

***REal-time Assessment of Community Transmission
Genomics England (REACT-GE)***

COVID-19 Susceptibility and Severity Research Study

Information Sheet for Participants

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish.

What is the purpose of this study?

REACT-GE is an extension study to the Real-time Assessment of Community Transmission (REACT) programme. The main aim of the study is to better understand why some people experience mild or no symptoms with COVID-19, whilst others develop more severe cases requiring hospitalisation and even intensive care. However, this research will also further our work to monitor and understand how COVID-19 is spreading across England.

Research has already uncovered some important risk factors for severe illness from COVID-19, such as being of an older age or having a certain underlying health condition. However, one of the biggest remaining puzzles is why some people who are younger or previously fit and well unexpectedly develop very severe or long-lasting COVID-19 symptoms, and in turn why people who have a known risk factor, only experience mild illness. Through this study, we hope to understand whether the answer lies within people's DNA (the genetic code which determines how our bodies are made and function). Such insight could optimise care of patients and support the development of better treatments or vaccines.

This study is being carried out as a partnership between Imperial College London, who lead the REACT study programme, and Genomics England, who are leading a study called GenOMICC. This means that by agreeing to take part in this REACT-GE study you will also be agreeing to take part in the GenOMICC study, which is managing the genetic analysis part of this research. Please read the separate Participant Information booklet provided for the GenOMICC study to learn more about this aspect of the study.

You can read more about the ongoing REACT testing programme at www.imperial.ac.uk/medicine/research-and-impact/groups/react-study/

Why have I been invited to take part?

You have been invited to take part in this study because:

1. You previously took part in a REACT study carried out by Imperial College London and tested positive for either COVID-19 infection (via an at-home swab test) or past COVID-19 infection (via an at-home antibody test);
and
2. You agreed that we could invite you to take part in further research studies.

If you agree to take part in this REACT-GE study then we will transfer data that we hold about you from the REACT study to this new REACT-GE study. This will include your NHS number, the result of the test carried out and the information you answered in response to the questionnaire.

Do I have to take part?

No. Whether you take part in the study is entirely up to you. Even if you do decide to take part, you can change your mind at any time without giving a reason.

What is involved?

Taking part in this study involves:

1. Completing a short (15-20 minute) online questionnaire, which includes questions about your health and lifestyle. If you cannot access the internet, we can arrange a convenient time for a researcher to call you to complete the questionnaire by phone instead.
2. Visiting a research assessment centre that is most convenient to you in order to:
 - Confirm your identity and sign a consent form that allows us to include you in the study
 - Provide a urine sample
 - Have your weight, waist circumference and blood pressure measured by a nurse
 - Have a blood sample (up to 50ml, about three tablespoons) taken from your arm by a nurse

Before taking the blood and body measurements, you may be asked additional questions (e.g. relating to pregnancy or menstruation) to ensure it is appropriate to continue and to provide further context for the results

The whole visit should take around 30 minutes.
3. After your appointment you may also be invited to take part in a survey about your recent food intake

What will happen to my samples and data?

We will carry out detailed biological and genetic analysis of the samples to understand whether genes, or any proteins and small molecules present in blood and urine, play a role in determining people's susceptibility to COVID-19 infection (how likely we are to become infected) or the severity of illness (how mild or severe the symptoms are). We will also re-test your blood for antibodies against the virus that causes COVID-19.

All samples will be sent to a laboratory in London operated by Affinity Biomarkers Labs who will process and prepare them for sending to other academic and commercial partners in the UK and overseas to carry out analyses for research purposes only.

Imperial College London will also need to use information from your medical records held by NHS Digital and other NHS bodies for this research project. This information will include your:

- NHS number
- Name
- Contact details.

Investigators will use this information to monitor the long term health status of participants from this study. Unless they really need to know who you are, they will not be able to see your name or contact details. Your data will have a code number instead. The number of people who access this information will be kept to a minimum.

We will keep all information about you safe and secure.

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.

Imperial College and other research institutions both academic and commercial may continue to carry out research using the anonymised data and samples collected during the study, including genetic analysis to identify genes that may predispose people to disease. The results of any research that is published, whether by Imperial College or anyone else, will never identify you. See p6 'Do you share my information with others' to learn more. From time to time we will inform you of other research studies that you might be interested in participating in. We will only share your contact details with other researchers if you give us consent to do so. Even if you receive invites to future studies, there is no obligation to take part in.

Will I receive any of my results?

Yes. We will report to you whether you still have antibodies to SARS-CoV-2, the virus that causes COVID-19. We will provide you with measurements of your weight, waist circumference and blood pressure and the results of your standard blood analyses to provide indications of your cholesterol levels and risk of diabetes. These measurements and analyses enable us to provide you with a QRISK3 assessment. This tells you to what extent you may be at risk of a heart attack or stroke in the next 10 years. Further information is available at <https://qrisk.org>.

How will this research help others?

The study aims to support the development of treatments for COVID-19 by identifying and understanding the biochemical and genetic factors that determine whether or not someone becomes severely ill after becoming infected.

Who is carrying out this research?

This research is being run by doctors and researchers from Imperial College London, Genomics England and the GenOMICC study. This research is funded by UK Research and Innovation.

Genomics England sequences and analyses DNA for the NHS and is the guardian of the National Genomics Research Library. This contains the health data and genetic sequences of tens of thousands of NHS patients. They allow researchers to use their data to make discoveries and help develop new treatments.

GenOMICC is a research study run by many doctors and scientists determined to find out why some people end up needing intensive care because of infections such as COVID-19, flu and sepsis, while others get only mild infection or no symptoms.

You have been provided with a separate Participant Information booklet about the GenOMICC study, but you can also go to <https://covid.genomicc.org/> for additional information.

What are the possible risks or side-effects of taking part?

You may develop an irritation or skin reaction such as a bruise on your arm where the needle to take the blood sample was inserted.

Are the assessment centres COVID-19 safe?

Our assessment centres are only attended by healthcare staff and study participants. We adhere to social distancing, hand washing and mask wearing according to government guidance. We provide hand sanitiser. Our staff wear appropriate PPE. A regular cleaning schedule is in place and each test station is cleaned between participants. We also limit touch points, implement one-way systems where appropriate and limit the number of people in a centre at any one time.

How do I sign up for the study?

If you choose to take part, you will need to complete a registration form, which can be completed online or by phone. This information is given in your personal invitation letter, which also includes your personal registration ID.

Once you have registered, you will be contacted by phone and SMS to arrange an appointment to attend your most convenient assessment centre.

Can I withdraw from the study?

Yes, you can withdraw from the study at any time without giving reasons. You will have to inform the study team of your wish by phone or email or letter (details in this leaflet). We will

then send you a *Withdrawal from Study Form* which has to be signed by you and sent back to the research team at Imperial College.

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.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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.

What will happen to the results of this research study?

The results of this study may be shared in many different ways, such as being published in medical journals, presented at meetings of scientists and reported to both Imperial College, London and the Health Research Authority who oversee and review how research takes place in England. No personally identifiable information about you will be made available outside of the study team.

There is more information about how your personal data will be used and stored in the study privacy policy at: <https://www.imperial.ac.uk/medicine/react-ge>

Who has reviewed the study?

To protect your interests, all research at Imperial College London is reviewed by an independent group of people called a Research Ethics Committee. This study has been reviewed and granted approval by the South Central Berkshire B Research Ethics Committee.

What will happen to the information I provide?

Imperial College London is the sponsor for this study and will act as joint data controller for this study along with Genomics England. This means that we are responsible for looking after your information and ensuring that the processing complies with the General Data Protection Regulation (GDPR). You can access Imperial College London's Privacy Notice and Genomic England's Privacy Notice at: <https://www.imperial.ac.uk/medicine/react-ge>.

Imperial College London will keep your personal data for 20 years after the study has finished.

MSS, the company which provides the nurses and the system used to record your data at the assessment centre, are data processors, acting on behalf of Imperial College London and Genomics England. They will only keep your data in a way that can identify you for as long as is necessary to support the research project and findings. When the collection of the samples is complete MSS will delete your personal data from their systems.

Imperial College London has regular internal and external audits of their information security controls and working practices and are accredited to the International Standard for Information Security, ISO 27001.

Do you share my information with others?

So that the maximum information can be obtained from your participation in this study we may make the samples and data available to other researchers.

It is important that researchers understand as broadly as possible the factors concerning your health now, and in the future to identify as accurately as possible the real links to the susceptibility and severity of a COVID-19 infection. We therefore require your consent for Imperial College London to link data held by NHS Digital and other NHS bodies to the study data. This will provide information on the long term health status of the participants. An example of the use of this information would be to enable the monitoring of the longer term effects of COVID-19 on health. You can withdraw this consent at any point.

Researchers in the UK and overseas who wish to access the data from this study and/or to contact participants about future research will have to apply to a Data Access Committee composed of at least three of the study investigators and at least one public representative.

There is more information about how your personal data will be used and stored in the study privacy policy at <https://www.imperial.ac.uk/medicine/react-ge>.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to servicedesk@genomicsengland.co.uk, or
- by ringing us on 0808 2819 535

Confidentiality

If you consent to take part in the research your name or other identifying information will not be shared outside the research team. Your personal data will never be available to the general public in any circumstances. The results of this research are likely to be published but will not contain personal information which could identify you such as name, age, gender, ethnicity. Please keep this information sheet for reference.

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

For the purposes referred to in participant information sheet and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies and they are required to delete the data when no longer needed to provide the service.

Legal basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

Our legal basis for using your information, under General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is “performance of a task carried out in the public interest” (Article 6(1)(e) in the GDPR); and, where sensitive personal information is involved, “scientific or historical research purposes or statistical purposes (Article 9(2)(j) in accordance with Article 89(1))”.

Your usual statutory rights to be able to access, change or move your information are limited, because of exceptions applicable to some types of research, and also because we need to manage your information in specific, lawful ways in order for the research to be reliable and accurate.

Can I claim compensation if I am harmed during the study?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigators on ge-servicedesk@genomicsengland.co.uk. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College [Research Governance and Integrity Team at \[rgitcoordinator@imperial.ac.uk\]\(mailto:rgitcoordinator@imperial.ac.uk\)](#).

How To Make A Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact:

- The REACT-GE Study Team on 0808 2819 535 or by email at ge-servicedesk@genomicsengland.co.uk
- Genomics England's Data Protection Officer via email at dataprotection@genomicsengland.co.uk and/or by post to REACT-GE Data Protection Officer, Genomics England, Dawson Hall, Charterhouse Square, London, EC1M 6BQ
- Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial College London and Genomics England) first before involving the regulator. You can find details about how to contact the Information Commissioner's Office at <https://ico.org.uk/global/contact-us/> or by sending an email to: casework@ico.org.uk

Additional Contact Details

If you have further questions before deciding whether to take part, please contact the Research Team on 0808 2819 535 or email us at ge-servicedesk@genomicsengland.co.uk.

If you have any questions, you can contact a member of the study team at:

Phone: 0808 2819 535

Portal: <https://bit.ly/ge-participants>

E-mail: ge-servicedesk@genomicsengland.co.uk

For Genomics England:

Post: REACT-GE

Genomics England

Dawson Hall

Charterhouse Square

London

EC1M 6BQ

For Imperial College London:

Post: REACT-GE

Department of Epidemiology & Biostatistics

Faculty of Medicine, School of Public Health

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Thank you for considering taking part in this research.