

## CONSULTEE INFORMATION SHEET FOR USE IN ENGLAND, WALES AND NORTHERN IRELAND

Version 2.4 27th July 2020

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This study complies with the Mental Capacity Act 2005 (England and Wales) and the Mental Capacity Act (2016) Northern Ireland

### INTRODUCTION

We are undertaking a research study involving people with severe illness (such as Covid-19, influenza, sepsis and other causes of critical illness).

You are the best person to represent the interests of a patient who may be able to participate in this research, which is why we have approached you. We would ask you to set aside your own views and consider their interests and what you feel would be their wishes and feelings. Before you decide it is important for you to understand why the research is being done and what it would involve for the patient.

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 their 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.

### 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. Additional information about Genomics England is available: <https://www.genomicsengland.co.uk/privacy-policy/>). Genomics England is responsible for hosting the National Genomic Research Library, a national resource for researchers and the NHS. We may also partner with other organisations in future to conduct research.

### WHAT WILL HAPPEN IF THE PATIENT TAKES PART IN THIS STUDY?

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

### WHAT WILL HAPPEN TO THE SAMPLES?

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We will use the blood sample to extract and analyse the patient's DNA, which could include the whole sequence of their 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 the patient's blood sample, together with 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 the 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 the patient's sample will always be under the control of the GenOMICC investigators, or partner organisations, and subject to UK regulations.

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#### WHAT DATA IS LOOKED AT?

GenOMICC investigators and partners will always protect the patient's 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:

- The patient's clinical test data
- Electronic copies of all of the patient's records from the NHS, your GP and other organisations (such as NHS Digital and Public Health bodies)
- Information about any illnesses or stays in hospital – including information that you may not think is related to the patient
- 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 the patient's NHS records, such as MRI scans, X-rays or photographs
- Data from other research registries and studies that may be relevant

We will include the patient's 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 the patient about future opportunities to participate in research. It will not be used to make decisions about future services that might be available, such as insurance.

Where there is a risk that the patient could be identified, their data will only be used in research that has been independently reviewed by an ethics committee and the sponsor.

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#### 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 the patient's health from their DNA. If this unlikely GenOMICC consultee information sheet (England, Wales and NI) v2.4 27th July 2020 [IRAS: 189676/269326]

event happens, we will try to contact their 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 the patient by doctors or nurses with relevant expertise.

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#### WILL THE 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 the patient's medical records and data to carry out this research.

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

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#### WILL YOU CONTACT THEM AGAIN?

Although we can learn a lot from DNA, we may be able to learn even more from studying the cells in the patient's blood, or other research. For this reason we might contact them in future about participation in studies related to critical illness. Importantly, by agreeing to this first blood sample, you are not automatically agreeing to further blood samples. You, or if able the patient themselves, can agree to a blood sample now and say no if asked again in the future.

GenOMICC investigators may also contact the patient directly or through their clinical care team about other studies that they might wish to take part in. These studies may be related to disease or just to biological differences between people. This may be because researchers have already looked at the patient's health data, or data from the samples they gave, and would like further information based on these findings. You can choose to say yes or no to taking part in further studies and it will not affect this study or the patient's treatment in any way.

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#### WHAT WILL HAPPEN IF I DO NOT AGREE?

Absolutely nothing. You are free to choose not to provide a consultee declaration, and this would not affect the patient's treatment in any way.

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

Yes you are free to withdraw the patient from this study at any time without giving reason and without detriment to the patient's medical care. All samples that we hold from the patient 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 the patient from the study, no new information about the patient will be collected, but information that has already been collected will continue to be used for the study.

A withdrawal form will be required to record this decision. The form can be requested from the patient's healthcare professional or downloaded from the GenOMICC website: <http://genomicc.org/uk/withdrawal>  
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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](mailto: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](mailto: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](mailto: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. The information below details what data is held about a participant in a research study, 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 the patient's 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 the patient's information and using it properly. The co-sponsors will keep identifiable information about the patient for 5 years after the study has finished.

The patient's rights to access, change or move their information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If you withdraw the patient from the study, we will keep the information about them that we have already obtained. To safeguard the patient's 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 the patient's name, NHS number and contact details to contact them about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Individuals from the University of Edinburgh and NHS Lothian and regulatory organisations may look at the patient's 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 the patient's medical records. The only people in the University of Edinburgh and NHS Lothian who will have access to information that identifies the patient will be people who need to contact them about study follow up or audit the data collection process.

[NHS\_site\_name] will keep identifiable information about the patient from this study for 5 years after the study has finished.

Providing personal data indirectly e.g. from the patient's medical records

The University of Edinburgh, NHS Lothian and Genomics England will collect information about the patient for this research study from [NHS\_site\_name]. This information will include the patient's name/ NHS number/ contact details and health information, which is regarded as a special category of information. We will use this information to access their medical records where applicable and study follow up.

### USE OF DATA FOR FUTURE RESEARCH

When you agree that the patient can take part in a research study, the information about their 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. The patient's 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.

The patient's information could be used for research in any aspect of health or care, and could be combined with information about them from other sources held by researchers, the NHS or government. Where this information could identify the patient, 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 the patient's information and our legal basis for doing so in our Privacy Notice at [www.accord.scot](http://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](http://www.genomicsengland.co.uk)

If you wish to raise a complaint on how we have handled the patient's 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](mailto:dpo@ed.ac.uk)

**NHS Lothian**

Data Protection Officer  
NHS Lothian  
Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Tel: 0131 465 5444  
[Lothian.DPO@nhs.net](mailto:Lothian.DPO@nhs.net)

**Genomics England**

Data Protection Officer  
Genomics England  
Dawson Hall,  
Charterhouse Square,  
London  
EC1M 6BQ  
[dpo@genomicsengland.co.uk](mailto:dpo@genomicsengland.co.uk)