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Information Sheet for Participants

*The **F**easibility and **A**cceptability of community **C**OVID-19 rapid **T**esting **S**trategies (**FACTS**) study.*

CUREC ethics reference: R72896/RE001

We would like to invite you to take part in our research study. Taking part is voluntary. Before you decide whether to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you want to. Please ask us if there is anything that is not clear or if you would like any more information.

Study overview and key points

- We are doing a research study to see if it is feasible and acceptable to test people regularly for coronavirus (SARS-CoV-2) infection when they don't have symptoms.
- The government hopes that regular testing like this might help stop the spread of coronavirus.
- We will use a rapid point-of-care test (POCT) that looks a bit like a pregnancy test, and is called a 'Lateral Flow Immunoassay' (LFIA) test. LFIAs are read in a similar way to a pregnancy test, but unlike a pregnancy test they don't work with urine. A nose and throat swab collects a sample. The swab goes into a tube of liquid for a short time, and then the liquid goes into the test. The result is read 20 to 30 minutes later.
- These rapid tests would be extra to, not a replacement for, laboratory tests.
- LFIAs will be done when people feel well, and the laboratory tests would still need to be done for people with symptoms to confirm if they have COVID-19.
- You have been invited to take part in this study because you work, study, or live at one of the participating study sites.

You do not have to take part in this study if you do not want to and can withdraw at any time. Withdrawing will not affect your work or study at the University of Oxford, or your access to testing services for people with symptoms.

Please ask the study team if you have any questions about the study, or you do not understand the additional information we have provided over the next few pages.

What is the purpose of this research?
We are doing a research study to see if it is feasible and acceptable to test people regularly for coronavirus (SARS-CoV-2) infection when they don't have symptoms.

Who is doing the study?
The study is being done by researchers from the Nuffield Department of Primary Care Health Sciences, University of Oxford.

What is rapid testing for COVID-19?
Rapid testing is a way of identifying people with COVID-19 quickly (20-30 minutes in the FACTS study) instead of waiting for tests to be completed by a local testing service using laboratory tests.

Why would rapid testing for COVID-19 be helpful?
Rapid tests for COVID-19 could potentially be used to allow quick access to infection status, even when you are feeling well, and have no symptoms, so that you can self-isolate if necessary and halt the spread of the virus as early as possible.

However, rapid tests are not as reliable as, or a replacement for, a laboratory test. An incorrect or misinterpreted result could lead to a false sense of reassurance or unnecessary concern about being infected. If you have a positive rapid test result you should self-isolate with your household, follow the University and site COVID-19 guidance, and book a laboratory test through the University Early Alert Service to confirm that the POCT result is accurate. If you have a negative rapid test result you should repeat the rapid test each week and continue to adhere to social distancing rules. If you develop symptoms during this time you should follow the University and site COVID-19 guidance, and book a laboratory test through the University Early Alert Service.

Why have I been invited to take part?
You have been invited because you work, study or reside at a participating study site at the University of Oxford.

What will happen if I agree to take part?
- If you would like to take part in the study based on the information provided by email you will be able to download the study app and complete the consent process.
- If you require further information, group information sessions will be conducted either face-to-face or via video link including information on swabbing, how to use the POCT, how to upload the results, and the safe disposal of the tests after use. You will have the opportunity to get further details on the study, and ask questions. If you haven't already and want to, you will then be able to consent using the study app. You will be sent a copy of the consent form for your records.
- The study team will ask to observe some people by video link when they are self-testing to ensure that the training provided is effective.
- If you are willing to self-test each week you will be asked to write your initials and date on the rapid test using a permanent marker, use the rapid test, and then capture a photograph of the results using the study app.

- If you don't want to, or are unable to, self-administer the tests you will be asked to attend the screening clinic at the recruiting site each week where the FACTS team will conduct the test and record the results.
- If you get a positive rapid test result or develop COVID-19 related symptoms, you should book a laboratory test with the University's Early Alert Service and follow the University and recruiting site's self-isolation guidance.
- If the rapid test is negative, you should continue to follow the University and recruiting site's COVID-19 guidance. If you develop symptoms should book a laboratory test with the Early Alert Service.
- We will ask you for permission to share Early Alert Service laboratory results with the study team.
- We will ask you to agree not to give your rapid tests to anyone and to use them only for the intended purpose according to guidance provided.
- We will ask you to track your health status daily using the app to identify any developing symptoms of COVID-19.
- You will be asked to answer questions about the acceptability of the testing strategy via five minute online surveys.
- We will ask a subset of participants to take part in an interview to explore their experience and views of testing, what worked, and what could be done better. If you are invited to participate in the interviews it is up to you whether to take part. You are free to refuse if you want to and it will not affect your participation in the rest of the study. If you are happy to participate you will be asked to provide verbal consent to a remote interview, and you will be provided with a copy of a written record of your consent for your records. The interview can be done by telephone (or alternative means such as Microsoft Teams). The interview will be arranged at a time to suit you and should take between 15 and 30 minutes. All interviews will be audio recorded.

How will infection control be managed?

FACTS will be conducted remotely, where possible, to reduce opportunities for infection. If you attend a face-to face training session or screening clinic, as per University and recruiting site guidance, you will be required to wear a face covering, to use hand sanitiser and, when not being tested, keep your distance. The study team will be wearing appropriate personal and protective equipment (PPE), which may involve masks, gloves and aprons. We will minimise contact time with you as much as possible, and provide appropriate materials for disposing of used rapid tests correctly. If you are self-testing, the study team will arrange for regular collections and disposal of your used rapid test.

Does the result of the test affect how I should follow self-isolation guidance?

