## Genomicc VOLUNTEER INFORMATION SHEET

Version X.X DD/MM/YYYY

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

### 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. Your decision is completely voluntary and if you decide not to take part, this will not affect any health care you receive now or in the future.

### 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.

We are asking for healthy volunteers who are over the age of 18, with no history of critical illness to be part of our study. We are aiming to match healthy volunteers with critically ill participants in age, sex, ethnicity and other factors. For the people who match, in the future, we would ask them to provide a blood sample that we can sequence and compare with samples from people who were severely ill.

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

You will be asked to confirm your consent by [enter your consent process]. A single blood sample will be taken (4-9mls; roughly 1-2 teaspoons) to get a DNA sample. [Explain where this process will happen].

If you are unable to give a blood sample for any reason, we can send you a saliva sample kit instead. [delete if not applicable]

### 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 [your country] regulations. If your blood sample is processed in the UK, this will comply with relevant tissue regulations in the UK.

### 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.

### What data is looked at?

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

* Your clinical test data
* Electronic/paper copies of all your past and future records from the healthcare provider, your GP and other organisations (such as 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 healthcare 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 healthcare provider. We will include your data in secure analysis systems within the University of Edinburgh research environment. 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 Healthcare 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.

### 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 do not 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, you are under no obligation to volunteer for our study.

### 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 a reason. All samples that we hold from you would be destroyed.

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 [enter local details]. 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, [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 the [enter your country]. As a central coordinating place, your 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 that countries regulations [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, [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: [enter local information]