

UNIVERSITY^{OF} BIRMINGHAM

Birmingham Clinical Trials Unit

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22nd March 2019

Dear REC

Full title of study:A Randomised Controlled Trial to investigate the effectiveness of ThOracic
Epidural and Paravertebral Blockade In reducing Chronic Post-
Thoracotomy Pain: 2Short Title:TOPIC2REC reference number:18/SS/0131IRAS project number:248427Chief Investigator:Professor Fang Gao SmithSubstantial Amendment Number:1

Please find enclosed signed notice of substantial amendment form and corresponding amended documents that I am submitting on behalf of the Chief Investigator, Prof. Fang Gao Smith for your review.

If you require any further information please do not hesitate to contact me.

Yours Sincerely,

UNS

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Enc: Notification of Substantial Amendment 1, Protocol V2.0, 04/03/3019 (clean and tracked changes), Trial Summary V2.0, 04/03/2019 (clean and tracked changes), GP Letter V2.0, 04/03/2019 clean and tracked changes), Trial Patient Information Sheet V3.0, 04/03/2019 clean and tracked changes), Audio-recording Discussuins and Interviews Patient Information Sheet V3.0, 04/03/2019 clean and tracked changes)