Jordan Evans (Birmingham Clinical Trials Unit)

From: noreply@harp.org.uk
Sent: 21 March 2019 10:33
To: f.g.smith@bham.ac.uk; TOPIC2@trials.bham.ac.uk
Subject: ?spam? 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:	12 March 2019
Amendment No./ Sponsor Ref:	Non-Substantial Amendment 3
Amendment Date:	11 March 2019
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.
Implementation date in NHS organisations in England and/or Wales	35 days from date amendment information together with this email, is supplied to participating organisations **(providing conditions are met).**
Implementation date in NHS/HSC organisations in Northern Ireland and/or Scotland	25 April 2019 **(providing conditions are met)**
For NHS/HSC R&D Office information	
Amendment Category	**B**

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.

Information relating to the addition of new sites

This amendment also adds new participating NHS/HSC organisations to the study. The 35 day implementation date does not apply to the new sites. Please set up new sites as detailed below (as processes change from time to time, we recommend that you refer to the most up to date guidance about site set up, found within IRAS).

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

For new sites in Northern Ireland and/or Scotland:	Please start to set up your new sites. Sites may not open until NHS/HSC management permission is in place.
For new sites in England and/or Wales:	For studies which already have HRA and HCRW Approval: **This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further**. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable). For studies which do not yet have HRA and HCRW Approval: **HRA and HCRW Approval for the initial application is pending.** You can start the process of setting up the new site but cannot open the study at the site until HRA and HCRW Approval is in place and the site has confirmed capacity and capability (where applicable). For studies with HRA Approval adding Welsh NHS organisations for the first time. Please take this email to confirm your **original HRA Approval letter is now extended to cover NHS organisations in Wales. You now have HRA and HCRW Approval.** Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).

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.

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

Kind regards

Hayley Kevill

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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