

Jordan Evans (Birmingham Clinical Trials Unit)

From: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>
Sent: 27 November 2018 12:11
To: f.g.smith@bham.ac.uk; TOPIC2@trials.bham.ac.uk; Ben Watkins (Birmingham Clinical Trials Unit)
Cc: elizabeth.adey@heartofengland.nhs.uk
Subject: IRAS 248427. Amendment categorisation and implementation information

Amendment Categorisation and Implementation Information

Dear Prof Gao Smith,

IRAS Project ID:	248427
Short Study Title:	TOPIC 2: Thoracic Epidural and Paravertebral Blocks In reducing CPTP
Date complete amendment submission received:	22 November 2018
Amendment No./ Sponsor Ref:	Non-Substantial Amendment 1
Amendment Date:	21 November 2018
Amendment Type:	Non-substantial
Outcome of HRA and HCRW Assessment	This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.
For NHS/HSC R&D Office information	
Amendment Category	C

Thank you for submitting an amendment to your project. We have now categorised your amendment and please find this, as well as other relevant information, in the table above.

What should I do next?

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment **we will** forward the information to the relevant national coordinating function(s).

You should now inform participating NHS/HSC organisations of the amendment.

- For NHS/HSC organisations in Northern Ireland and/or Scotland this notification should be to the research team at participating NHS/HSC organisations. You do not need to inform the R&D offices, as we have separately made it available via their national coordinating functions.
- For NHS organisations in England and/or Wales, this notification should include the [NHS R&D Office](#), [LCRN](#) (where applicable) as well as the local research team.

When can I implement this amendment?

You may implement this amendment **immediately**. Please note that you may only implement changes described in the amendment notice.

Who should I contact if I have further questions about this amendment?

If you have any questions about this amendment please contact the relevant national coordinating centre for advice:

- England – hra.amendments@nhs.net
- Northern Ireland – research.gateway@hscni.net
- Scotland – nhsq.NRSPCC@nhs.net
- Wales – research-permissions@wales.nhs.uk

Additional information on the management of amendments can be found in the [IRAS guidance](#).

User Feedback

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Please do not hesitate to contact me if you require further information.

Kind regards

Hayley Kevill

Health Research Authority

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E. hra.amendments@nhs.net

W. www.hra.nhs.uk

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