

## South East Scotland REC 01

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27 March 2019

Prof Fang Gao Smith  
Professor of Anaesthesia, Critical Care and Pain  
University of Birmingham  
Birmingham Clinical Trials Unit  
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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:** 18/SS/0131/AM04

**Amendment date:** 25 March 2019

**IRAS project ID:** 248427

Thank you for submitting the above amendment, which was received on 26 March 2019. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

### Documents received

The documents to be reviewed are as follows:

<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)		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

### Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

### **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/SS/0131:**

**Please quote this number on all correspondence**

Yours sincerely



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**REC Manager**

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