



# Health Research Authority

## South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)  
Ground Floor, Temple Quay House, 2 The Square  
BS1 6PN

Tel: 0207 104 8241

05 February 2021

Ms Nicola McGowan  
Warwick Clinical Trials Unit  
University of Warwick  
Gibbett Hill Campus  
Coventry  
CV4 7AL

Dear Ms McGowan

**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:** SA 05  
**Amendment date:** 02 February 2021  
**IRAS project ID:** 209815

The above amendment was reviewed at the meeting of the Sub-Committee held on 05 February 2021.

### 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>
Completed Amendment Tool [Amendment Tool (Locked PDF)]		03 February 2021
Research protocol or project proposal [ADAPT-Sepsis Trial Protocol]	5.0	02 February 2021
Research protocol or project proposal [ADAPT-Sepsis Trial Protocol - Tracked changes]	5.0	02 February 2021

### 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.

### **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 - 209815:**

**Please quote this number on all correspondence**

Yours sincerely



PP  
**Dr Lee Potiphar**  
**Chair**

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

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

*Copy to: Professor Paul Dark, University of Manchester*

## South Central - Oxford C Research Ethics Committee

### Attendance at Sub-Committee of the REC meeting on 05 February 2021

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Linda Cartwright (Alternate Vice Chair and Meeting Chair)	Retired Consultant Epidemiologist	Yes	
Dr Pamela Susan Ross	GP Principal	Yes	

#### Also in Attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Charlotte Ferris	Approvals Officer
Mr Philip Evans	Approvals Administrator