

Consultee Information Sheet

Facilitating Accelerated Clinical Evaluation of Novel Diagnostic Tests for COVID -19

(FALCON)

We are inviting all people aged 18 or older with suspected or confirmed COVID-19 infection to participate in a study to improve the diagnosis of this disease. The virus that causes COVID 19 is SARS-CoV-2 and the NHS currently relies on a lengthy laboratory processes to detect the presence of this virus. The long wait for the test results (up to 48 hours) makes safe and effective care more difficult to provide. This study aims to find out how accurate new and faster tests are so that patients and staff can be cared for as safely as possible.

The information below will help you to make an informed decision about whether you would like your relative/partner/friend/patient to participate or not. Whether your relative/partner/friend/patient takes part or not, the clinical care they receive will be the same during and after the study.

**1) Why are we doing this research?**

There are limitations to the current tests available; it can take 48 hours for a result and the accuracy is not well understood. This study aims to find out how accurate current tests are, and measure the accuracy of new faster tests. Your relative/partner/friend/patient’s doctors plan to do tests to see if they may have been exposed to the novel coronavirus.

**2) What is the purpose of this study?**

We need to understand the accuracy of current and new tests for COVID-19 and the underlying novel coronavirus infection (SARS-CoV-2). The current tests for COVID-19 were deployed rapidly and were based on well proven theory. However the accuracy of these tests in the clinical environment is not well understood. Also, we do not know the accuracy of more rapid tests that are now available. These tests are being used to screen the population and patients admitted to hospital, it is therefore of critical national importance that we thoroughly understand the strengths and any limitations of this testing.

**3) Who are the researchers?**

The study is being conducted by researchers across the United Kingdom. Manchester University NHS Foundation Trust is acting as the sponsor for the study.

**4) Who is eligible to participate?**

Anyone aged 18 years or older, who has a suspected or confirmed diagnosis of COVID-19.

**5) What would happen if I agree for my relative/partner/friend/patient to be included?**

If you agree for your relative/partner/friend/patient to be included, we would take additional swabs from their nose and throat and /or saliva and/or blood samples (approx. 3 teaspoons). We would also collect information about their health that would be entered into a secure study database. We might also require your relative/partner/friend/patient to provide further swabs, saliva and blood samples (about 1 teaspoon) on five more occasions over the next 90 days. If they need to stay in the hospital, we will try to take these samples at the same time as they are having routine tests. If we still need more samples after they have left hospital, we will arrange a convenient time for them to return for more tests and we will cover their travel expenses. Depending on the type of new test being evaluated, we may test your relative/partner/friend/patient’s samples immediately or we may store them and analyse them later in batches, which may happen at a different location. We may also make these samples and your relative/partner/friend/patient’s anonymised data available to other researchers for future research, which may include researchers working abroad. However, these researchers will not be able to identify your relative/partner/friend/patient from the data we provide. We would also keep a record of their contact details so that we can inform them of the findings from the study.

**6) What are the downsides to being involved?**

Apart from the inconvenience of having further samples taken there are no additional risks.

**7) What are the benefits of being in the study?**

Whilst there are no individual benefits to being involved in this study, society and the national response to the pandemic will benefit from the confidence that new tests used by the NHS to detect COVID 19 will be accurate, reliable and give the results quickly.

**8) Can I end my relative/partner/friend/patient’s participation early?**

Yes at any point you can choose to end your relative/partner/friend/patient’s participation by telling a doctor or nurse treating them, or using the contact details at the end of this information sheet. This includes if they are invited to take part in a different clinical trial of a new treatment, if it is not possible or desirable for them to take part in both studies. Withdrawing will not affect your relative/partner/friend/patient’s clinical care. The samples we have collected from your relative/partner/friend/patient will be destroyed, however, we will keep any data that we have already collected.

**9) What if something goes wrong?**

If you wish to complain, or have any concerns about any aspect of the way you have been approached or your relative/partner/friend/patient has been treated during the course of this study, please feel free to contact Prof. Richard Body or the Patient Advice and Liaison Service using the contact information below to discuss your concerns. The normal NHS complaints mechanisms will also be available to you.

[INSERT local PALS contact details]

**10) How will you keep my relative/partner/friend/patient’s information secure?**

Your relative/partner/friend/patient’s health data will be kept private and only reviewed by: (1) clinical study team members who will have permission to securely access their data; or (2) by staff at the sponsor organisation who are working on the study or by regulatory authorities, who must check we are running the study correctly.

**11) How will we use information about your relative/partner/friend/patient?**

We will need to use information from your relative/partner/friend/patient’s medical records and their GP for this research project.  This information will include their NHS number, name and contact details.  People will use this information to do the research or to check their records to make sure that the research is being done properly.

People who do not need to know who your relative/partner/friend/patient is will not be able to see their name or contact details. Their data will have a code number instead.  We will keep all information about your relative/partner/friend/patient safe and secure.  Some of their information may be sent to researchers based in other countries. They must follow our rules about keeping their information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your relative/partner/friend took part in the study.

**12) What are your choices about how your relative/partner/friend/patient’s information is used?**

You can request that your relative/partner/friend stops being part of the study at any time, without giving a reason, but we will keep information about your relative/partner/friend/patient that we already have.  If you agree for your relative/partner/friend/patient to take part in this study, you will have the option for them to take part in future research using their data saved from this study.

**13) Where can you find out more about how your relative/partner/friend/patient’s information is used?**

You can find out more about how we use your relative/partner/friend/patient’s information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to covid.research@mft.nhs.uk, or
* by ringing us on 0161 701 7540

**14) Is there any cost or financial benefit?**

There is no cost to participating in this study, nor is there any financial reward for staff or participants. If your relative/partner/friend/patient is asked to return to provide more samples, we will offer to pay for their reasonable travel expenses. The hospital where your relative/partner/friend/patient is receiving care will be paid to cover the costs of running the study.

**15) Who is funding the research?** The research is funded by United Kingdom Research & Innovation (UKRI), which is the national funding agency investing in science and research in the United Kingdom.

**16) Where will the findings of the research be published?** We will try to publish our findings in medical journals and on websites relating to COVID-19 diagnosis, so that others may learn from them. It will not be possible to identify your relative/partner/friend/patient from the information that is published.

**17) Where can I go if I have more questions?**

The hospital study team is available to answer any questions you may have. You can also contact us using the details below.

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| **Chief Investigator:**  Professor Richard Body  Emergency Department  Manchester Royal Infirmary  Oxford Road  Manchester  M13 9WL  Email: [emerging@mft.nhs.uk](mailto:emerging@mft.nhs.uk) | **Trial Co-ordinator:**  Dr Eloïse Cook  EMERGING Research Group  Manchester Royal Infirmary  Oxford Road  Manchester  M13 9WL  Email: [emerging@mft.nhs.uk](mailto:emerging@mft.nhs.uk)  Tel: 0161 701 7540 |