

Research Participant Information Sheet, Regained Capacity

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

(FALCON)

We are inviting all people aged 18 years 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.

Due to your medical condition, until now we have not been able to confirm if you would be willing to take part in this study. Because we could not ask you, we may have consulted with a relative or welfare attorney/guardian, to check if they think you would like to take part in the study. Now that you are able to decide, the information below will help you to make an informed decision about whether you would like to continue participating or not. Whether you do decide to continue to take part or not, the clinical care you receive will be the same during and after the study.

**1) Why am I already in this study?**

During your recent admission to hospital you were unable to give consent for entry into a study, we therefore asked your Welfare Attorney/Welfare Guardian/Nearest Relative, who gave consent on your behalf to enter this study. This is permissible under the Adults with Incapacity Act (Scotland) 2000.

**2) 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 doctors plan to do tests to see if you may have been exposed to the novel coronavirus.

**3) 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.

**4) 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.

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

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

**6) What would happen if I agree to be included?**

This study may involve testing of the following samples for evidence of COVID-19:

* swab samples from your nose and throat
* saliva samples
* blood samples (approx. 3 teaspoons)

However the specific samples needed will depend on the test we are currently evaluating and so all of these samples may not be needed and someone from the research team will discuss this with you. Some of these samples may have already been taken.

We will also collect information about your health that would be entered into a secure study database. We may also ask you to provide further swabs, saliva and blood samples (about 1 teaspoon) on five occasions over the next 90 days. If you need to stay in the hospital, we will try to take these samples at the same time as you are having routine tests. If we still need more samples after you have left hospital, we will arrange a convenient time for you to return for more tests and we will cover your travel expenses. Again, this depends on the test we are currently looking at, and a member of the research team will discuss this with you.

Depending on the type of new test being evaluated, we may test your 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 available to other researchers for future research, which may include researchers working abroad. However, these researchers will not be able to identify you from the data we provide. We would also keep a record of your contact details so that we can inform you of the findings from the study.

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

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

**8) 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.

**9) Can I end my participation early?**

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

**10) 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 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]

**11) How will you keep my information secure?**

Your health and personal data will be kept private and only reviewed by: (1) clinical study team members who will have permission to securely access your 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. Your personal details will be stored on secure NHS servers at the same organisation where you are receiving care

**12) How will we use information about you?**

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

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.  We will keep all information about you safe and secure.  Some of your information may be sent to researchers based in other countries. They must follow our rules about keeping your 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 you took part in the study.

**13) What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.  If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**14) Where can you find out more about how your information is used?**

You can find out more about how we use your 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 emerging@mft.nhs.uk, or
* by ringing us on 0161 701 7540

**15) 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. The hospital where you are receiving care will be paid to cover the costs of running the study. If we ask you to return to the hospital to provide more samples, we will offer to pay for your reasonable travel expenses.

**16) 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. The study is also receiving funding from Asthma UK and British Lung Foundation.

**17) 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 you from the information that is published.

**18) 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.

|  |  |
| --- | --- |
| **Chief Investigator:**Professor Richard BodyEmergency DepartmentManchester Royal InfirmaryOxford RoadManchesterM13 9WLEmail: emerging@mft.nhs.uk | **Trial Co-ordinator:**Dr Eloïse CookEMERGING Research GroupManchester Royal InfirmaryOxford RoadManchesterM13 9WLEmail: emerging@mft.nhs.ukTel: 0161 701 7540 |