample pack and/or return your sample.

In order to check the accuracy of our lab testing equipment and assays we will be sending completely anonymised summary quality control data to our collaborators based in University of California, Los Angeles. It is not possible for you to be identified from any of the data sent.

Are There Any Benefits or Disadvantages In Taking Part?

The main benefit from being tested regularly for COVID-19 is that researchers anticipate that they will be able to identify those participants who test positive to the virus before they exhibit symptoms, and advise them to self-isolate. This means that the workplace in the University and other educational institutions will be much safer for staff and students, and it will be possible for more work and teaching to occur in person once restrictions allow. Another benefit is that by identifying asymptomatic carriers, staff and students will be less likely to infect relatives or friends who are not part of the University of Edinburgh, and other educational institutions communities and organisations. Your participation will also contribute to research that may improve pandemic control. By taking part in the online surveys to provide feedback on the screening, you will help improve the process for others.

One of the disadvantages of large-scale testing methods is the risk of obtaining a false positive or false negative result. The TestEd team will minimise these risks by using best standard laboratory methods. You may also experience some anxiety while waiting for your test results and you may have privacy concerns. However we operate within strict data controls and will ensure that your data will be handled securely to minimise the risk of any disclosure occurring.

Being given a positive result from this test may cause you some anxiety. However, by helping to find asymptomatic cases, we will be keeping ourselves and our community safer, which is a beneficial action. The TestEd project team will aim to give support online by email and will also provide a phone help line to those participants who test positive.

What Will I Be Asked To Do?

If you'd like to join, it would involve:

- Registering your interest providing your contact details and answering some brief questions about yourself to confirm your eligibility.
- Consenting to participate that you are willing to be sent links to brief online surveys to be completed after you have been tested.
- Once you consent you will receive a barcode to store on your phone or print out and bring to sample collection points.
- You will also be asked to complete a demographic form which will involve providing details including age, gender, ethnicity, if you have a disability, COVID-19 vaccine status, staff/ student status.

- Providing a saliva (spit) sample. You'll be given a specimen pack, linked by a barcode to your unique identifier at the collection point you go to. This code will ensure that your sample is anonymous to those transporting and processing the samples.
- We will ask you to wait until at least 30 minutes after you have been eating, drinking, chewing gum or smoking before you provide your sample.
- You'll be asked to follow the instructions and provide approx. 1ml (half a teaspoon) saliva (spit) sample into the tube. This will be done within selected University buildings and exact arrangements for location to provide a sample may vary for each collection point.
- The saliva sample can be collected into the beaker and tube at the sample collection point or at another convenient location including the participant's home, provided it is returned to a designated sample collection location within 24 hours.
- Return the sample to the container provided at the designated collection point.
- RNA will be isolated from your saliva and assayed for the presence of the virus which causes COVID-19 and also the strain of COVID-19 virus.
- If your result is positive, negative, or the analysis fails for a technical reason, we will notify you by text message (and/or email if you have not provided a mobile number for a smart phone) and advise you to log-in to the TestEd dashboard to view your result.
- After each test, with your test result, we will ask you if there has been any change in your vaccination status, which will help us to analyse and interpret your test results.

What Happens If My Test Comes Back Negative?

A negative result means that the virus was not detected using the TestEd methodology. This is research methodology rather than diagnostic methodology. You will be advised to continue to follow the public health guidance. <https://www.gov.scot/coronavirus-covid-19/>

What Happens If My Test Comes Back Positive?

After checking, a positive test result for COVID-19 will be linked back to your personal information by a member of the research team authorised to do so.

If your test comes back positive we will advise you to self isolate. You may choose to contact the TestEd mobile phone number which will accompany your result.

All staff and students should follow the established process by completing an online form on the University of Edinburgh web site. If you are a member of University of Edinburgh staff you are also required to inform your line manager.

Information for University of Edinburgh students who test positive can be found on the University of Edinburgh's website following the link below:

[Self-isolation | The University of Edinburgh](#)

Information for University of Edinburgh staff who test positive can be found following the link below:

[Staff | The University of Edinburgh](#)

For other educational institution or organisation please follow the guidelines for your institution.

Further provision of support can be found on the Scottish Government website.

<https://www.gov.scot/publications/coronavirus-covid-19-test-and-protect/pages/support-grants/>

If your TestEd or any other test result is positive you should not submit another saliva sample to TestEd for 60 days because people who are infected with the virus can remain positive for some time, even up to several weeks in some cases, from a single infection.

How Do I Get a Specimen Pack?

Register (once only) for the project and sign the online consent form.

Go to one of the specimen pack collection sites across the University of Edinburgh, or other educational institution or organisation. The location of these sites is detailed on the TestEd study website. www.ed.ac.uk/tested-covid

Sample packs with detailed instructions will be available at the collection site.

