## Participant information sheet for child aged 12-16

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

Chief Investigator: Dr 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.

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, up to 4mls (roughly 1 teaspoons), 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.

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.

### 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 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.

### 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.

### Will you contact me again?

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. For this reason we might contact you in future about participation in studies related to critical illness. Importantly, by consenting to this first blood sample, you are not automatically consenting to further blood samples. You can give consent to a blood sample now and say no if asked again in the future.

GenOMICC investigators may also contact you directly or through your clinical care team about other studies that you 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 your health data, or data from the samples you 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 your treatment in any way.

### 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.

A withdrawal form will be required to record this decision. The form can be requested from your healthcare professional or downloaded from the GenOMICC website: [http://genomicc.org/uk/withdrawal](http://genomicc.org/uk/withdrawal/)

### 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]