

From: NRESCCommittee.EastofEngland-Essex@nhs.net <noreply@harp.org.uk>
Sent: 07 January 2020 14:54
To: Perkins, Gavin; Sponsorship Resource
Cc: nhsg.nrspcc@nhs.net; research.amendments@hscni.net;
HCRW.amendments@wales.nhs.uk; Hamilton, Louisa
Subject: IRAS PROJECT ID 260350, REC Reference 19/EE/0228 : Amendment
acknowledgement, REC FO, and implementation information
Attachments: 19-EE-0228 IRAS 260350 Confirmation of Opinion 07.01.20.pdf

New Site Amendment, REC Favourable Opinion and Implementation Information

Dear Professor Perkins,

IRAS Project ID:	260350
Short Study Title:	SOS trial: Hyperosmolar therapy in traumatic brain injury
Date complete amendment submission received:	06 January 2020
Sponsor Amendment Reference Number:	Substantial Amendment 02
Sponsor Amendment Date:	06 January 2020
Amendment Type:	Substantial
For new sites in Northern Ireland and/or Scotland:	Please start to set up your new sites. Sites may not open until a REC Favourable Opinion and NHS permission is in place.
For new sites in England and/or Wales:	<p><u>For studies which already have HRA and HCRW Approval: This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.</u> Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).</p> <p><u>For studies which do not yet have HRA and HCRW Approval: HRA and HCRW Approval for the initial application is pending.</u> You can start the process of setting up the new site but cannot open the study at the site until HRA and HCRW Approval is in place and the site has confirmed capacity and capability (where applicable).</p> <p><u>For studies with HRA Approval adding Welsh NHS organisations for the first time.</u> Please take this email to confirm your original HRA Approval letter is now extended to cover NHS organisations in Wales. You now have HRA and HCRW Approval. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).</p>

Thank you for submitting an amendment to your project. This amendment relates solely to the addition of **new sites**.

Please also find attached the letter confirming that the favourable ethical opinion has been extended to the new site.

What should I do next?

Please set up the new site(s) as per the guidance found within [IRAS](#). **Please note** that processes change from time to time so please use the most up to date guidance about site set up.

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

If you have listed new sites in any other UK nations **we will** forward the information to the national coordinating function(s) for nations where the new site(s) are being added. In Northern Ireland and Scotland, NHS/HSC R&D offices will be informed by the national coordinating function.

Note: 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
- Northern Ireland – research.gateway@hscni.net
- Scotland – nhsq.NRSPCC@nhs.net
- Wales – HCRW.amendments@wales.nhs.uk

Additional information on the management of amendments can be found in the [IRAS guidance](#).

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/>.

Please do not hesitate to contact me if you require further information.

Kind regards

Miss Katie Arnold

Approvals Administrator

Health Research Authority

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

E. hra.amendments@nhs.net

W. www.hra.nhs.uk

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