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From: NRESCCommittee.EastofEngland-Essex@nhs.net <noreply@harp.org.uk>
Sent: 11 November 2019 14:30
To: Perkins, Gavin; Sponsorship Resource
Cc: nhsg.nrspcc@nhs.net; research-permissions@wales.nhs.uk; SOS trial, Resource
Subject: IRAS PROJECT ID 260350, REC Reference 19/EE/0228 Confirmation of favourable opinion for substantial amendment
Attachments: 19-EE-0228 IRAS 260350 Favourable Opinion of a Substantial Amendment 11.11.2019.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:	01 November 2019
Amendment No./ Sponsor Ref:	Substantial Amendment 01
Amendment Date:	29 October 2019
Amendment Type:	Substantial
Outcome of HRA Assessment	HRA and HCRW Approval for the amendment is pending – HRA and HCRW Approval for the amendment will be separately confirmed by email.

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, HRA and HCRW Approval for this amendment is pending. HRA and HCRW Approval for the amendment will be separately confirmed by email. You should not implement this amendment at participating NHS organisations in England and/or Wales until HRA and HCRW Approval is issued, and the conditions detailed in the categorisation email have been met.

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

19/EE/0228/AM01 Please quote this number on all correspondence

Kind regards

Katie Arnold
Approvals Administrator
Health Research Authority

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