

Hamilton, Louisa

From: Essex.REC@hra.nhs.uk <noreply@harp.org.uk>
Sent: 28 May 2020 14:48
To: Perkins, Gavin; Sponsorship Resource
Cc: nhsg.nrspcc@nhs.net; research.amendments@hscni.net; research-permissions@wales.nhs.uk; SOStrial, Resource
Subject: IRAS PROJECT ID 260350, REC Reference 19/EE/0228 Confirmation of favourable opinion for substantial amendment
Attachments: 260350 19-0228 Substantial Amendment 4 Favourable Opinion.pdf

Dear Professor Perkins

IRAS project ID:	260350
REC reference:	19/EE/0228
Short Study title:	SOS trial: Hyperosmolar therapy in traumatic brain injury
Date complete amendment submission received:	02 April 2020
Amendment No./ Sponsor Ref:	Substantial Amendment 4
Amendment Date:	02 April 2020
Amendment Type:	Substantial
Outcome of HRA Assessment	This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment.** No separate notice of HRA and HCRW Approval will be issued. You should implement this amendment at NHS organisations in England and/or Wales, in line with the conditions outlined in your categorisation email.

- If this study has HRA and HCRW Approval, this amendment may be implemented at participating NHS organisations in England and/or Wales once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England and/or Wales that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England and/or Wales that do not have NHS Permission, these sites should be covered by HRA and HCRW Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA and HCRW Approval, I have passed your amendment to my colleague and you should receive separate notification that the study has received HRA and HCRW Approval, incorporating approval for this amendment.

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/>.

If you require further information, please contact amendments@hra.nhs.uk

19/EE/0228/AM05 Please quote this number on all correspondence

Kind regards

Vic Strutt

Approvals Officer

Health Research Authority

The Old Chapel | Royal Standard Place | Nottingham HRA1 Meeting Room | NG1 6FS

T. 0207 1048106

E. Essex.REC@hra.nhs.uk

W. www.hra.nhs.uk

Sign up to receive our newsletter [HRA Latest](#).