

Jordan Evans (Birmingham Clinical Trials Unit)

From: noreply@harp.org.uk
Sent: 17 April 2019 14:57
To: f.g.smith@bham.ac.uk; TOPIC2@trials.bham.ac.uk
Subject: ?spam? IRAS Project ID 248427. HRA Approval for the Amendment

Dear Prof Gao Smith,

IRAS Project ID:	248427
Short Study Title:	TOPIC 2: Thoracic Epidural and Paravertebral Blocks In reducing CPTP
Amendment No./Sponsor Ref:	Substantial Amendment 1
Amendment Date:	25 March 2019
Amendment Type:	Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the conditions outlined in your categorisation email.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Michael Pate

Approvals specialist

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E. hra.amendments@nhs.net

W. www.hra.nhs.uk

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Dear Prof Gao Smith

IRAS Project ID:	248427
REC Reference:	18/SS/0131
Short Study Title:	TOPIC 2: Thoracic Epidural and Paravertebral Blocks In reducing CPTP
Date complete amendment submission received:	26 March 2019
Sponsor Amendment Reference Number:	Substantial Amendment 1
Sponsor Amendment Date:	25 March 2019
Amendment Type	Substantial
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment is pending - HRA and HCRW Approval for the amendment will be separately confirmed by email.
Implementation date in NHS organisations in England and Wales	35 days from date amendment information together with this email, is supplied to participating organisations (provided HRA and HCRW Approval for the amendment is in place and conditions are met)
Implementation date in NHS/HSC organisations in Northern Ireland, and/or Scotland	01 May 2019 (providing conditions are met)

For NHS/HSC R&D Office information

Amendment Category

A

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?

Please read the information in [IRAS](#), which provides you with information on how and when you can implement your amendment at NHS/HSC sites in each nation, and what actions you should take now.

If you have participating NHS/HSC organisations in any other UK nations please note that **we will** forward the amendment submission to the relevant national coordinating function(s).

If not already provided, please email to us any regulatory approvals (where applicable) once available.

When can I implement this amendment?

You may implement this amendment in line with the information in [IRAS](#). 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 – nhsg.NRSPCC@nhs.net
- Wales – research-permissions@wales.nhs.uk

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

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

Kind regards

Dr Ashley Totenhofer
Technical Assurance Officer
Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E. hra.amendments@nhs.net

W. www.hra.nhs.uk

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