

North East - York Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Tel: 0207 972 2503

**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.**

27 March 2020
Reissued 02 April 2020

Professor Danny McAuley
Centre for Experimental Medicine
Wellcome-Wolfson Institute for Experimental Medicine
97 Lisburn Rd, Belfast
BT9 7BL To be appointed

Dear Professor Danny McAuley

Study title:	Repair of Acute Respiratory Distress Syndrome by Stromal Cell Administration (REALIST) trial: An open label dose escalation phase 1 trial followed by a randomised, double-blind, placebo-controlled phase 2 trial.
REC reference:	18/NE/0006
Protocol number:	16154DMcA-AS
EudraCT number:	2017-000584-33
Amendment number:	8 (HRA reference 6)
Amendment date:	27 March 2020
IRAS project ID:	227090

The above amendment was reviewed at the Sub-Committee meeting held on 27 March 2020.

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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment [MHRA Eudract snapshot]	1	27 March 2020
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence	1	30 March 2020
Cover Letter [Cover email]	1	27 March 2020
Cover Letter [SAAF Classification]	1	24 March 2020
Other [Summary of key changes]	2	25 March 2020
Other [Telephone PerLR agreement]	1	23 March 2020
Protocol [Protocol clean]	4	23 March 2020
Protocol [Protocol tracked]	4	23 March 2020

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.

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/>

18/NE/0006:	Please quote this number on all correspondence
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Yours sincerely



Catherine Adams
Approvals Manager on behalf of

Mr Chris Turnock
Chair

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

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

Copy to: To be appointed

North East - York Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 27 March 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Steve Chandler	Retired Consultant Medical Physicist	Yes	
Mr Chris Turnock	Retired Nurse	Yes	