

Research Participant Information Sheet

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

**(FALCON): Work Stream C**

We are inviting all people aged 18 years or older who have COVID-19, or might have COVID-19, to take part in a study to improve diagnosis of this disease. The NHS currently uses a laboratory test which can take up to 48 hours to detect and report the presence of the COVID-19 virus. This long wait makes it harder to decide how best to treat the patient in a safe and effective way. Scientists are working hard to find faster COVID-19 diagnostic tests.

We would be grateful if you would consider helping our research which aims to make sure that any new tests used by the NHS are not only quicker than the standard laboratory test, but that they give clear and reliable results.

Below you’ll find answers to some of the questions you may have which will help you to decide whether you want to take part. If you have any other questions, ask the hospital study team or the people named at the end of this information Sheet. You may not want to take part. That’s fine. Your care and treatment will be no different.

**1. Why are you doing this study?**

The tests we use now to find out if someone has COVID-19 are based on similar tests used to diagnose other types of virus. When the pandemic struck, these tests had to be introduced very quickly. We know they are slow and don’t always give the correct result. We urgently need new ways to test for viruses which overcome these problems. Our study will make sure that any new test we want to use in a particular place, like a hospital, care home or testing centre, gives clear, rapid and reliable results.

**2. Who are the researchers?**

Our study involves researchers across the United Kingdom. Manchester University NHS Foundation Trust is responsible for managing the study.

**3. Who can take part in the study?**

Anyone aged 18 years or older, who has been diagnosed as having COVID-19, or is suspected of having COVID-19, may take part.

**4. If I agree to take part what happens next?**

We will start by collecting information about your health. We then take more swabs from your nose and throat and collect about 1 teaspoon of saliva (spit). The swabs look like long cotton buds and will be used to take a sample of mucus from the back of your throat and the back of your nose. We will do this at the same time as you are having your test to see if you have COVID-19.

**5. What happens to my samples?**

We will send your samples to a laboratory, where the new tests will be run. The remaining samples will be stored and used later to analyse other new tests. The scientists who handle those samples will not be able to identify you from the sample tubes or from any data we might share.

**6. What are the downsides to being involved?**Apart from the possible inconvenience of having further samples taken there are no additional downsides.

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

You will not benefit directly from taking part in the study. However, if we are confident that the new, faster tests give clear and reliable information, which means that health care professionals will be able to provide more effective patient care. People with negative results will be able to immediately get on with their lives without the need for lengthy quarantine. Public health officials and the government will be able to make more appropriate choices when deciding how best to control virus spread.

**8. Can I drop out of the study early?**Although we would encourage you to work with us and provide the samples we need for our research, you are free to drop out at any time. You don’t have to give a reason.

To leave the study use the contact details at the end of this information sheet. This will not affect your clinical care.

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

If you have any concerns or complaints about the way you have been approached or treated, before or during the study, please feel able to contact Professor Richard Body (richard.body@mft.nhs.uk) or the study sponsor (getinvolvedresearch@mft.nhs.uk). The normal NHS complaints mechanisms will also be available to you.

**10. How will you keep my information secure?**

Your health data will be kept private and only reviewed by: (1) 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.

**11. How will you use the information about me?**

We will need to use information from you for this research project. This information will include your 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.

**12. What choices do I have about how my information is used?**

You can stop being part of the study at any time, without giving a reason. You need to be aware that we are required to keep some of the data we already have from you in case we are inspected by a regulatory authority. It will not be possible to take your data out of the results analysis once your personal information has been deleted at the end of the study.

**13. Where can I find out more about how my information is used?**

You can find out more:

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/);
* in 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 a cost or financial benefit in taking part?**

There is no cost to participating in this study, nor is there any financial reward for staff.

**15. Who is funding the research?**

The research is funded by the Department of Health and Social Care and the National Institute for Health Research, the national funding agency which invests in science and research in the United Kingdom.

**16. Where will the study results be published?**The results will be published in medical journals and on websites relating to COVID-19 diagnosis, so that others doing similar work can learn from them. It will not be possible to identify you from the information that is published.

**17. What 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 following details:

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

**By returning this parcel you confirm that you have read the Patient Information Sheet and give your consent for your samples to be used.**