

TRACK-C**VID****UNIVERSITY OF
CAMBRIDGE**

Information Sheet for TRACK-COVID Study Participants

Version 1.0
22.04.2020

Summary

To provide scientists and national decision-makers with detailed information that helps control and understand the coronavirus pandemic (“COVID-19”), we aim to track up to 90,000 individuals across England during the coming year or so. We will send you a brief online questionnaire every month. We will also ask some participants to provide a self-collected sample of saliva or finger-prick blood at home every month, using kits we will mail to you. We will link the questionnaire and sample data with your health-related records. Results from this effort will feed into national bodies responsible for helping to make decisions to help control COVID-19.

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.

What are the purposes of the research?

The primary aim is to track symptoms related to coronavirus disease (“COVID-19”) and antibody levels to the virus (“SARS-CoV-2”) across a large and diverse sample of the population of England. A secondary aim is to find out why some people who carry the virus have symptoms while others do not.

How will the TRACK-COVID study be carried out?

We aim to recruit up to 90,000 people across England. Participants will be asked to complete an online questionnaire every month for about one year, focusing symptoms related to COVID-19.

Some participants will also be asked to provide a self-collected sample of saliva or finger-prick blood at home every month, using kits we will mail to you. If you are selected to participate in this further study, then you will be provided with more information and asked to complete a separate consent form; you can opt-out of this at any time.

Why I have I been invited to join?

We are specifically inviting participants from the INTERVAL, COMPARE and STRIDES studies to this survey. Because key data (e.g. blood sample measurements, genetic results, lifestyle factors, health records etc.) have already been recorded for participants in these

previous efforts, it makes these individuals (i.e., you) ideal to study in order to help understand factors related to COVID-19.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you do decide to take part, you will be asked to complete a consent form. You are free to withdraw at any time and without giving a reason.

Am I eligible to take part?

You are eligible to take part if you:

- Reside in mainland England
- Have a good understanding of the English language, both written and oral (as study materials are not tailored to support non-English language speakers).

You are not eligible to take part if you have:

Received 3 invitations from the INTERVAL, COMPARE or STRIDES research study team to take part in other studies in the past year

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

Following your electronic consent, we will also ask you to complete a brief (10-minute) questionnaire to monitor symptoms of potential infection on a monthly basis. In addition, and only when necessary, we will send you a text/email reminder to complete the monthly questionnaire.

If you agree to provide additional samples (determined by your answers in the first questionnaire), then you may be contacted to provide these a saliva or finger-prick blood on a monthly basis. If selected, and if you agree to participate, more information will be provided and you will be asked to complete a separate consent form. If you do not want to provide samples then it will not prevent you taking part in the questionnaire part of this study.

We will access data about you which is already held as part of the INTERVAL, COMPARE or STRIDES studies, including information obtained from your health, blood donor and other health related records. We may also need to request additional information from your health and health related records from the organisations responsible for these, such as NHS Digital, Public Health England and others in order to understand your medical history and current health and to track this over time.

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 to the relevant organisation to allow them to identify you and provide the requested information.

Why do you need my consent?

Your participation in TRACK-COVID study is entirely voluntary. By completing the online consent form, you would be confirming your willingness to take part. In particular, you would be agreeing to:

- Answer study questionnaires on a monthly basis (for a duration of approximately 12 months)

- Allow for long-term access to your existing and future medical and other health-related records
- Being contacted again in the future by University of Cambridge about this study and other approved studies.

How is my data kept confidential?

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

Your data will not include any personal identifiable details, other than to run the study. Therefore, researchers working with your data will never know your identity. Your 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 is 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).
- 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.

Your de-personalised 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 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 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 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 or health risks associated with this research.

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 **Tel:** 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 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 Freephone: 0800 021 7182 or email us at: helpdesk@trackcovid.org.uk

Thank you for considering taking part in our study and for taking the time to read this information leaflet