

## Flawn, Maddy

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**From:** NRESCCommittee.EastofEngland-Essex@nhs.net <noreply@harp.org.uk>  
**Sent:** 11 July 2019 12:34  
**To:** tony.whitehouse@uhb.nhs.uk; STRESS-L, resource  
**Cc:** research.amendments@hscni.net; research-permissions@wales.nhs.uk  
**Subject:** 17/EE/0368 IRAS 213669. Amendment categorisation and implementation information  
**Attachments:** 17-EE-0368 IRAS 213669 Acknowledgement of a Valid Notice of a Substantial Amendment 11.07.19.pdf  
**Categories:** Emma to action

### Amendment Categorisation and Implementation Information

Dear Whitehouse

<b>IRAS Project ID:</b>	<b>213669</b>
<b>REC Reference:</b>	<b>17/EE/0368</b>
<b>Short Study Title:</b>	<b>Study into the Reversal of Septic Shock with Landiolol (Beta Blockade)</b>
<b><u>Date complete amendment submission received:</u></b>	<b><u>08 July 2019</u></b>
<b>Sponsor Amendment Reference Number:</b>	<b>Notice of Substantial Amendment 10</b>
<b>Sponsor Amendment Date:</b>	<b>03 July 2019</b>
<b>Amendment Type</b>	Substantial
<b>Outcome of HRA and HCRW Assessment</b>	<b>HRA and HCRW Approval for the amendment is pending</b> - HRA and HCRW Approval for the amendment will be separately confirmed by email.
<b>Implementation date in NHS organisations in England and Wales</b>	35 days from date amendment information together with this email, is supplied to participating organisations ( <b>provided HRA and HCRW Approval for the amendment is in place and conditions are met</b> )

<b>Implementation date in NHS/HSC organisations in Northern Ireland, and/or Scotland</b>	<b>12 August 2019 (providing conditions are met)</b>
For NHS/HSC R&D Office information	
<b>Amendment Category</b>	<b>A</b>

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.

### What should I do next?

Please read the information in [IRAS](#), which provides you with information on how and when you can implement 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 please note that **we will** forward the amendment submission to the relevant national coordinating function(s).

If not already provided, please email to us any regulatory approvals (where applicable) once available.

### When can I implement this amendment?

You may implement this amendment in line with the information in [IRAS](#). Please note that you may only implement changes described in the amendment notice.

### 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](mailto:hra.amendments@nhs.net)
- Northern Ireland – [research.gateway@hscni.net](mailto:research.gateway@hscni.net)
- Scotland – [nhsq.NRSPCC@nhs.net](mailto:nhsq.NRSPCC@nhs.net)
- Wales – [HCRW.amendments@wales.nhs.uk](mailto:HCRW.amendments@wales.nhs.uk)

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

**Miss Katie Arnold**

**Health Research Authority**

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

**E.** [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)

**W.** [www.hra.nhs.uk](http://www.hra.nhs.uk)

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