If you have current symptoms of COVID-19 infection you must self-isolate according to local, PHE and government COVID-19 guidelines, even if the rapid test is negative. You can find the latest government guidance here: https://www.gov.uk/coronavirus.

If you have a positive rapid test result you should self-isolate with your household, follow the site COVID-19 guidance, and book for a laboratory test from the University Early Alert Service (EAS). Everyone at the recruiting site will receive information regarding the study and a positive test means that you follow the same guidelines as you would if you developed COVID-19 related symptoms. Once you have received an EAS test result you will be told what to do. Your doctor or nurse can discuss this further with you. If you

live in a household with other people you should follow the current household isolating guidance on the government website above.

Do I have to take part?
No, taking part is completely voluntary. Your decision whether or not to take part will not affect your work or study at the University, or your access to the usual testing services.

Can other members of my household take part?
Only adults (>16) who are working, studying or resident at a participating site can take part. If your household members also do, they can take part. Student or staff members who are living off-site and are exclusively working remotely are not eligible to take part.

What are the advantages and disadvantages for me of taking part?
There are no direct advantages or disadvantages to you but taking part will help us to understand how to improve the provision of regular testing to people who do not have symptoms in the community. This will help us to find ways to stop the spread of COVID-19.

Nose and mouth swabs can be uncomfortable but discomfort should only last a few seconds. They are safe to use. You should seek advice from your doctor or nurse if you are concerned about any problems after the tests. There is a small chance that the result from the test is wrong. You could be told that you have COVID-19 when you do not or vice-versa. It is important that if you became seriously unwell you seek help from a medical provider or telephone 111, even if you have had a negative test, and continue to follow University guidance.

Will I receive any payment if I take part?
Taking part in this research is voluntary. You will not incur any additional expenses by taking part in this study and will not receive any payment.

What will happen if I no longer want to take part in the study?
You can leave the study at any time without giving a reason. Your work, study and ability to access local testing centre services will not be affected.

What will happen to the samples that I provide?
The samples taken for the rapid tests should be thrown away as soon as they have been used using the disposal materials and instructions that you will be provided with when you consent to take part in the study. The study will provide you with appropriate disposal materials. This may involve providing bags suitable for potentially infected materials that can be sealed before disposal in a central clinical waste collection point on site. Clinical waste will be collected and disposed of in coordination with sites.

If you have a follow-up laboratory test, the sample material taken by the laboratory for testing will fall under the testing laboratory and not the study remit, and the laboratory may retain the swab for up to five years.

Will anyone know that I have taken part in the study?
The research team will know that you have participated in the study. If you get a positive POCT result, develop COVID-19 related symptoms, are waiting on a laboratory test, and/or receive a positive laboratory test you will have to self-isolate with your household, in which case your household will know that you are in the study. In addition, you will need to follow University and recruiting site guidance by notifying your College and Department nominated COVID-19 contacts.

What will happen to my data?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. For this study, Sensyne (the app developers) act as data processors under agreement with the University.

All participant data will be stored confidentially. We will use the minimum personally identifiable information possible. All participants will be given a unique participant number, and where possible research data will be stored with that number instead of anything that identifies you. Personal details (e.g. name and email address which will be used if we want to invite you to take part in an interview, and consent form with your name on it) will be held securely and separately by the study team on University of Oxford computer networks.

The data collected by the CVm-Health+ app (participant details, consent, health status diary, rapid test and laboratory test results), will be uploaded to the Nuffield Department of Primary Care Health Sciences (NDPCHS) secure network each day. Sensyne will retain a secure copy of your name, contact details and password until study data collection is complete, but will delete other research data once transferred to NDPCHS. All data handling and management will follow the Data Management Standard Operating Procedures (SOPs) which are standard University of Oxford SOPs, and additionally the Sensyne SOPs to ensure compliance with ISO 27001.

The audio recording of your interview will be stored in password protected computer files. The recording will be transcribed by the researcher or will be sent securely to an independent transcription company who will type up the recording. The company has been assessed and approved for data security by the University of Oxford. Once the recording has been transcribed, it will be deleted. The transcript of the audio recording will be de-identified.

Consent forms will be held securely at the University of Oxford for at least three years after the end of the study. Other research data will be de-identified once study data collection and analysis is complete. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to the results of this study?

We may publish the study findings through journal articles, press reports, presentations and conference papers. We will provide a summary of the study results on the study webpage and will provide a link to all participants. You will not be able to be identified in any written or verbal reports from the study.

Future research

If you are willing to be contacted about research we do in the future, we would hold your contact details securely at the University of Oxford's Nuffield Department of Primary Care Health Sciences for five years. These will be held separately from the research data. We will keep a copy of your consent form as evidence of this permission. Agreeing to be approached does not oblige you to take part in any further research, and you can ask to be removed from this list at any time.

Who do I contact if I have a concern about the study or I wish to complain?

If you have a concern about any aspect of this study, please contact:

FACTS Study Team - Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care Building. University of Oxford, Woodstock Rd, Oxford OX26GG
FACTSStudy@phc.ox.ac.uk

We will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.

If you remain unhappy or wish to make a formal complaint, please contact:

The Chair - Medical Sciences Interdivisional Research Ethics Committee
Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD
ethics@medsci.ox.ac.uk

Who is organising and funding the study?

This study is organised by researchers at the University of Oxford's Nuffield Department of Primary Care Health Sciences, it is being funded internally by the university.

Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: R72896/RE001).

Where can I get further information?

If you would like to take part in the study or if you have any further questions, please do not hesitate to get in touch with the lead researcher using the contact details below:

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Thank you for considering taking part in this study.