Jordan Evans (Birmingham Clinical Trials Unit)

From: noreply@harp.org.uk
Sent: 08 February 2019 13:08
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: ?spam? IRAS PROJECT ID 248427, REC Reference 18/SS/0131 : Amendment acknowledgement and implementation information

New Site Amendment, 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:	04 February 2019
Sponsor Amendment Reference Number:	Non-Substantial Amendment 2
Sponsor Amendment Date:	30 January 2019
Amendment Type:	Non-substantial
For new sites in Northern Ireland and/or Scotland:	Please start to set up your new sites. Sites may not open until NHS 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).

Thank you for submitting an amendment to add one or more new sites to your project. This amendment relates solely to the addition of **new sites**.

What should I do next?

Please set up the new site(s) as per the guidance found within IRAS. **Please note** that processes change from time to time so please use the most up to date guidance about site set up.

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).

If you have listed new sites in any other UK nations **we will** forward the information to the national coordinating function(s) for nations where the new site(s) are being added. In Northern Ireland and Scotland, NHS/HSC R&D offices will be informed by the national coordinating function.

Note: 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.

User Feedback

We are 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 amendment procedure. If you wish to make your views known please use the feedback form available at: 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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