

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

South East Scotland REC 01

Waverley Gate
2 - 4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131 465 5473

14 November 2018 (re-issued 15.11.2018)

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:
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REC reference: 18/SS/0131

Protocol number: RG 17_255

IRAS project ID: 248427

Thank you for your letter of 12 November 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 November 2018

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Other [TOPIC 2 Study Audio-recording discussions and interviews PCF Clean]	2.0	12 November 2018
Other [TOPIC2 Healthcare Professional Information Study and Audio-recording Consent Form Clean]	2.0	12 November 2018
Other [Topic2 Audio-recording discussions and interviews PIS]	2.0	12 November 2018
Other [TOPIC2 Cover Letter REC conditions response 12.11.18]	1.0	12 November 2018
Participant information sheet (PIS) [TOPIC2 PIS Clean]	2.0	12 November 2018

Approved documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UMAL insurance letter]		16 July 2018
GP/consultant information sheets or letters [TOPIC2 GP Letter]	1.0	12 September 2018
IRAS Application Form [IRAS Form 13092018]	248427/1248998/37/484	13 September 2018
Letter from funder [TOPIC2 Letter from funder (NIHR)]		23 November 2017
Other [TOPIC 2 QRI - Interview Schedule for Recruiters]	1.0	16 July 2018
Other [TOPIC2 QRI - Interview Schedule for Patients]	1.0	16 July 2018
Other [REC response cover letter 19.10.2018]	1.0	19 October 2018
Other [TOPIC2 Patient Completed Booklet Baseline V1.0a, 29-Oct-2018]	1a	29 October 2018
Other [TOPIC2 Patient Completed Booklet Acute Phase V1.0, 29-Oct-2018]	1.0	29 October 2018
Other [TOPIC2 Patient Completed Booklet 3, 6 and 12 month v1.0, 29-Oct-2018]	1.0	29 October 2018
Other [TOPIC 2 Study Audio-recording discussions and interviews PCF Clean]	2.0	12 November 2018
Other [TOPIC2 Healthcare Professional Information Study and Audio-recording Consent Form Clean]	2.0	12 November 2018
Other [Topic2 Audio-recording discussions and interviews PIS]	2.0	08 November 2018
Other [TOPIC2 Cover Letter REC conditions response 12.11.18]	1.0	12 November 2018
Participant consent form [TOPIC2 ICF]	1.0	12 September 2018
Participant information sheet (PIS) [TOPIC2 PIS Clean]	2.0	12 November 2018
Research protocol or project proposal [TOPIC2 Protocol V1a Clean]	1a	12 October 2018
Summary CV for Chief Investigator (CI) [Prof F Gao Smith CV]	*November*	01 November 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [TOPIC2 Trial Summary]	1.0	04 September 2018

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.

18/SS/0131

Please quote this number on all correspondence

Yours sincerely



Sandra Wyllie
REC Manager

E-mail: sandra.wyllie@nhslothian.scot.nhs.uk

*Copy to: Ben Watkins
Ms Elizabeth Adey, Heart of England NHS Foundation Trust*

*Lead Nation
England: HRA.Approval@nhs.net*