

PARTICIPANT INFORMATION LEAFLET

**Title of study:** Investigating the capacity of emerging SARS-CoV-2 variants of concern (VOCs) to evade antibody responses to infection and/or vaccination.

* You are being invited to take part in a research study.
* Before you decide it is important for you to understand why the research is being done and what it will involve.
* Please take time to read the following information carefully and discuss it with others if you wish.
* Please ask us if there is anything that is not clear or if you would like more information.
* Take time to decide whether or not you wish to take part.
* Thank you for reading this.

**What is the purpose of the study?**

SARS-CoV-2 is the virus responsible for the worldwide pandemic since March 2020. It causes COVID-19 disease in a high percentage of infected individuals, which ranges in severity from mild to severe disease and death. Vaccines and therapeutics were rapidly generated to the virus and deployed worldwide. Vaccine effectiveness, which is measure of the proportionate reduction in disease outcomes among vaccinated compared to non-vaccinated persons, has been remarkably high so far in diminishing the frequency of severe disease and death. However, many parts of the world remain poorly vaccinated, and the virus is circulating freely. A number of companies have generated therapeutic monoclonal antibodies, which are approved to treat very ill COVID-19 patients. A therapeutic monoclonal antibody is an antibody that recognises and binds to one specific part of the virus and prevents the virus from infecting host cells. These antibodies are referred to as virus neutralising antibodies and help prevent further infection with the virus in the body. Extensive unmitigated circulation of the virus periodically results in the emergence of new variants of concern (VOCs) that may have enhanced abilities to transmit from person to person and/or cause more severe disease. Of greatest concern are VOCs that evade immunity provided either by prior infection or vaccination, or neutralisation by therapeutic monoclonal antibody drugs.

Five VOCs have been identified so far by the World Health Organisation (WHO), with the latest VOC, Omicron, having multiple mutations that suggest the possibility of reduced effectiveness of the vaccines and the monoclonal antibodies. This study, therefore, will extract serum from blood donations from infected and/or vaccinated individuals. Serum is the part of the blood that contains the antibodies. We will use the serum from each donor to determine whether the vaccines and/or prior infection induce antibodies that effectively neutralise different VOCs, including Delta and most especially Omicron. Our data will provide urgent information about the residual effectiveness of the vaccines in protecting against infection with different VOCs.

**Why have I been asked to take part?**

You are being asked to participate because you have been vaccinated and/or infected with SARS-CoV-2.

**Do I have to take part in the study?**

No, you can decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. The consent form consists of a series of questions. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect any future treatment.

**What will happen if you agree to take part?**

We will give you information about the research study and an opportunity to ask questions, before you sign the consent form.

You will then be asked to attend an appointment to give a blood sample. The blood will be drawn by putting a needle into a vein in your arm. Approximately 5 mL of blood, which corresponds to approximately 1 tablespoon, will be taken. This will take about ten minutes*.*

We will separate serum from your blood and discard all cellular material. We will ask for your consent to store the serum indefinitely, so that if new VOCs emerge we will be able to use the stored samples for future research. We may also, with your consent, share samples with other academic, governmental, and/or industrial research teams nationally or internationally to help advance our research efforts. We will dispose of your samples after this research if you prefer, and this will be discussed with you in the consent process.

We would also ask you if you would like to be contacted by the research team at a later date and invited to take part in similar related studies. You would only be agreeing to receive information and would not be under any obligation to take part in any future studies. If you decide not to consent to being contacted in the future it would not have any influence on your involvement in this particular research study and will not affect any standard of care that you receive.

**Are there any potential risks?**

There is a small risk of bruising and fainting, and a rare risk of infection associated with providing a blood sample. A fully trained individual will take the blood samples to ensure that any discomfort is kept to a minimum.

**What are the possible benefits of taking part?**

There will be no direct benefits for you personally. However, we hope that this study will improve our understanding of the ability of new VOCs to evade vaccine-induced immunity or treatment of COVID-19 patients with monoclonal antibodies and help public health authorities decide on mitigations required to control the spread and health consequences of new SARS-CoV-2 VOCs. We also hope that the information will support future studies.

**Will your taking part in this study be kept confidential?**

All personal information provided during this study will be stored securely in the School of Medicine, Dentistry and Biomedical Sciences in accordance with the Data Protection Act 2018. The University will keep identifiable information about you for you for a minimum 5 after the study has finished.

**What will happen to the results of the research study?**

Once the study has been completed, we will make public health authorities aware of the data as soon as possible following appropriate analysis and validation. We would hope to publish the findings in medical and scientific journals and communicate them at scientific meetings. If appropriate, the results may also be used to generate intellectual property in the event of the discovery of novel drug targets that could help treat or prevent COVID-19. You will not be identifiable in any way. Should you wish a copy of the results we will be happy to provide this.

**Who is organising the study and the research?**

The study is being organised by scientists and doctors working at The Wellcome-Wolfson Institute for Experimental Medicine, at The Queen's University of Belfast.

**What happens if something goes wrong?**

If you have any concerns about any aspects of the study, you can contact the Chief Investigator, whose contact details are indicated below. Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at Queen’s University Belfast Email: researchgovernance@qub.ac.uk).

**Contact for further information:**

**Chief Investigator:**

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*This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection please visit the Queen’s University Belfast website* -

<https://www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants.html>

**Thank you for your interest in this study and for taking the time to read through this information sheet.**