



**Health Research
Authority**

South Central - Oxford C Research Ethics Committee

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BS1 2NT

Tel: 0207 104 8049

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.

11 December 2017

Professor Paul Dark
Chair of Critical Care Medicine
University of Manchester
Research and Development Department
First Floor, Summerfield House, Salford Royal NHS Foundation Trust
Salford, Greater Manchester
M6 8HD

Dear Professor Dark

Study title:	Biomarker-guided duration of antibiotic treatment in hospitalised patients with suspected sepsis. The ADAPT-Sepsis Trial.
REC reference:	17/SC/0434
Protocol number:	R121074
Amendment number:	1.0
Amendment date:	21 November 2017
IRAS project ID:	209815

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.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [HRA Covering Letter 21-Nov-2017.pdf]		21 November 2017
GP/consultant information sheets or letters [GP Letter V2.0 17-Nov-2017 (tracked).doc]	2	17 November 2017
GP/consultant information sheets or letters [GP Letter V2.0 17-Nov-2017 (clean)]	2.0	17 November 2017
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_SA 01 21-Nov-2017.pdf]	1.0	21 November 2017
Other [HRA Covering Letter 30-Nov-2017 (Trial Summary)]		30 November 2017
Other [ADAPT-SepsisTrial+Summary+V1.0+18JUL2017]	1.0	18 July 2017

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/SC/0434:	Please quote this number on all correspondence
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Yours sincerely



pp. Ms Helen Sivey
REC Manager

Professor Nigel Wellman

Chair

E-mail: nrescommittee.southcentral-oxfordc@nhs.net

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 15 December 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Anna Rathmell	Medical Manager - GI	Yes	
Professor Nigel Wellman (Chair and Meeting Chair)	Professor of Health and Human Sciences	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Amy Peters	REC Assistant