



**Health Research
Authority**

South Central - Oxford C Research Ethics Committee

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Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

20 October 2017

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
IRAS project ID: 209815

Thank you for your letter of 20 October 2017. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 06 September 2017

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant consent form [ADAPT Sepsis Assent (N.Ireland) V1.4 20-Oct-2017 tracked changes]	1.4	20 October 2017
Research protocol or project proposal [ADAPT-Sepsis Trial Protocol V1.2 20OCT2017 tracked changes]	1.2	20 October 2017

Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [ADAPT-Sepsis HTA 15-99-02 Branding]	Logo	08 June 2017
Covering letter on headed paper [HRA Covering Letter]		31 July 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Signed Insurance Assessment Form]		13 June 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity Statement]		31 July 2017
GP/consultant information sheets or letters [GP Letter]	1.0	27 July 2017
IRAS Application Form [IRAS_Form_04082017]		04 August 2017
IRAS Checklist XML [Checklist_19092017]		19 September 2017
Letter from funder [funding letter]		
Letter from sponsor [Sponsor Letter]	V1.0	01 August 2017
Other [Sponsor Indemnity Statement]	V1.0	01 August 2017
Other [Sponsor CT, Medical Malpractice and PI Confirmation]	V1.0	01 June 2017
Other [HRA Clarification Letter]		04 August 2017
Other	Lay Summary	08 September 2017
Other [HRA Reply Letter]		08 September 2017
Participant consent form [ADAPT Sepsis Assent (N.Ireland) V1.4 20-Oct-2017 tracked changes]	1.4	20 October 2017
Participant information sheet (PIS) [ADAPT-Sepsis PIS Patient at Commencement]	1.2	08 September 2017
Participant information sheet (PIS) [ADAPT-Sepsis PIS Recovery]	1.2	08 September 2017
Participant information sheet (PIS) [ADAPT-Sepsis CIS Consultee]	1.2	08 September 2017
Research protocol or project proposal [ADAPT-Sepsis Trial Protocol V1.2 20OCT2017 tracked changes]	1.2	20 October 2017
Summary CV for Chief Investigator (CI) [Paul Dark short CV]	July 2017	03 July 2017

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

17/SC/0434

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'H. Sivey', with a horizontal line drawn through the middle of the letters.

Ms Helen Sivey
REC Manager

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