From: nrescommittee.london-queensquare@nhs.net  noreply@harp.org.uk
Subject: IRAS 234524. Amendment categorisation and implementation information
Date: 28 January 2020 at 17:07
To: ramani.moonesinghe@ucl.ac.uk, uclh.randd@nhs.net, semerton@nhs.net
Cc: nhsg.nrspcc@nhs.net, research.amendments@hscni.net, HCRW.amendments@wales.nhs.uk, a.sogbodjor@ucl.ac.uk

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**Amendment Categorisation and Implementation Information**

Dear Prof Moonesinghe

<table>
<thead>
<tr>
<th>IRAS Project ID:</th>
<th>234524</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC Reference:</td>
<td>19/LO/0267</td>
</tr>
<tr>
<td>Short Study Title:</td>
<td>Children's Acute Surgical Abdomen Programme: CASAP v1.0</td>
</tr>
<tr>
<td>Date complete amendment submission received:</td>
<td>29/11/2019</td>
</tr>
<tr>
<td>Sponsor Amendment Reference Number:</td>
<td>Non-substantial Amendment 6</td>
</tr>
<tr>
<td>Sponsor Amendment Date:</td>
<td>29 November 2019</td>
</tr>
<tr>
<td>Amendment Type</td>
<td>Non Substantial</td>
</tr>
<tr>
<td>Outcome of HRA and HCRW Assessment</td>
<td>This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.</td>
</tr>
<tr>
<td>Implementation date of Category B elements in NHS organisations in England and/or Wales</td>
<td>35 days from date amendment information together with this email, is supplied to participating organisations (providing conditions are met)</td>
</tr>
</tbody>
</table>

For NHS/HSC R&D Office information

Amendment Category: B/C

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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.

Please note that elements of this amendment have been categorised as Category B (where specific sites are impacted and should be given time to consider its implementation) and elements as Category C (where no sites are impacted and you can implement as soon as all regulatory approvals are in place). You should therefore read the below instructions carefully in order to implement the amendments appropriately.

Please note that you may only implement changes described in the amendment notice.

What should I do now and when can I implement the Category B elements of this amendment?
The category B elements of this amendment are regarding a change of PI at one of the sites in England.

Please read the information in IRAS, which provides you with information on how and when you can implement the category B elements of 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 that are affected by this amendment please note that we will forward the amendment submission to the relevant national coordinating function(s).

What should I do now and when can I implement the Category C elements of this amendment?

The remainder of this amendment has been categorised as Category C. You should follow the information below in order to implement this change at all participating NHS/HSC organisations.

You should now inform participating NHS/HSC organisations of the amendment.

- For NHS/HSC organisations in Northern Ireland and/or Scotland this notification should be to the research team at participating NHS/HSC organisations. You do not need to inform the R&D offices, as we have separately made it available via their national coordinating functions.
- For NHS organisations in England and/or Wales, this notification should include the NHS R&D Office, LCRN (where applicable) as well as the local research team.

You may implement the category C elements of this amendment immediately.

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 – HCRW.amendments@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

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