

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

21 November 2024

Dear Professor Baillie,

**Study title:** Genetics of susceptibility and mortality in critical care (GenOMICC)  
**REC reference:** 15/SS/0180  
**EudraCT number:** n/a  
**Amendment number:** SA\_014 (England) SA\_011 (Scotland)  
**Amendment date:** 29 October 2024  
**IRAS project ID:** 189676

The above amendment was reviewed by the Sub-Committee in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee would also like to make the following recommendation:

'The Committee noted that in pages 5 & 6 of the Acute Parent/Guardian information sheet v1, there were numerous instances of the wrong pronoun being used such as, 'yours', 'your data' 'your medical records', rather than 'your child', 'your child's data' and 'your child's medical records'. The Committee would like to recommend that all incorrect pronouns on page 5-6 of the Acute Parent/Guardian information sheet V1 should be corrected to reflect the fact that this is the Acute Parent/Guardian Info Sheet.

As these are the only changes required to the paperwork this would be considered minor and would not have to be submitted to Scotland A REC for review. It might be prudent however to ensure the change has been made before the paperwork is submitted and reviewed by the English/Welsh REC on the 27<sup>th</sup> November 2024.'

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Completed Amendment Tool [189676 (Scotland) 269326 (Rest of UK) _SA_014 (England) and SA_011 (Scotland)_]	1.6	29 October 2024	
Copies of materials calling attention of potential participants to the research [GenOMICC video explainer QR card v1]	1	23 October 2024	
Copies of materials calling attention of potential participants to the research [Patient retrospective recruitment invite v5]	5	23 October 2024	
Copies of materials calling attention of potential participants to the research [Tracked patient retrospective recruitment invite v4 to v5]	5	23 October 2024	
Covering letter on headed paper [GenOMICC Summary of changes SA 23 October 2024 Amended 18.11.2024]		18 November 2024	
Other [GenOMICC Summary of changes SA 23 October 2024 (3)]	1	23 October 2024	
Other [Community sampling instructions v5]	5	23 October 2024	
Other [Community sampling letter v5]	5	23 October 2024	
Other [Patient regained capacity letter v5]	5	23 October 2024	
Other [Telephone consent script v5]	5	23 October 2024	
Other [Withdrawal form v5]	5	23 October 2024	
Other [Tracked community sampling instructions v4 to v5]	5	23 October 2024	
Other [Tracked community sampling letter v4 to v5]	5	23 October 2024	
Other [Tracked patient regained capacity letter v4 to v5]	5	23 October 2024	
Other [Tracked telephone script v4 to v5]	5	23 October 2024	
Other [Tracked withdrawal form v4 to v5]	5	23 October 2024	
Participant consent form [Child 12 to 15 assent v5]	5	23 October 2024	
Participant consent form [Child under 12 assent v5]	5	23 October 2024	
Participant consent form [Parent guardian consent form v5]	5	23 October 2024	
Participant consent form [Participant consent form v5]	5	23 October 2024	
Participant consent form [Personal consultee telephone opinion form v5]	5	23 October 2024	

Participant consent form [Scotland relative consent form deceased patient v5]	5	23 October 2024	
Participant consent form [Scotland relative consent form v5]	5	23 October 2024	
Participant consent form [Tracked child 12 to 15 assent v4 to v5]	5	23 October 2024	
Participant consent form [Tracked child under 12 assent v4 to v5]	5	23 October 2024	
Participant consent form [Tracked parent guardian consent form v4 to v5]	5	23 October 2024	
Participant consent form [Tracked participant consent form v4 to v5]	5	23 October 2024	
Participant consent form [Tracked personal consultee telephone opinion form v4 to v5]	5	23 October 2024	
Participant consent form [Tracked Scotland relative consent form deceased patient v4 to v5]	5	23 October 2024	
Participant consent form [Tracked Scotland relative consent form v4 to v5]	5	23 October 2024	
Participant consent form [Acute child 12 to 15 assent v1]	1	23 October 2024	
Participant consent form [Acute child under 12 assent v1]	1	23 October 2024	
Participant consent form [Acute parent and guardian consent form v1]	1	23 October 2024	
Participant consent form [Acute participant consent form v1]	1	23 October 2024	
Participant consent form [Acute Scotland relative consent form v1]	1	23 October 2024	
Participant consent form [Acute Scotland relative consent form deceased patient v1]	V1	23 October 2024	
Participant information sheet (PIS) [Parent guardian info sheet v5]	5	23 October 2024	
Participant information sheet (PIS) [Participant info sheet child age 12 to 15 v5]	5	23 October 2024	
Participant information sheet (PIS) [Participant info sheet children under 12 v5]	5	23 October 2024	
Participant information sheet (PIS) [Participant info sheet v5]	5	23 October 2024	
Participant information sheet (PIS) [Scotland relative info v5]	5	23 October 2024	
Participant information sheet (PIS) [Tracked parent guardian info sheet v4 to v5]	5	23 October 2024	
Participant information sheet (PIS) [Tracked participant info sheet for child aged 12 to 15 v4 to v5]	5	23 October 2024	
Participant information sheet (PIS) [Tracked participant info sheet for child under 12 v4 to v5]	5	23 October 2024	

Participant information sheet (PIS) [Tracked participant information sheet v4 to v5]	5	23 October 2024	
Participant information sheet (PIS) [Tracked scotland relative info sheet v4 to v5]	5	23 October 2024	
Participant information sheet (PIS) [Acute Participant info sheet v1]	V1	23 October 2024	
Participant information sheet (PIS) [Acute Participant info sheet children under 12 v1]	V1	23 October 2024	
Participant information sheet (PIS) [Acute Participant info sheet child age 12 to 15 v1]	V1	23 October 2024	
Participant information sheet (PIS) [Acute Parent guardian info sheet v1]	V1	23 October 2024	
Participant information sheet (PIS) [Acute Scotland relative info v1]	V1	23 October 2024	
Research protocol or project proposal [Protocol v5]	5	23 October 2024	
Research protocol or project proposal [Tracked protocol v4 to v5]	5	23 October 2024	

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

### Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.



**Scotland A: Adults with Incapacity only**

**Attendance at Sub-Committee of the REC meeting on 08 November 2024**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Miss Joanne Douglas	Head of Research Governance	Yes		
Dr Jessica MacLaren	Registered Nurse-Lecturer in Mental Health	Yes		
Dr Lindsay Ramage	Director of Policy, Systems & Performance, Research & Innovation Services	Yes		

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>	
Manx Neill	Scotland A/B REC Manager	
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC	