

PARTICIPANT INFORMATION SHEET

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Local Lead Investigator: Jade Cole

Chief Investigator: Dr JK Baillie, University of Edinburgh

INTRODUCTION

We are undertaking a research study involving people with severe illness (such as Covid-19, influenza, sepsis and other causes of critical illness), and healthy volunteers, which is why we have approached you.

Before deciding whether to participate, it is important for you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information, and take time to decide. Your decision is completely voluntary. The decision you make will not affect your care or treatment in any way.

WHAT IS THE STUDY ABOUT?

Infectious diseases and severe injuries affect millions of people around the world every year. Most cases are mild, but some people become very unwell. Our genes (or DNA) determine how vulnerable we are to critical illness. If we could find the genes that cause some people to be more vulnerable, we may be able to develop better treatments for patients in the future.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

You will be asked to confirm your consent by signing a consent form. A single blood sample will be taken (9mls; roughly 2 teaspoons) to get a DNA sample. If you are unable to give a blood sample for any reason, a sample of saliva may be taken instead in some circumstances.

If you have now recovered from being very sick then we may have asked someone else to decide on your behalf whether you would like to participate. If so, we may already have a sample of your DNA and we would like your consent to use it for research.

WHAT WILL HAPPEN TO THE SAMPLES?

We will use your blood sample to extract and analyse your DNA, which could include the whole sequence of your genome. Your genome is your body's 'instruction manual' that contains the information needed to make you, run you and repair you. Your genome is made up of all 3 billion letters of your DNA.

Data from your blood sample, together with your health data, will be looked at by researchers and compared with DNA and health data from the rest of the population, and from others with critical illness from different causes. This will help us to try and find patterns about how diseases affect people and potentially find a cause of the disease factors that affect how mild or severe a disease is.

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.

WHO WILL BE INVOLVED IN THE STUDY?

GenOMICC is a collaboration of doctors and scientists who are trying to better understand critical illness.

We have partnered with Genomics England in order to do some analyses. Genomics England is a company set-up and owned by the Department of Health and Social Care. Genomics England is responsible for hosting the National Genomic Research Library, a national resource for researchers and the NHS. Additional information about Genomics England is available: <https://www.genomicsengland.co.uk/privacy-policy/>.

We may also partner with other organisations in future to conduct research.

WHAT DATA IS LOOKED AT?

GenOMICC investigators and partners will always protect your data and control who has access to it. Researchers will access the following de-identified (meaning that name, date of birth and other identifying information have been removed) information:

- Your clinical test data
- Electronic copies of all of your past and future records from the NHS, your GP and other organisations (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

Your original records remain within the NHS. We will include your data in secure analysis systems, including the National Genomic Research Library (run by Genomics England). Data taken out of these environments will be restricted to data that cannot be used to re-identify anyone in any way.

The information will only be used for the purpose of healthcare research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee and/ or the sponsor. 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. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard the privacy of research participants at every stage. Study researchers will need access to your medical records and data to carry out this research.

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.

WHAT IS LIFE COURSE FOLLOW-UP?

Life course follow-up involves gathering the data types listed above in future. This will make it possible to discover genetic factors that influence health events that have not happened yet. This information is only used for the purpose of healthcare research, and will continue over your lifetime and after your death, unless you have withdrawn.

ARE THERE ANY BENEFITS OR DISADVANTAGES TO TAKING PART IN THIS STUDY?

We hope that this study may help other people who become critically ill in future. There is a very small possibility that we will discover information about your health from your DNA. If this unlikely event happens, we will try to contact your clinical care team to explain the findings and there may be a need for additional tests. This information may be complex and difficult to interpret with certainty, and it may change over time as we discover more about the genome. For this reason the significance of this information would be explained to you by doctors or nurses with relevant expertise.

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 WILL HAPPEN IF I DO NOT PROVIDE CONSENT?

Absolutely nothing. You are free to choose not to consent, and this would not affect your treatment in any way.

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: <http://genomicc.org/uk/withdrawal>

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

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 the Local Lead Investigator, Jade Cole, or contact the study coordinator, Critical Care Research Nurses on: 02920 748 384 or 02920 743 608 or email Helen.Hill@wales.nhs.uk

If you would like to discuss this study with someone independent of the study team please contact: David Dorward on: 0131 650 1000 or email: david.dorward@ed.ac.uk

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)

GENERAL DATA PROTECTION REGULATION (GDPR) PARTICIPANT INFORMATION

The EU General Data Protection Regulation (GDPR), along with the new UK Data Protection Act 2018, will govern the processing (holding or use) of personal data in the UK. You are receiving this as you are currently a participant on this clinical research study. The information below details what data is held about you and who holds or stores this.

The University of Edinburgh and NHS Lothian are the co-sponsors for this study based in the United Kingdom. We will use information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The co-sponsors will keep identifiable information about you for 5 years after the study has finished. 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 personally-identifiable information possible.

PROVIDING PERSONAL DATA DIRECTLY E.G. VERBALLY, IN A QUESTIONNAIRE OR FROM YOUR CARE PROVIDER

[NHS site name] will keep your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Edinburgh and NHS Lothian and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site name] will pass these details to the University of Edinburgh and NHS Lothian along with information collected from you and your medical records. The only people in the University of Edinburgh and NHS Lothian who will have access to information that identifies you will be people who need to contact you about study follow up or audit the data collection process.

[NHS site name] will keep identifiable information about you from this study for 5 years after the study has finished.

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 from [NHS site name]. 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, NHS organisations or companies involved in health and care research in this country or abroad. 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; <https://www.hra.nhs.uk/information-about-patients/>.

You can find out more about how Genomics England uses your data here: www.genomicsengland.co.uk

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 <https://ico.org.uk/>.

Data Protection Officer contact information:

University of Edinburgh

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

NHS Lothian

Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
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Genomics England

Data Protection Officer
Genomics England
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Charterhouse Square,
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