

Lothian NHS Board

South East Scotland Research  
Ethics Committee 01

Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG

[www.nhslothian.scot.nhs.uk](http://www.nhslothian.scot.nhs.uk)

Date 8 April 2019

Enquiries to : Sandra Wyllie  
Extension: 35473  
Direct Line: 0131 465 5473  
Email: [Sandra.Wyllie@nhslothian.scot.nhs.uk](mailto:Sandra.Wyllie@nhslothian.scot.nhs.uk)

**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.**

08 April 2019

Prof Fang Gao Smith  
Professor of Anaesthesia, Critical Care and Pain  
University of Birmingham  
Birmingham Clinical Trials Unit  
Institute of Applied Health Research  
University of Birmingham  
B15 2TT

Dear Prof Gao Smith

**Study title:** A Randomised Controlled Trial to investigate the effectiveness of Thoracic Epidural and Paravertebral Blockade In reducing Chronic Post- Thoracotomy Pain: 2

**REC reference:** 18/SS/0131

**Protocol number:** RG 17\_255

**Amendment number:** Substantial Amendment 1

**Amendment date:** 25 March 2019

**IRAS project ID:** 248427

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.

The Committee had no ethical concerns regarding this amendment.

### 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		22 March 2019
GP/consultant information sheets or letters	Version 2	04 March 2019
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 1	25 March 2019
Other [Trial Summary]	Version 2	04 March 2019
Other [Audio-recording discussions and interviews PIS]	Version 3	04 March 2019
Participant information sheet (PIS)	Version 3	04 March 2019
Research protocol or project proposal [Tracked Change]	Version 2	04 March 2019
Research protocol or project proposal	Version 2	04 March 2019

### **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**

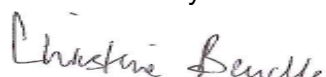
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **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/>

<b>18/SS/0131:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Mrs Christine Beadle**  
**Chair**

E-mail: [sandra.wyllie@nhslothian.scot.nhs.uk](mailto:sandra.wyllie@nhslothian.scot.nhs.uk)

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

*Copy to:*                              *Ben Watkins*

**South East Scotland REC 01**

**Attendance at Sub-Committee of the REC meeting on 01 April 2019**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Christine Beadle	Research Nurse	Yes	(In the Chair)
Ms Sarah Clark	Senior Research Nurse - Critical Care Research Team	Yes	
Dr Eve Miller-Hodges	Specialty Registrar in Renal Medicine	Yes	
Dr Lillian Schweizer	Retired Molecular Geneticist	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Sandra Wyllie	REC Manager