## Genomicc ACUTE: TELEPHONE SCRIPT TO GUIDE PERSONAL CONSULTEE consent CONVERSATIONS

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### NOTES ON TELEPHONE CONSENT Conversations

* **Ensure that you have spoken to the clinical team (bedside nurse or consultant) and they consider it acceptable to approach the patient’s relatives or other appropriate consultee or welfare guardian or attorney.**
* **Ensure that you understand the clinical state of the patient, particularly if death or withdrawal of life-sustaining treatment is imminent.**
* **Double-check the patient’s name before you start the call**
* **Use the ‘Personal Consultee Telephone Opinion Form’ to record opinion/consent, if given and send a copy of the relevant GenOMICC ACUTE information sheet depending on your area (England, Wales, NI Consultee information sheet or Welfare Attorney/Guardian or nearest relative information sheet if in Scotland)**
* **Answer any questions that the relative/guardian has in plain, understandable language.**
* **If the relative/guardian becomes distressed, then gently bring the conversation to a close.**

### The role of the consultee - please explain this, relevant to your area as part of your call - see script below

**[England, Wales and Northern Ireland only]**

The consultee is someone close to the patient, such as a relative or close friend who are asked to advise the research team on what they believe [**NAME OF PATIENT**] wishes and feelings would be if they were able to consent for themselves, and on whether they should take part.

Acting as a consultee is completely voluntary and it’s important to set aside your own feelings and wishes and consider what [**NAME OF PATIENT**] would like as best you can.

**[Scotland]**

Only a legal representative can give consent on behalf of an adult who lacks capacity to do so for themselves and those are the patients nearest relative, welfare guardians or attorneys.

Legal representatives are asked to consider what they believe the feelings and wishes of **[NAME OF PATIENT]** would be and give consent on their behalf.

Acting as a legal representative is completely voluntary and it’s important to set aside your own feelings and wishes and consider what [**NAME OF PATIENT**] would like as best you can.

### Script

Hello, is that [NAME OF PERSON YOU ARE EXPECTING TO SPEAK TO]? My name is [YOUR NAME]. I am a [job/role] at [NHS\_site\_name]. I’m working with the clinical team in the ICU. Do you have a moment to speak (**if answer is no, offer to call back at a more convenient time)**?

[Name of hospital] is one of the many hospitals around the country that is taking part in a clinical study called GenOMICC. This is a research study to try to find the genes that influence the development of critical illness. This could help us develop better treatments for critical illness [OR, NAME THE RELEVANT DISEASE].

We’re contacting you as you are best placed to represent the wishes and interests of [Patient Name], who may be able to take part in this study. If you agree, we’d like to collect some personal information about them and their illness and take a single blood sample to look at their DNA. Taking part won’t affect their care in any way.

[Explain the role of the consultee relevant to your area - See role of the consultee above].

If you are willing to consider this, I’d like to email you an information sheet about the study, or direct you to a website where you can read it. Alternatively, I can read a summary over the phone to you [SEE SUMMARY SECTION, BELOW].

**[The relative/guardian may wish to read to the full PIS/website in which case, arrange a call back], Or proceed to read the summary - below].**

Do you think you would be willing to give permission for us to enrol [Patient Name] in this study? Your decision is completely voluntary, and whatever decision you make will not affect [Patient Name]’s treatment in any way whatsoever. **If answer is 'no', please thank them for their time and their attention, and bring the conversation to a close.**

**If answer is ‘yes’:** Thank you, we really appreciate this. I’m now going to read out a series of statements from the consent form. And if you have any questions about any of the statements, or would like something clarified, then please feel free to ask.

**Read out statements on the GenOMICC ACUTE Personal Consultee Telephone Opinion form, one by one, and let them confirm that they agree.**

Thank you. What will happen now is that we’ll speak with the doctors and nurses looking after [Patient Name], and let them know that you’ve provided permission for us to enrol [Patient Name] in this study. We’ll also send you a copy of a Personal Consultee Telephone Opinion Form confirming your permission and an information sheet. That information sheet has a phone number which you can ring if you have any problems, or would like any additional information about the study. Could you please let me know the best way for us to send you these documents?

**[Check health status of patient - if end of life is near or if the patient never had capacity to consent prior to their illness then this statement is not relevant] As you have decided that [NAME OF PATIENT] should take part in our study, then we’ll also let them know about their participation when they are able, and they will have the opportunity to consider whether they want to be part of the GenOMICC study themselves.**

**Take email/postal address**
Do you have anything you’d like to ask us at this time?
Many thanks for taking the time to speak with us today. We really appreciate it.

**End Conversation**

## Summary of information sheet to be read out over the phone if requested

### 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 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 and we can find out even more by studying the biological processes that are happening in some cells of the body during the early stages of critical illness.

### What does taking part in the study involve?

The study requires a blood sample of 17mls which is roughly the same as 4 teaspoons of blood. We need this volume of blood so that we can use it to look at the different cells and molecules in the patient’s blood and extract a sample of their DNA.

### 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 to 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 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.

### What data is looked at?

GenOMICC investigators and partners will always protect your friend or relative’s data and control who has access to it. We will access information that has been de-identified (meaning that name, date of birth and other identifying information have been removed), including medical records and images.

We will include your friend or relative’s data in secure analysis systems in the UK. Access to these systems is strictly controlled. 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 person 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.

### 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.

### What will happen to the DNA sample and Data?

With your permission, we will store the samples and genetic data to 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 sample and data will always be under the control of the GenOMICC investigators, or partner organisations, and subject to UK 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.

### Can I request that I 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.

If you change your mind, let us know and we’ll remove {NAME OF PATIENT} from the study. The information sheet we’ll send has all the details, but you should know that we can’t delete data from research that has already happened or is underway.