

Partner Organisations:

Health Research Authority, England

NHS Research Scotland

HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	A Randomised Controlled Trial to investigate the effectiveness of Thoracic Epidural and Paravertebral Blockade In reducing Chronic Post- Thoracotomy Pain: 2 (TOPIC2)
IRAS Project ID:	248427
Sponsor Amendment Notification number:	Non-Substantial Amendment 1
Sponsor Amendment Notification date:	21-Nov-2018
Details of Chief Investigator:	
Name [first name and surname]	Professor Fang Gao Smith
Address:	University of Birmingham
Postcode:	B15 2TT
Contact telephone number:	0121 371 3243
Email address:	f.g.smith@bham.ac.uk
Details of Lead Sponsor:	
Name:	University of Birmingham
Contact email address:	Topic2@trials.bham.ac.uk
Details of Lead Nation:	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	Yes
Name of lead R&D office:	Birmingham Heartlands Hospital

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2. Summary of amendment(s)

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No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>	R&D category of amendment <i>(category A, B, C) For office use only</i>	
		Nation	Sites			
1	<p>Patient completed booklets have been separated out into individual booklets for each time point.</p> <p>Visual Analogue Scale has been changed so the scale is 10cm in length following advice from a pain specialist.</p> <p>Short-Form McGill Pain Questionnaire-2, Hospital Anxiety and Depression Scale have been reformatted so they are the required size as per suppliers requirements for distribution.</p>	<p>England</p> <p>Northern Ireland</p> <p>Scotland</p> <p>Wales</p>	<p>All sites or list affected sites</p> <p>All sites or list affected sites</p> <p>All sites or list affected sites</p> <p>All sites or list affected sites</p>	<p>TOPIC2 Patient Completed Booklet Baseline</p> <p>TOPIC2 Patient Completed Booklet Acute Day 1</p> <p>TOPIC2 Patient Completed Booklet Acute Day 2</p> <p>TOPIC2 Patient Completed Booklet Day 3</p> <p>TOPIC2 Patient Completed Booklet Hospital Discharge</p> <p>TOPIC2 Patient Completed Booklet 3 Month Follow-up</p> <p>TOPIC2 Patient Completed Booklet 6 month Follow-up</p> <p>TOPIC2 Patient Completed Booklet 12 month Follow-up</p>	<p>All V2.0, 16-Nov-2018</p>	

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3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:

Fang Gao Smith

Print name:

FANG GAO SMITH

Date:

16th Nov 2018

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative:

Susan Terbs

Print name:

SUSAN TERBS

Post:

DEPUTY DIRECTOR

Organisation:

BCTU

Date:

16th November 2018