

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

2 Redman Place  
London  
EC20 1 JQ

15 September 2023

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>SA012</b>
<b>Amendment date:</b>	<b>11 August 2023</b>
<b>IRAS project ID:</b>	<b>260350</b>

The above amendment was reviewed at the meeting of the Sub-Committee held on 18 September 2023 via 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 SA12]	1	11 August 2023
Cover Letter [Cover Letter]	1	15 August 2023

Other [Summary of changes]	1	03 August 2023
Other [SOS follow up reminders]	4	03 August 2023
Other [SOS follow up reminders tracked]	4	03 August 2023
Other [SOS Voucher Only Cover Letter]	2	20 July 2023
Other [SOS Voucher Only Cover Letter tracked]	2	20 July 2023
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet]	8	08 August 2023
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet tracked]	8	08 August 2023
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet]	8	08 August 2023
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet tracked]	8	08 August 2023
Participant information sheet (PIS) [SOS ProfL Post Enrolment Information Sheet]	7	08 August 2023
Participant information sheet (PIS) [SOS ProfL Post Enrolment Information Sheet tracked]	7	08 August 2023
Participant information sheet (PIS) [SOS ProfL Pre Enrolment Information Sheet]	7	08 August 2023
Participant information sheet (PIS) [SOS ProfL Pre Enrolment Information Sheet tracked]	7	08 August 2023
Participant information sheet (PIS) [SOS_PatientInformationSheet]	8	08 August 2023
Participant information sheet (PIS) [SOS_PatientInformationSheet tracked]	8	08 August 2023
Summary CV for Chief Investigator (CI) [CV_Kolias_June 2023]	NA	
Validated questionnaire [SOS Qualtrics 3m Questionnaire]	2	26 October 2021
Validated questionnaire [SOS Qualtrics 6m Questionnaire]	2	26 October 2021
Validated questionnaire [SOS Qualtrics 12m Questionnaire]	2	26 October 2021
Validated questionnaire [SOS_Qualtrics 6m Questionnaire_V2_tracked]	2	27 July 2023
Validated questionnaire [SOS_Qualtrics 12m Questionnaire_V2_tracked]	2	27 July 2023
Validated questionnaire [SOS_Qualtrics 3m Questionnaire_V2_tracked]	2	27 July 2023

## 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.

A Research Ethics Committee established by the Health Research Authority

## 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>
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<b>Please quote this number on all correspondence</b>
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Yours sincerely  
pp.



**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  
on 18 September 2023 via correspondence**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Rani Badhan	Clinical Trials Project Manager & Senior Trial Practitioner	Yes	
Dr Niki Bannister (Chair)	Retired Hospital Doctor	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Richard Reed	Approvals Administrator