

**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.**

03 December 2021

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 07</b>
<b>Amendment date:</b>	<b>29 October 2021</b>
<b>IRAS project ID:</b>	<b>260350</b>

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 SA07]	1.0	29 October 2021
Cover Letter [Cover letter]	1.0	08 October 2021
Other [SOS Questionnaire cover letter]	1.0	26 October 2021
Other [SOS Unreturned questionnaire cover letter]	1.0	26 October 2021
Other [Summary of changes]	1.0	08 November 2021
Participant consent form [SOS Consent form - Patient post-enrolment]	3.0	26 October 2021
Participant consent form [SOS Consent form - Patient post-enrolment_tracked]	3.0	26 October 2021
Participant consent form [SOS Consent form - PerLR post-enrolment]	3.0	26 October 2021
Participant consent form [SOS Consent form - PerLR post-enrolment_tracked]	3.0	26 October 2021
Participant consent form [SOS Consent form - PerLR pre-enrolment]	3.0	26 October 2021
Participant consent form [SOS Consent form - PerLR pre-enrolment_tracked]	3.0	26 October 2021
Participant consent form [SOS Consent form - ProfLR post-enrolment]	3.0	26 October 2021
Participant consent form [SOS Consent form - ProfLR post-enrolment_tracked]	3.0	26 October 2021
Participant consent form [SOS Consent form - ProfLR pre-enrolment]	2.0	26 October 2021
Participant consent form [SOS Consent form - ProfLR pre-enrolment_tracked]	2.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - PerLR post-enrolment]	5.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - PerLR post-enrolment_tracked]	5.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - PerLR pre-enrolment]	5.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - PerLR pre-enrolment_tracked]	5.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - ProfLR post-enrolment]	4.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - ProfLR post-enrolment_tracked]	4.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - ProfLR pre-enrolment]	4.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - ProfLR pre-enrolment_tracked]	4.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - Patient]	5.0	26 October 2021
Participant information sheet (PIS) [SOS Information sheet - Patient_tracked]	5.0	26 October 2021
Research protocol or project proposal [SOS Protocol]	4.0	26 October 2021
Research protocol or project proposal [SOS Protocol_tracked]	4.0	26 October 2021
Summary of product characteristics (SmPC) [SmPC Mannitol 15%_Baxter]	1.0	13 March 2018
Validated questionnaire [SOS 3 month questionnaire]	2.0	26 October 2021
Validated questionnaire [SOS 3 month questionnaire_tracked]	2.0	26 October 2021

Validated questionnaire [SOS 6 month questionnaire]	2.0	26 October 2021
Validated questionnaire [SOS 6 month questionnaire_tracked]	2.0	26 October 2021
Validated questionnaire [SOS 12 month questionnaire]	2.0	26 October 2021
Validated questionnaire [SOS 12 month questionnaire_tracked]	2.0	26 October 2021

## 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**

Yours sincerely

PP



Tracy Hamrang

**Dr Gerry Kamstra**  
**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 PrewettConfidentiality 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 Gerry Kamstra ( Chair)	Retired Solicitor	Yes	
Dr Nkiruka Umaru	Pharmacist	Yes	

### **Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Tracy Hamrang	Approvals Administrator