## PARTICIPANT INFORMATION SHEET FOR CHILD AGED 12-15

Version: 5, 23 October 2024

Local Lead Investigator: [local\_lead\_investigator\_name]

Chief Investigator: Prof JK Baillie, University of Edinburgh

### Introduction

Parents and carers are asked to go through this information with their child. Please ask study staff if you or your child has any questions.

We are undertaking a genetic research study involving people with critical illness and healthy volunteers. Some of our genes (or DNA) affect how vulnerable we are to critical illness. We are trying to find these genes because they can help us to develop better treatments for other patients in the future.

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

Your decision is completely voluntary and if you choose not to take part then it will not affect your care or treatment in any way.

### What will happen if I take part in this study?

A single blood sample will be taken, up to 4mls (roughly 1 teaspoon), but we may take much less than this depending on your weight, 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.

We will use your sample to analyse your DNA which could include the whole sequence of your genome. Your genome is the ‘instruction manual’ that contains the information needed to make, run and repair everything in the body. We will safely store your DNA sample and hold your genetic information, and other health information, on a secure computer.

Data from your DNA 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.

### Are there any benefits or disadvantages to taking part in this study?

There is no direct benefit to taking part in the study, but 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 that 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 uncertain and difficult to interpret.

### What data is looked at?

We will collect personal information about you and your illness, such as your name, date of birth and NHS or CHI number. This will be held on a secure computer that only a very limited number of people can access. Your personal information will be linked to your DNA sample and genetic information using a unique number meaning you can never be identified by any scientist or investigator undertaking an analysis of your data.

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 any information that could identify you, such as your name or date of birth, has 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 and Public Health bodies)
* Information about any illnesses or stays in hospital – including information that you may not think is 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 that you have participated in
* 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. Data taken out of these environments will be restricted to data that cannot be used to re-identify anyone in any way.

### 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 your information at every stage. Study researchers will need access to your medical records and data to carry out this research.

### What will happen to my DNA sample and data?

With your permission, we will store your DNA sample and genetic data to use 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.

### Will you contact me again?

When you reach the age of 16, an attempt will be made to contact you to ask for your own continued consent for data linkage to health records. If consent can’t be obtained, then data linkage will cease at age 16. The GenOMICC central management team will alert research sites to any instance of a child reaching 16 to discuss how best to approach re-consent, if appropriate.

If you agree, we may contact you again for further information or to tell them about other research opportunities. 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. If this was the case, we would contact you as we would need a second blood sample. You don’t have to agree to this or to any future requests.

### 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.

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 not 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**

* + delete the personal information we hold about you
	+ destroy your DNA sample
	+ delete your genetic information (if it has not already been included in an analysis)

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 but the information we hold at this stage is de-identified, meaning no-one would know anything was related to you
	+ remove original records held by the NHS and an audit trail confirming your participation in GenOMICC will remain with the NHS

Contact the local lead investigator or study co-ordinator and let them know if you decide to withdraw consent. Their details are noted in the next section below.

### 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, [local\_lead\_investigator\_name], or contact the study coordinator, [study\_coordinator\_name] on: [study\_coordinator\_phone\_number] or email [study\_coordinator\_email\_address]

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: [Enter local patient experience team or complaint contact information / Patient Advice and Liaison Service (PALS) details]