Boota, Nafisa

From: NRESCommittee.EastofEngland-Essex@nhs.net <noreply@harp.org.uk>
Sent: 04 January 2018 09:37
To: tony.whitehouse@uhb.nhs.uk; STRESS-L, resource
Cc: research.amendments@hscni.net; research-permissions@wales.nhs.uk; chris.counsell@uhb.nhs.uk
Subject: IRAS 213669. Amendment confirmation of REC Validation, categorisation and implementation information
Attachments: 2018.01.04 17-0368 New Site PI Favourable Opinion.pdf; Notification of SA Form_22 Dec 2017.pdf; REC Cover Letter_22 Dec 2017.docx

Amendment Confirmation of REC Favourable Opinion Categorisation and Implementation Information

Dear Tony Whitehouse,

Thank you for submitting an amendment to your project. Please find attached a copy of the REC Favourable Opinion for the submitted amendment.

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment we will forward the information to the relevant national coordinating function(s).

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

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with participating NHS organisations in England that are affected by this amendment. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the HRA website.
2. You do not need to share with participating NHS organisations in England that are not affected by this amendment.
3. The participating NHS organisations in England that are affected by this amendment should prepare to implement.
4. You may implement your amendment at affected participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment**. If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.
5. You may not implement the amendment at any participating NHS organisations in England that request additional time to assess, until it confirms that it has concluded its assessment.
6. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

Information Specific to Participating NHS/HSC Organisations in Northern Ireland, Scotland and/or Wales

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with the research teams at participating NHS/HSC organisations in Northern Ireland, Scotland and/or Wales that are affected by this amendment.
2. You do not need to include the R&D offices in this correspondence, as we have separately made it available via their national coordinating functions.
3. You do not need to share with participating NHS/HSC organisations in Northern Ireland, Scotland and/or Wales that are not affected by this amendment.
4. The participating NHS/HSC organisations that are affected by this amendment should prepare to implement.
5. You may implement your amendment at affected NHS/HSC participating organisations in Northern Ireland, Scotland and/or Wales on the date provided in the table below (or as soon as the participating NHS/HSC organisation confirm that you may implement, if sooner), so long as you have a REC Favourable Opinion and any other applicable regulatory approvals (e.g. from the MHRA) for your amendment by this date. **NHS/HSC organisations do not have to confirm they are happy with the amendment.** If you receive any applicable regulatory approval subsequent to this date, you may implement once you receive the last relevant approval. Please note that HRA Approval is not required to implement this amendment outside of England.
6. You may not implement the amendments at any participating NHS/HSC organisation that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS/HSC organisation that declines to implement the amendment.

IRAS Project ID:	213669
Short Study Title:	Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)
Date complete amendment submission received:	
Amendment No./ Sponsor Ref:	SA 2017/12/22
Amendment Date:	22 December 2017
Amendment Type:	Substantial
Outcome of HRA Assessment	**This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.**
Implementation date in NHS organisations in England	35 days from date amendment information together with this email, is supplied to participating organisations **(provided HRA Approval for the amendment is in place and conditions above are met)**
Implementation date in NHS/HSC organisations in Northern Ireland, Scotland and/or Wales	**26/01/2018 (providing conditions above are met)**
For NHS/HSC R&D Office information	
Amendment Category	**B**

Information relating to the addition of new sites

This amendment also adds new participating NHS/HSC organisations to the study.

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).

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).

For new sites in Northern Ireland, Scotland and/or Wales only:	Please start to set up your new sites. Sites may not open until a REC Favourable Opinion and NHS/HSC management permission is in place.
For new sites in England only:	For studies which already have HRA Approval:**This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA**. 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 Approval: **HRA Approval is pending** and you will receive confirmation of HRA Approval. You can start the process of setting up the new site but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net.

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant national coordinating function.

Additional information on the management of amendments can be found in the IRAS guidance.

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

Kind regards

Teagan Allen
REC Assistant
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E.hra.amendments@nhs.net
W. www.hra.nhs.uk

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