

IRAS 186097 Confirmation of Amendment Categorisation as Category A
amendments hra (HEALTH RESEARCH AUTHORITY) Wickham Alex (IMPERIAL COLLEGE
HEALTHCARE NHS TRUST);Allen Lauren (HEALTH RESEARCH
AUTHORITY);Cameron.Berg@uclh.nhs.uk;Martin, Daniel <daniel.martin@ucl.ac.uk>;info@i-
hype.org;'RandD@uclh.nhs.uk';

Dear Alex,

IRAS Project ID:	186097
Short Study Title:	Intraoperative Hypotension in Elder Patients (IHypE)
Date complete amendment submission received:	31/10/2016
Amendment No./ Sponsor Ref:	Non Substantial Amendment 1 - 31/10/2016
Amendment Date:	31/10/2016
Amendment Type:	Non-substantial

Thank you for submitting the above referenced amendment. In line with the [UK Process for Handling UK Study Amendments](#) I can confirm that this amendment has been categorised as:

- **Category A** - An amendment that has implications for, or affects, ALL participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the three conditions below, you will be able to implement the amendment at your participating NHS organisations in England **35 days after you notify them of the amendment**. A template email to notify participating NHS organisations in England is provided [here](#).

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion where applicable, (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England, plus to local research teams at any participating NHS organisations in Northern Ireland, Scotland or Wales*.
- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.

Note: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below) after the 35 days have passed, you may then immediately implement this amendment at all participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study.

There is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

* Where the study involves NHS organisations in Northern Ireland, Scotland or Wales, the HRA will forward regulatory approvals to the relevant national coordinating function to distribute to their research management support offices.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the

categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;

- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

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

Kind regards

Jade

Jade Robinson | Amendment Coordinator – North East REC Centre
Health Research Authority
Room 001. Jarrow Business Centre, Rolling Mill, Jarrow, Tyne & Wear


If you have any queries please email the address below:

E: hra.amendments@nhs.net | T: 0207 104 8089

www.hra.nhs.uk

IMPORTANT – [Click here](#) for details of significant changes to the REC booking and submission process
The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

If your email is regarding a formal request for information under the Freedom of Information Act, please resend to HRA.FOI@nhs.net to ensure it is dealt with promptly

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