

East of England - Essex Research Ethics Committee

2 Redman Place
London
EC20 1 JQ

**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.**

12 April 2024

Dr Angelos Koliass
Neurosurgical Trials Expertise
Department of Neurosurgery, Addenbrookes Hospital
Addenbrookes Hospital
Hills Road
Cambridge
CB0 2QQ

Dear Dr Koliass

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 13
Amendment date:	06 March 2024
IRAS project ID:	260350

The above amendment was reviewed at the meeting of the Sub-Committee held on 15 April 2024 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 [SA13 Amendment Tool]	1.0	06 March 2024
Cover Letter [Cover Letter]	1	28 March 2024
Other [Summary of Changes]	1.0	24 January 2024
Research protocol or project proposal [SOS Protocol Tracked]	8.0	06 March 2024
Research protocol or project proposal [SOS Protocol Clean]	8.0	06 March 2024

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.



(Richard Reed)

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 15 April 2024 via correspondence**

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Niki Bannister (chair)	Retired Hospital Doctor	Yes	
Miss Sarah Collison	Science Administrator	Yes	

Also in attendance:

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