What Happens If I Choose Not To Participate?

If you choose not to participate that is absolutely fine. You do not have to join the TestEd study. This will have no bearing on your studies/role within the University nor incur any penalties or loss of access to any University services. Taking part in the study does not affect your rights in any way.

Can I Request That I Be Withdrawn From The Study At Any Point?

Yes, you can withdraw from the study at any time and do not have to give a reason for doing so. If you decide to withdraw from the study, there are two options for doing so.

1. "No further contact" This means you will no longer be contacted by the study team. However, permission would still be in place to use the information and sample which you provided.
2. "No further use" In addition to "No further contact" this means that your data or samples could no longer be used in any future research, although it would not be possible to remove your information or sample from the current research.

What If I Have Any Problems Or Would Like Further Information About the Study?

If you would like more information about the study you can request more information by emailing the dedicated TestEd mailbox: TestEd@ed.ac.uk

If you would like to discuss this study with someone independent of the study team please contact (Professor Margaret Frame, Director of MRC Institute of Genetics and Molecular Medicine, email address M.Frame@ed.ac.uk).

Thank you for taking time to read this participant information sheet.

General Data Protection Regulation (GDPR) Participant Information

All information collected in this study will be kept on a secure online server in accordance with the EU General Data Protection Regulation (GDPR), along with the UK Data Protection Act. All electronic data will be stored on a password-protected computer file. Your consent information will be kept separately from your survey responses in order to minimise risk.

Message to participants from the TestEd team on behalf of the University:

We will use information from you in order to develop and to implement TestEd and the University of Edinburgh will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Identifiable information (name, contact details) will be used to inform you of your test results and for administrative purposes only, during the study period. These details will be deleted at the end of the study. Anonymised data which will be used for research purposes will be stored for a minimum of 5 years after the study has ended. Identifiable audio recordings will also be kept securely for this period of time.

As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will only use your data in the ways needed to conduct and analyse the research study.

This document explains how we will use any data that you share with us. We are legally required to tell you how we will use this information and to give you the opportunity to tell us not to use your information in that way.

Providing personal data by registering as a participant, by providing regular saliva samples, by completing questionnaires or verbally, in follow-up interviews.

To sign up to TestEd you will be asked to carefully read the study information sheet before providing your consent to participate. You will be asked to fill in a registration form, providing your name, contact details, and eligibility for the study. You will also be asked to provide some demographic details. The data collected will only be that which is appropriate and necessary for our specific research project.

The study investigators will keep your name and contact details, as well as the other information you provide, strictly confidential and will not pass this information on to third parties. We will use this information only as needed, to contact you about your test results, to make sure that information relevant to the study is properly recorded, and to ensure the quality of the study.

What happens to my data?

1. Registration form and survey

When you consent to the agreement to participate, you will enable us to access the data you provide on your registration form, the data resulting from regular tests of saliva in the samples you provide and the responses you provide through the online survey which is part of TestEd. All of this information is hosted on a secure server accessible only to the project team.

The data will serve two purposes only: first, to securely and confidentially convey your test results to you. The only members of the TestEd team with access to this data will be qualified IT professionals responsible for data protection and secure information management. Only anonymised data (which does not identify you) will be made accessible to TestEd researchers for the purpose of monitoring the progress of the project.

If you tell us that you are interested in taking part in an in-depth interview, the demographic data (age, gender, ethnicity, staff-professional services or academic/student-living in University owned accommodation or elsewhere) provided by you when you registered to take part in TestEd will be shared with the TestEd interviewers. This is to allow the interviewers to select a sample of participants for interview that reflects the make-up of the whole of the TestEd population.

2. Analysis

Your anonymous survey data will be imported into quantitative data analysis software where it will be combined with others for analysis by the same research team. The survey data will be retained on our server for a minimum of 5 years after the end of the study.

3. Publication

The anonymised results of TestEd will be analysed for research purposes and may be quoted in the reports and academic publications we write. Likewise, survey responses may be used in such publications. Your name will never be used in any of these reports or publications and they will not include any personal identifiable information about you. When we publish our findings, we will upload all of the anonymised data to an online repository. When using research repositories, researchers are often required to upload their supporting or underlying data. The repositories have technical controls in place to ensure that only authorised individuals can access the information.

Certain individuals from the University of Edinburgh and regulatory organisations may examine our research records to check the accuracy of the research study, and for audit purposes. They will only be able to access de-identified (coded) and unlinked information.

Contact for further information

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at <https://www.ed.ac.uk/data-protection/privacy-notice-research>

For further information on the use of personal data by the University of Edinburgh, please go to website: <https://www.ed.ac.uk/records-management/privacy-notice-research>

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>.

Data Protection Officer contact information:

University of Edinburgh

Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk