THE GenOMICC COVID-19 STUDY
PARTICIPANT INFORMATION

Chief Investigator:
Dr JK Baillie,
University of Edinburgh
Could you help us unlock the COVID puzzle?

Our genomes

A genome is the body’s instruction manual and contains all the information needed to make you, run you and repair you. It’s unique to you and you inherit it from your parents. It’s made of DNA and is written in DNA’s special code.

Each one of the 3 billion letters in a genome can be read using a technique called sequencing.

Why do we think there might be clues in our DNA?

We already know that our chances of dying of any infection are passed on from parents to their children. We also know instructions for our body’s defence systems which fight COVID are a very important part of our genomes.

So we are trying to spot differences between the DNA sequences of people with mild COVID and those with severe COVID to find ones that might be important. If we find these differences, we may be able to protect those that have them and hopefully find better and more effective treatments for severe COVID.

Could you be a match?

Thousands of people who had to go to intensive care with COVID-19 have generously agreed to donate their DNA, along with their health records for this study.

Now we need to compare their genomes with those of people with mild illness. But because we must compare like with like, we need to match by age, sex, ethnicity and other factors.

So, could you be a match for someone who developed life-threatening COVID?
WHO ARE WE?

GenOMICC is a research study run by many doctors and scientists determined to find out why people end up needing intensive care because of infections such as COVID, flu and sepsis.

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 and medicine.

There is more information here. 
www.genomicsengland.co.uk/national-genomic-research-library/ 

WHAT WILL HAPPEN TO MY BLOOD?
There are white blood cells in your blood. These contain DNA. The DNA is extracted from the samples in Edinburgh (home of GenOMICC). Then it’s sent to our researchers in Cambridge for sequencing.

Once the DNA is extracted, any leftover blood is destroyed. Your DNA sequence will be stored in the National Genomic Research Library and the GenOMICC data analysis repository at the University of Edinburgh.

With your permission, we will store your DNA sample and use it for future ethically approved medical research. Some of this research may make use of facilities in other countries, or those provided by commercial organisations, but your sample will always be under the control of the GenOMICC investigators, or partner organisations, and subject to UK regulations.

WHAT DO I NEED TO DO?

We need to ask you formally for your consent to use your data and get you to sign a form.

We need some blood (about 2 teaspoons). That’s it.

Your blood will be taken by a nurse from one of our partner companies. The only information they receive is your name, gender and contact details, just enough to ensure that they can make an appointment and take your blood safely.

Nothing else.

WHY DO YOU NEED OTHER DATA?

Your genome sequence is very important but it’s your health data that gives it more meaning for scientists. We also aim to keep collecting your health data as you get older and for the rest of your life. Even after you die your data remains important.

Collecting data over such a long time is important for studies of many aspects of your health, but also because COVID may have lifelong effects.

This means that comparing your data as you age with someone who got very sick may become even more valuable than it is now.
WHAT DATA DO YOU COLLECT AND WHERE DOES IT GO?
Your original records remain within the NHS. But if you agree, electronic copies of your health records will be deposited in the National Genomic Research Library along with your DNA data.

Your name, date of birth and any other other identifying information are removed before researchers are able to use it. Your data will be in secure systems. Your data cannot be removed from the library. Any results of research that are taken out cannot be used to re-identify you in any way.

This is what your data may include:

- Your clinical test data
- Electronic copies of all of your past and future records from the NHS, your GP and other organizations (such as NHS Digital, Public Health bodies)
- Information about any illnesses or stays in hospital – including information that you may not think are related to you
- Copies of hospital or clinic records, medical notes, social care, and local or national disease registries, and data from other research studies
- Relevant images from your NHS records, such as MRI scans, X-rays or photographs
- Data from other research registries and studies that may be relevant

GenOMICC and Genomics England protect your data and control who has access to it.

This information will only be used for healthcare research, or to contact you about future opportunities to participate in research. This research will be done by doctors and scientists, including those working for commercial organisations.

This information cannot be accessed by insurers or by the police or other authorities.

In rare cases if there was a risk of you being identified because of research, we would contact you again and get your permission first. Where recruitment is performed in the community by an appropriately trained practitioner from a third party organisation, minimal patient identifiers will be passed to the organisation to allow the visit to be scheduled and carried out.

WILL MY DATA BE KEPT CONFIDENTIAL?
Yes. There are strict laws which ensure your privacy and keep your information confidential.

More information on these laws, called The EU General Data Protection Regulation (GDPR), and the new UK Data Protection Act 2018.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor or NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

WILL YOU CONTACT ME AGAIN?
We may contact you again for further information or to tell you about other research opportunities.

Although we can learn a lot from your DNA, we may be able to learn even more from studying the cells in your blood, or other research. If this was the case, we would contact you as we would need a second blood sample.

You don’t have to say yes to this or to any future requests.
**WHAT IF I HAVE ANY PROBLEMS OR WOULD LIKE FURTHER INFORMATION ABOUT THE STUDY?**

If you would like more information about the study you can contact us at Genomics England, either through the website at: covid.genomicc.org

email at covid19study@genomicsengland.co.uk

or call us on 0808 2819 535.

We have a team stood by to answer any questions you might have, and to discuss any concerns you might have about giving us your sample.

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**CAN I REQUEST THAT I BE WITHDRAWN FROM THE STUDY AT ANY POINT?**

Yes, you are free to withdraw from this study at any time without giving reason and without detriment to your medical care. All samples that we hold from you would be destroyed. This applies if you are a parent wanting to withdraw your child, or a relative/consultee wanting to withdraw on behalf of somebody else.

If you decide to withdraw from the study, no new information about you will be collected, but information that has already been collected will continue to be used for the study.

You will need to sign a withdrawal form to record your decision. The form can be requested from your healthcare professional or downloaded from the GenOMICC website: genomicc.org/uk/withdrawal.

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**There are two options to consider when withdrawing:**

1. **Partial withdrawal**
   - This option is for situations where you would be content for your data to continue to be used for research, but want no further contact.
   - We will update our records to ensure you are no longer contacted.
   - We will continue to update and store information from your health and other records for use in approved research.

2. **Full withdrawal**
   - This option is for situations where you no longer wish for your data to be used for research and want no further contact.
   - We will not:
     - contact you directly
     - continue to update and store information from your health and other records
     - allow new research access to information that is held about you
     - use your information for purposes other auditing
   - We cannot:
     - remove data from research that is underway or has already been done; or
     - remove all records related to you from our databases
       - an audit record is needed to confirm that you were once part of the study and then withdrew; this information includes your first name, surname, date of birth, address and contact details.

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If you wish to make a **complaint** about the study please contact:

Patient Experience Team, 2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG.

Tel: 0131 536 3370
Email: feedback@nhslothian.scot.nhs.uk

or contact:

Genomics England at: info@genomicsengland.co.uk

**Thank you** again for participating in this study.

Your data will make a real and valuable difference in researching COVID.

Dr Kenneth Baillie
Principal Investigator
you will be people who need to contact you about study follow up or audit the data collection process.

Genomic England will keep information used to contact you about this study for 2 years after recruitment has finished. Where your information is to be used in research, we will keep the data for 30 years, at which point it will be reviewed to determine its use in research. If we cannot, it will be deleted in line with our secure destruction procedures.

PROVIDING PERSONAL DATA INDIRECTLY E.G. FROM YOUR MEDICAL RECORDS

The University of Edinburgh, NHS Lothian and Genomics England will collect information about you for this research study. This information will include your name/ NHS number/ contact details and health information, which is regarded as a special category of information. We will use this information to access your medical records where applicable and study follow up.

USE OF DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities or companies involved in health and care research in this country or abroad. We also provide basic identifiers such as your name, date of birth and NHS Number to NHS Digital and other organisations so that they may collate your medical history records and return this data to us. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information.

CONTACT FOR FURTHER INFORMATION

You can find out more about how we use your information and our legal basis for doing so in our Privacy Notice at www.accord.scot.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website: www.hra.nhs.uk/information-about-patients.

You can find out more about how Genomics England uses your data here: www.genomicsengland.co.uk/covid-19/taking-part.

You can read the Genomics England privacy policy here: www.genomicsengland.co.uk/privacy-policy.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. 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) at ico.org.uk.

DATA PROTECTION OFFICER CONTACT INFORMATION:

University of Edinburgh
Data Protection Officer
Goverance and Strategic Planning
University of Edinburgh
Old College
Edinburgh EH8 9YL
0131 651 4114
dpo@ed.ac.uk

NHS Lothian
NHS Lothian Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh EH1 3EG
0131 465 5444
lothian.DPO@nhs.net

dpo@genomicsengland.co.uk

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NHS Lothian
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2-4 Waterloo Place
Edinburgh EH1 3EG
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THANK YOU FOR YOUR HELP
Let’s solve the COVID puzzle together.