

West Midlands - Coventry & Warwickshire Research Ethics Committee

2 Redman Place
Stratford
London
E20 1JQ

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.

24 January 2025

Chris Coner
The Queen's Medical Research Institute
47 Little France Crescent
EH16 4TJ

Dear Chris Coner

Study title: Genetics of susceptibility and mortality in critical care (GenOMICC)
REC reference: 19/WM/0247
Amendment number: SA14_Scotland SA_011 (rest of UK) - MODIFIED
Amendment date: 17 January 2025
IRAS project ID: 269326

Thank you for submitting the above amendment, which was received on 17 January 2025. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 02 December 2024 refers). The modified amendment was reviewed on 27 January 2025 by the Sub-Committee *in correspondence*. A list of the members who took part in the review is attached.

Ethical opinion

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

Document	Version	Date
Covering letter on headed paper [GenOMICC_Headed letter_19WM0247]	n/a	17 January 2025

Covering letter on headed paper [GenOMICC Summary of changes SA 23 October 2024 Amended 17.01.2025.]	n/a	17 January 2025
Notice of Modified Amendment [AMENDMENT TOOL - 189676 (Scotland) 269326 (Rest of UK) _SA14_Scotland SA_011 (rest of UK) - MODIFIED]	n/a	17 January 2025
Other [Acute Telephone consent script v1]	1	23 October 2024
Other [GenOMICC video explainer QR card v1]	1	-
Other [Acute Telephone consent script v1]	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 patient retrospective recruitment invite 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
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 [Patient retrospective recruitment invite v5]	5	23 October 2024
Other [Personal consultee telephone opinion form v5]	5	23 October 2024
Other [Telephone consent script v5]	5	23 October 2024
Other [Withdrawal form v5]	5	23 October 2024
Participant consent form [Acute Personal consultee telephone opinion form v1]	1	23 October 2024
Participant consent form [Acute Eng Wales NI consultee consent form deceased patient v1]	1	23 October 2024
Participant consent form [Acute Eng Wales NI consultee consent form 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 Personal consultee telephone opinion form v1]	1	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 eng wales ni consultee consent form deceased patient v4 to v5]	5	23 October 2024
Participant consent form [Tracked eng wales ni consultee 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 [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 [Eng Wales NI consultee consent form deceased patient v5]	5	23 October 2024
Participant consent form [Eng Wales NI consultee consent form 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 [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 information sheet (PIS) [Acute Eng Wales NI consultee info v1]	1	23 October 2024
Participant information sheet (PIS) [Acute Parent guardian info sheet v1]	1	23 October 2024
Participant information sheet (PIS) [Acute Participant info sheet child age 12 to 15 v1]	1	23 October 2024
Participant information sheet (PIS) [Acute Participant info sheet children under 12 v1]	1	23 October 2024
Participant information sheet (PIS) [Acute Participant info sheet v1]	1	23 October 2024
Participant information sheet (PIS) [Tracked eng wales ni consultee information sheet v4 to 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 Parent guardian info sheet 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) [Eng Wales NI consultee info v5]	5	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
Research protocol or project proposal [Tracked protocol v4 to v5.]	5	23 October 2024
Research protocol or project proposal [Protocol v5]	5	23 October 2024

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 269326:

Please quote this number on all correspondence

Yours sincerely



pp.
Miss Stephanie Ellis, BEM
Chair

E-mail: coventryandwarwick.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr John Kenneth Baillie, The Roslin Institute

West Midlands - Coventry & Warwickshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 27 January 2025, via correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Stephanie Ellis, BEM	Former Civil Servant	Yes	Chair
Dr Jane Richardson	Retired Senior Lecturer	Yes	