



GENOMICC ACUTE RECRUITMENT- SITE GUIDANCE

Thanks so much for agreeing to help recruit participants to the GenOMICC Acute sub-study.

GenOMICC Acute follows the same process as recruiting to GenOMICC, with only two key differences:

- 1. Acute participants must be recruited and sampled within 48 hours of admission to critical care.
- 2. Acute participants will need to give three samples, the usual DNA sample, then 2 others.

This guidance note applies to GenOMICC Acute participants only.

ELIGIBLE PARTICIPANTS

All participants who are eligible for GenOMICC are also eligible for the Acute sub-study (if they can be recruited and sampled within 48 hours of admission to critical care).

Entry criteria is here - https://genomicc.org/countries/uk/entry/

GENOMICC ACUTE STUDY DOCUMENTS

We have a separate information sheets and consent forms to use when obtaining consent for the Acute sub-study.

The documents have a GenOMICC Acute logo at the top, so it's easy to tell them apart from the usual GenOMICC set. We'll localise the forms for you and send them on, if you have not already received them.

SAMPLING SCHEDULE

We need three samples from GenOMICC Acute participants, and although there is no sample processing at site, some samples do need some shaking and tilting. The details are noted below:

Draw Order	Sample Type	Volume	Action needed
1	DNA (standard GenOMICC sample)	4mls	None - fill EDTA tube and package as normal.
2	RNA	3mls	Immediately after collection shake tube vigorously for 10 seconds then package.
3	Cell-free RNA	10mls	Immediately after collection fully invert the filled tube 10 times then package. Care - these tubes are glass (extra padding has been added to each specimen kit to protect during transit).





SPECIMEN KITS

Information **Image** We have separate GenOMICC Acute UN3373 GenOMICC specimen kits. You'll be able to identify them easily as they have a large GenOMICC Acute sticker on the front. **UN3373** The return label is attached and already paid - these kits can be posted as normal through any Royal Mail post box. Information **Image** Each kit will have 3 tubes inside, already prelabelled with the participant ID stickers. There will be 2 spare ID stickers for the consent form/s. (Any unused stickers should be discarded). All 3 samples are returned at the same time in the same internal plastic bag and postage-paid specimen kit.

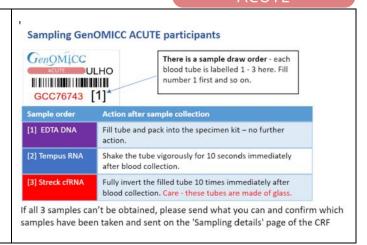




We have a sample 'draw' order, and the ID labels are numbered 1 to 3.

Please fill number 1 first and so on. In the unlikely event the full amount of blood is not available, please send what you can.

There are instructions inside each kit to remind you of the sample draw order and what needs to happen with each tube (see image).



COMPLETION OF THE CASE REPORT FORM ON REDCAP

No additional information is required for GenOMICC Acute participants other than confirmation of the date and time of recruitment and the date and time of sampling.

The 'Sampling details' page of REDCap will hold the additional data fields for the entry of this information as shown on the example below.

SAMPLING DETAILS PAGE ON REDCAP (ACUTE EXAMPLE) Sampling Details Assign record to a Data Access Group? -- select a group --Adding new GenOMICC ID number GCC99997 Event: Recruitment (Arm 1: Main study) GenOMICC ID number GCC99997 Prospective Recruitment (Patient is currently in ICU or still in hospital) O Patient attended for follow-up appointment after How was this participant recruited? discharge and was recruited by face-to-face discussion * must provide value O Retrospective Recruitment (Participant was contacted at home retrospectively after discharge) Is this participant part of the ACUTE sub-study? ● Yes ○ No ACUTE is a sub-study initally recruiting at a limited number of sites. Contact GenOMICC study team if you would like more details. Date and approximate time of admission to ICU 21-11-2024 08:25 Mow D-M-Y H:M Confirm that the 3ml sample for RNA was taken and processed Yes ○ No according to the protocol. reset Date and approximate time that the RNA sample was taken. 21-11-2024 08:25 Now D-M-Y H:M Confirm that the larger 10ml sample for cell-free RNA was taken ● Yes ○ No and processed according to the protocol. reset Date and approximate time that the cell-free RNA sample was 21-11-2024 08:25 Now D-M-Y H:M Confirm sample for DNA extraction (and additional samples if this is an ACUTE patient) has/have been taken using GenOMICC sample kit, boxed and sent for posting





POTENTIAL ISSUES

- We have a sample draw order to make sure we receive the samples in a specific order of importance in the unlikely event that not all of the samples can be obtained. If this happens, simply send what you can and let us know.
- Sadly, if the blood tubes are not shaken or tilted where required, this will affect the quality of the sample and the lab can usually tell. We'll let you know if there are any issues with quality.
- If sampling happens after 48 hours of admission to critical care, then patients can only be recruited to GenOMICC as normal in this instance.

Please contact the GenOMICC team with any queries you many have and if preferred we would be very happy to set up a call with your team for a training session.