## Parent/Guardian information sheet

Version X.X D/MM/YYYY

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

### Introduction

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 critical illness. We are trying to find these genes because they can help us to develop better treatments for other patients in the future.

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 your child.

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 child’s care or treatment in any way.

### What will happen if MY CHILD takes part in this study?

The study requires one DNA sample. There may already be a sample of their blood, or in some cases, of umbilical cord blood, that we could use if you agree. If not, we will obtain a sample of DNA from a single blood sample of 4mls (1teaspoon) or less. In some circumstances, if blood is not possible, we may be able to get a sample of DNA from a saliva sample.

We will use the sample to analyse your child’s DNA which could include the whole sequence of their 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 the DNA sample and hold the genetic information, and other health information, on a secure computer.

Data from the DNA sample, together with your child’s 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 to be able help other people who become critically ill in future. There is a very small possibility that we will discover information about your child’s health from their DNA. If this unlikely 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 you and your child by doctors or nurses with relevant expertise.

### What data is looked at?

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

GenOMICC investigators and partners will always protect your child’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:

* Your child’s clinical test data
* Electronic/paper copies of all your child’s records from the healthcare provider, your doctor and other organisations (such as Public Health bodies)
* Information about any illnesses or stays in hospital – including information that you may not think is related to your child
* 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 child’s healthcare records, such as MRI scans, X-rays or photographs
* Data from other research registries and studies that may be relevant

Your child’s original records remain within the healthcare provider. We will include your child’s 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.

The information will only be used for the purpose of healthcare research, or to contact you or your child about future opportunities for them 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 your child can be identified, their data will only be used in research that has been independently reviewed by an ethics committee and/ or the sponsor.

### Will my child’s 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 child’s 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 Healthcare Institution to access your child’s 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 will happen to the samples?

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 your child’s sample will always be under the control of the GenOMICC investigators, or partner organisations, and subject to local 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 may also partner with other organisations in future to conduct research. Only qualified, approved researchers will have access to your data.

### Will you contact me again?

When a young person reaches the age of 16 and was recruited as a child, an attempt will be made to contact them to ask for their 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 or your child 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 my child be withdrawn from the study at any point?

Yes, you are free to withdraw your child from this study at any time without giving reason and without detriment to your child’s 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 child’s 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 child’s health and other records for use in approved research.

**2. Full withdrawal**

This option is for situations where you no longer wish for your child’s data to be used for research and want no further contact.

We **will**

* + delete the personal information we hold
	+ destroy the DNA sample
	+ delete the 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 health and other records
	+ allow new research access to information that is held
	+ use your child’s 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 that was related to your child.

* + - remove original records held and audit trail confirming your child’s participation in GenOMICC.

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: [Insert local independent contact and details]

If you wish to make a complaint about the study please contact [Insert local complaints contact and details]

## Data Protection Participant Information

The [enter relevant local/country regulations and laws], will govern the processing (holding or use) of personal data in [enter your country]. As a central coordinating place, your child’s data may be sent to the UK, this data will not be identifiable. In this instance, the data will be processed to comply with UK data regulations.

[Enter sponsor name] is the sponsor for this study based in [add your location or country]. 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 sponsor 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

[Healthcare site name] will keep your name, healthcare 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 [sponsors name] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Healthcare site name] will pass these details to the sponsor along with information collected from you and your medical records. The only people 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. [Healthcare 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 sponsor will collect information about you for this research study from [Healthcare site name]. This information will include your name/ healthcare 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, healthcare 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 that country’s regulations and [enter any local requirements]

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 healthcare provider 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 [enter local information]

For further information on the use of personal data by healthcare sites, please link to [enter local information]

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 [enter local information]

Data Protection Officer contact information:

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| [enter local information] |  |  |