From: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)< hra.amendments@nhs.net>
Sent: 30 January 2017 16:36
To: Ramani Moonesinghe
Cc: Perioperative Quality Improvement Programme; Duncan Wagstaff; MOONESINGHE, Ramani (NHS ENGLAND)
Subject: RE: IRAS 215928. Confirmation of amendment assessment outcome

Dear Dr Moonesinghe,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

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

Yours sincerely,
Simon

Simon Connolly | Senior Assessor
Health Research Authority
Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
E: simon.connolly1@nhs.net | T: 020 7972 2552

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For more information on the HRA Approval process Click here

From: SURREY, NRESCommittee.SECoast- (HEALTH RESEARCH AUTHORITY)
Sent: 23 December 2016 11:37
To: 'S.R. Moonesinghe'
Cc: Perioperative Quality Improvement Programme; Duncan Wagstaff; MOONESINGHE, Ramani (NHS ENGLAND); 'research.amendments@hscni.net'; 'NRSPCC NHSG (NHS GRAMPIAN)'; 'Research-permissions@wales.nhs.uk'
Subject: IRAS 215928. Confirmation of REC Validation and Categorisation of Amendment

Dear Dr Moonesinghe

IRAS Project ID:	**215928**
REC Reference:	**16/LO/1827**
Short Study Title:	**Perioperative Quality Improvement Programme: Patient Study**
Date complete amendment submission	**20 December 2016**

received:	
Amendment No./ Sponsor Ref:	**2.0 01/12/16**
Amendment Date:	**19 December 2016**
Amendment Type:	**Substantial**

Thank you for submitting the above referenced amendment. I am pleased to confirm that this amendment has been submitted to the REC for ethical review. Please find attached a copy of the validation letter.

Categorisation of 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.

Subject to the same three conditions, you will be able to implement your amendment at participating NHS organisations in Northern Ireland, Scotland or Wales on 24 January 2017.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion, (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment). 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, this includes confirmation that the amendment has been granted HRA Approval) 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.

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

Kind regards

Wai Yeung

Mr Wai Yeung | Research Ethics Committee Assistant – 020 71048053
Mr Rajat Khullar | Research Ethics Committee Manager – 020 71048033
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