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From: Essex.REC@hra.nhs.uk

Mail received time: Fri, 15 Sep 2023 13:14:59

Sent: 15 September 2023 14:14:59

To: [Perkins, Gavin Sponsorship Resource](#) [SOStrial, Resource](#)

Subject: IRAS PROJECT ID 260350, REC Reference 19/EE/0228 Confirmation of favourable opinion for substantial amendment

Importance: Normal

Sensitivity: None

Attachments:

[IRAS Project ID 260350 - Favourable_opinion_of_a_substantial_amendment.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:	30 August 2023
Amendment No./ Sponsor Ref:	SA012
Amendment Date:	11 August 2023
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 confirmation of HRA and HCRW Approval will be issued.

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 me.

Kind regards

Richard Reed

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