

**From:** Essex.REC@hra.nhs.uk <noreply@harp.org.uk>  
**Sent:** 24 September 2020 14:50  
**To:** Perkins, Gavin; Sponsorship Resource; SOStrial, Resource  
**Subject:** IRAS 260350. Amendment categorisation and implementation information  
**Attachments:** Confirmation of Opinion Letter 19.EE.0228 SA 05 Amendment .docx

## Amendment Categorisation and Implementation Information

Dear Professor Perkins

<b>IRAS Project ID:</b>	<b>260350</b>
<b>REC Reference:</b>	<b>19/EE/0228</b>
<b>Short Study Title:</b>	<b>SOS trial: Hyperosmolar therapy in traumatic brain injury</b>
<b>Date complete amendment submission received:</b>	<b>06 August 2020</b>
<b>Sponsor Amendment Reference Number:</b>	<b>SA 05</b>
<b>Sponsor Amendment Date:</b>	<b>14 July 2020</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 Approval for the amendment will be separately confirmed by email.
<b>Implementation date in NHS organisations in England and/or 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>24 September 2020 (providing conditions are met)</b>
For NHS/HSC R&D Office information	
<b>Amendment Category</b>	<b>B</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 – [amendments@hra.nhs.uk](mailto:amendments@hra.nhs.uk)
- 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

**Noreen Ryan**

**Health Research Authority**

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

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

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

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