Boota, Nafisa

From: NRESCommittee.EastofEngland-Essex@nhs.net <noreply@harp.org.uk>
Sent: 09 February 2018 14:52
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 categorisation and implementation information
Attachments: 213669 17-EE-0368 SA2 Confirmation of opinion 09Feb18.rtf

Amendment Categorisation and Implementation Information

Dear Mr Whitehouse

Thank you for submitting an amendment to your project.

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?

Please ensure that you have sent this amendment to the Research Ethics Committee (REC) from which you received a favourable opinion for your project, as well as to any other regulatory body as appropriate.

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

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 affected by this amendment should prepare to implement.
4. In parallel to the REC review, an assessment against HRA standards will take place.
5. Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.

6. 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.
7. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
8. 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 organisations 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 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**
REC Reference:	**17/EE/0368**
Short Study Title:	**Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)**
Date complete amendment submission received:	**08.02.2018**
Sponsor Amendment Reference Number:	**2**
Sponsor Amendment Date:	**30 January 2018**
Amendment Type	Substantial
Outcome of HRA Assessment	**HRA Approval for the amendment is pending** - the HRA will separately confirm HRA Approval for the amendment by email.

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)**
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:	**HRA Approval for the amendment is pending**, You can start the process of setting up the new site but cannot open the study at the site until HRA Approval for the amendment is in place and the site has confirmed capacity and capability (where applicable).

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

Silje Dybing
REC assistant

Health Research Authority
Ground Floor | Skipton House | 80 London Road | London | SE1 6LH
E.hra.amendments@nhs.net
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.