

**East of England - Essex Research Ethics Committee**

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

**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.**

29 April 2022

Professor Gavin Perkins  
Heartlands Hospital  
Bordesley Green East  
Birmingham  
B9 5SS

Dear Professor Perkins

<b>Study title:</b>	<b>Sugar or Salt (SOS) trial: Hyperosmolar therapy in traumatic brain injury</b>
<b>REC reference:</b>	<b>19/EE/0228</b>
<b>Protocol number:</b>	<b>SC.14/18-19</b>
<b>EudraCT number:</b>	<b>2019-001688-66</b>
<b>Amendment number:</b>	<b>SA 08</b>
<b>Amendment date:</b>	<b>11 April 2022</b>
<b>IRAS project ID:</b>	<b>260350</b>

The above amendment was reviewed 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 [260350_SA 08_Amendment tool]	1.0	11 April 2022
Cover Letter [REC Cover Letter - SA08]	1.0	20 April 2022
Covering letter on headed paper [SOS_QuestionnaireCoverLetter_v2.0_12Apr22]	2.0	12 April 2022
Covering letter on headed paper [SOS_QuestionnaireCoverLetter_v2.0_12Apr22_tracked]	2.0	12 April 2022
Other [Summary of changes_SA08]	1.0	20 April 2022
Participant information sheet (PIS) [SOS ProfLR Pre Enrolment Information Sheet V5.0_11Apr22_tracked]	5.0	11 April 2022
Participant information sheet (PIS) [SOS ProfLR Pre Enrolment Information Sheet V5.0_11Apr22]	5.0	11 April 2022
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet V6.0_11Apr22_tracked]	6.0	11 April 2022
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet V6.0_11Apr22]	6.0	11 April 2022
Participant information sheet (PIS) [SOS_PatientInformationSheet_v6.0_11Apr22]	6.0	11 April 2022
Participant information sheet (PIS) [SOS ProfLR Post Enrolment Information Sheet V5.0_11Apr22]	5.0	11 April 2022
Participant information sheet (PIS) [SOS ProfLR Post Enrolment Information Sheet V5.0_11Apr22_tracked]	5.0	11 April 2022
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet V6.0_11Apr22]	6.0	11 April 2022
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet V6.0_11Apr22_tracked]	6.0	11 April 2022
Participant information sheet (PIS) [SOS_PatientInformationSheet_v6.0_11Apr22_tracked]	6.0	11 April 2022
Research protocol or project proposal [SOS_Protocol_v5.0_11Apr2022]	5.0	11 April 2022
Research protocol or project proposal [SOS_Protocol_v5.0_11Apr2022_tracked]	5.0	11 April 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/>

<b>IRAS Project ID - 260350:</b>
----------------------------------

<b>Please quote this number on all correspondence</b>
-------------------------------------------------------

Yours sincerely

PP



Tracy Hamrang

**Dr Niki Bannister**  
**Chair**

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

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

*Copy to:                              Mrs Jane Prewett 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>
Dr Niki Bannister (Chair)	Retired Hospital Doctor	Yes	
Mr Michael Tydeman	Retired Consultant in Drug Development	Yes	

### **Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Claire Adams	Registered Nurse
Ms Tracy Hamrang	Approvals Administrator