

East of England - Essex Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

22 March 2023

Mrs Jane Prewett
University of Warwick, Research & Impact Services
University House, Kirby Corner Road
Coventry
CV4 8UW

Dear Mrs Prewett

Study title:	Sugar or Salt (SOS) trial: Hyperosmolar therapy in traumatic brain injury
REC reference:	19/EE/0228
Protocol number:	SC.14/18-19
EudraCT number:	2019-001688-66
Amendment number:	SA 11
Amendment date:	21 February 2023
IRAS project ID:	260350

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [Amendment_Tool_v1_6_06Dec21_SA11]	1.0	21 February 2023
Cover Letter [REC Cover Letter - SA11]	1.0	06 March 2023
Cover Letter [SOS_VoucherOnlyCoverLetter_v1.0_23Feb2023]	1.0	23 February 2023
Other [Summary of changes_SA11]	1.0	06 March 2023
Other [SOS follow up reminders V2.0_16Feb2023]	2.0	16 February 2023
Other [SOS follow up reminders V2.0_16Feb2023_tracked]	2.0	16 February 2023
Participant consent form [SOS Consent form - ProfLR pre-enrolment v3.0_16Feb2023]	3.0	16 February 2023
Participant consent form [SOS Consent form - ProfLR pre-enrolment v3.0_16Feb2023_tracked]	3.0	16 February 2023
Participant consent form [SOS Consent form - ProfLR post-enrolment v4.0_16Feb2023]	4.0	16 February 2023
Participant consent form [SOS Consent form - ProfLR post-enrolment v4.0_16Feb2023_tracked]	4.0	16 February 2023
Participant consent form [SOS Consent form - PerLR pre-enrolment v4.0_16Feb2023_tracked]	4.0	16 February 2023
Participant consent form [SOS Consent form - PerLR pre-enrolment v4.0_16Feb2023]	4.0	16 February 2023
Participant consent form [SOS Consent form - PerLR post-enrolment v4.0_16Feb2023]	4.0	16 February 2023
Participant consent form [SOS Consent form - PerLR post-enrolment v4.0_16Feb2023_tracked]	4.0	16 February 2023
Participant consent form [SOS Consent form - Patient post-enrolment v4.0_16Feb2023]	4.0	16 February 2023
Participant consent form [SOS Consent form - Patient post-enrolment v4.0_16Feb2023_tracked]	4.0	16 February 2023
Participant information sheet (PIS) [SOS ProfL Pre Enrolment Information Sheet V6.0_16Feb2023]	6.0	16 February 2023
Participant information sheet (PIS) [SOS ProfL Post Enrolment Information Sheet V6.0_16Feb2023]	6.0	16 February 2023
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet V7.0_16Feb2023]	7.0	16 February 2023
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet V7.0_16Feb2023]	7.0	16 February 2023
Participant information sheet (PIS) [SOS_PatientInformationSheet_v7.0_16Feb2023]	7.0	16 February 2023
Participant information sheet (PIS) [SOS ProfL Post Enrolment Information Sheet V6.0_16Feb2023_tracked]	6.0	16 February 2023
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet V7.0_16Feb2023_tracked]	7.0	16 February 2023
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet V7.0_16Feb2023_tracked]	7.0	16 February 2023
Participant information sheet (PIS) [SOS_PatientInformationSheet_v7.0_16Feb2023_tracked]	7.0	16 February 2023
Participant information sheet (PIS) [SOS ProfL Pre Enrolment Information Sheet V6.0_16Feb2023_tracked]	6.0	16 February 2023
Research protocol or project proposal [SOS_Protocol_v7.0_16Feb2023]	7.0	16 February 2023
Research protocol or project proposal [SOS_Protocol_v7.0_16Feb2023_tracked]	7.0	16 February 2023
Validated questionnaire [SOS_6 month electronic questionnaire_v1.0_07Feb2023]	1.0	07 February 2023

Validated questionnaire [SOS_12 month electronic questionnaire_v1.0_07Feb2023]	1.0	07 February 2023
Validated questionnaire [SOS 6 month shortened questionnaire_v1.0_18Oct2022]	1.0	18 October 2022
Validated questionnaire [SOS 12 month shortened questionnaire_v1.0_18Oct2022]	1.0	18 October 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 260350:	Please quote this number on all correspondence
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Yours sincerely



PP

Miss Suzanne Cross
Chair

E-mail: Essex.REC@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Professor Gavin Perkins, Heartlands Hospital Confidentiality Advise Team

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Rachael Bass	Assistant Psychologist	Yes	
Miss Suzanne Cross (Chair)	Retired Deputy Corporate Secretary	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Tracy Hamrang	Approvals Administrator
Dr Mark Whiting	Consultant Nurse, Children's Specialist Services