



UNIVERSITY OF
CAMBRIDGE

Information Sheet for TRACK-COVID Study Participants – STAGE 2

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Why is the research important?

The new coronavirus (SARS-CoV-2 virus), which causes the disease COVID-19, has spread all over the world; scientists are working hard to understand more about the virus.

Initial surveillance has focused primarily on patients with severe symptoms (including those who require hospitalisation). There is, therefore, an important need to define and understand who gets no or mild symptoms, and how “immunity” to (i.e., protection against) the infection is developing in the general population. This information will help to determine the extent of infection in the general population as well as helping to design new ways to prevent and treat such infections

You are now being invited to join Stage 2 of this study.

What are the purposes of the research?

The main aim of TRACK-COVID Stage 2 study is to try and find out what proportion of the population have had the new coronavirus by testing for antibodies in their blood. This type of test looks at whether someone has been infected in the past.

A second aim is to find out how long these potential antibodies remain in the body and their effectiveness in preventing additional infections from the same virus. We will do this through testing each month over a period of approximately 1 year. The frequency at which we send these sample packs to you may vary, depending on the need of the study but it is unlikely to be more frequent than monthly.

As this is a new virus, it is not fully understood if these antibodies are present following an infection and remain in the body several months later, or if they provide some immunity.

How will the Track-COVID study (stage 2) be carried out?

Participants will be asked to provide a capillary blood sample at home (self-taken via a finger prick) on a monthly basis and to send this back to the lab for storage and analysis.

Why I have I been invited to join?

You are currently taking part in stage 1 of this study (by answering online questionnaires) and you expressed an interest in providing additional biological samples. We are now re-contacting those individuals who meet our eligibility criteria to join this second stage.

Do I have to take part?

No, it is up to you whether you take part in stage 2 or not. If you decide not to take part in stage 2 (providing a blood sample) you can still remain in stage 1 (answering the questionnaires).

What will happen to me if I agree to take part?

If you agree to take part, you will be asked to complete a new consent form and provide us with your name and postal address. Following this, you will be sent monthly study pack in the post to enable you to take a small blood sample at home (less than 1ml). You will be provided with instructions on how to take a finger prick capillary blood sample along with instructions on how to post it back to us. You will be asked to do this once per month.

We may also text or send you a text or email to remind you to take your blood sample each month.

Why do you need my consent again?

The consent form for stage 1 of this study was to allow us to collect questionnaire data from you in relation to new coronavirus infection. The new consent will ask your permissions to provide us with a small finger prick blood sample and to analyse this.

What will happen to my samples?

They will not be labeled with your name or contact details, but only with a unique study number. Once returned to the processing laboratory (NHS Blood and Transplant or University of Cambridge) we will try to test for the antibodies. A sample will be stored in the freezer long term for future health-related research purposes.

How are my samples and data kept confidential?

The following steps will be taken to ensure the confidentiality of your samples and data during the Track-COVID study:

Your samples and data will not include any personal identifiable details, other than to run the study. Therefore, researchers working with your samples and data will never know your identity. Your samples and data are stored using a unique, anonymous study identification number.

- In order to retrieve relevant health information we will use your NHS number. A single table linking your anonymous study identification number to your NHS number is stored on a separate password-protected location, which may be accessed only by the study data manager.
- The link table is used to retrieve only relevant health information from your medical and other health-related records. The retrieved information is -'de-personalised', meaning any details that directly identify you – such as your NHS number – are removed before it is added to the study database.
- All study data (including sample results) are stored in a restricted-access, study database on secure computers at the University of Cambridge and the NHS Blood and Transplant (NHSBT). The study data is linked to your study identification number, but your personal details (surname, first name, address) never appear in this database. Access to the study database is password-protected and used only by named researchers working on this study under the direct supervision of the senior scientific investigators
- Your personal details provided during the study will be stored in a secure location, separately from the study database and used for the purpose of study communication and retrieval of your NHS number.

What information will be stored on the research database?

Information that will be stored on the database will be anonymised and will include:

- Data from the online questionnaires (described above) and any blood sample results.
- Relevant data collected during your participation in the INTERVAL, COMPARE or STRIDES study including results from blood samples and questionnaire data (including genetic information from your participation in previous studies)
- Information on your health collected from routine medical and other health-related records at the time of joining the study and from time to time thereafter.
- Results from all laboratory measurements using your samples

Your de-personalised samples and data will be used by the study investigators to look at characteristics that may influence the development and transmission of the new coronavirus. Stored anonymised data will be used for future medical and health-related studies, which have relevant scientific approval.

Who will have access to my information?

The information collected about you during the course of this study will be kept strictly confidential. Any information you have provided will be de-personalised, therefore researchers working with your samples and data will never know your identity. Your de-personalised information is available only to researchers who have relevant scientific approvals for their planned research. This could include researchers who are working in other countries and in commercial companies who are looking for new treatments or laboratory tests. Insurance companies and employers will not be given any individual's information and we will not allow access to the police, security services, relatives or lawyers, unless forced to do so by the courts. All data will be stored securely by the Track-COVID study.

The Track-COVID study team will access details from your health, donor and other health-related records, including registers of deaths and cancers, held by, but not limited to, NHS Blood and Transplant, NHS Digital, Public Health England to understand your current health and track this over many years. These records include medical tests and their results, diagnoses, treatments and visits to your GP or to hospital, as well as other relevant information. To access these records we will securely send your NHS number and/or postcode to the relevant organisation to allow them to identify you and provide the requested information.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum of personally-identifiable information possible.

You can find out more about how we use your information at <https://www.information-compliance.admin.cam.ac.uk/data-protection/research-participant-data>.

What will happen to the study results?

The findings from this study will be discussed with key government agencies responsible for helping with the coronavirus pandemic (e.g., Public Health England), written up for publication in scientific journals, and presented to other researchers. You will not be identified personally in any report or publication. In due course we will also provide details of the findings of the study on the Track-COVID study website and/or send a study update newsletters.

Will the research benefit me?

We will not provide you with any new information or advice based on the samples and data you provide which means participating will have no direct benefit to you. However, it is an opportunity to help research, which addresses an important public health issues. We do not pay participants for taking part.

What are the possible disadvantages and risks of taking part?

There are no known disadvantages associated with this research. You *may* experience some small bruising or pain around the finger prick site.

Can I withdraw from the study?

You can choose to withdraw from the study any time. You will be asked to confirm this by signing a withdrawal form. You can withdraw from the study by telephoning us on 0800 021 7182 or by sending an email to study helpdesk (helpdesk@trackcovid.org.uk). This would allow us to determine the desired level of withdrawal from the following options:

- “No further contact”: In addition to no longer contacting you, we would no longer be able to obtain directly but would still have your permission to retains and use information and to retain access to information from your health records.
- “No further use”: in addition to no longer contacting you or obtaining information from your health records, any information collected previously would no longer be available for researchers.

Who is undertaking this research?

The University of Cambridge is running the TRACK-COVID study.

Who has reviewed the study?

The research has been reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the East Midlands - Nottingham 2 Research Ethics Committee.

What if there is a problem?

If you have any reason to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Helpdesk on 0800 021 7182 or email helpdesk@trackcovid.org.uk

What should I do next?

If you are interested in taking part, please click the link in your invitation email which will take you on to the next stage of enrolment.

Contact for further information

If you have any questions then you can contact: The Track-COVID study helpdesk on

E-mail: helpdesk@trackcovid.org.uk Tel: 0800 021 7182

Thank you for considering taking part in TRACK-COVID study Stage 2 and for taking the time to read this information leaflet