

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.

11 November 2019

Dear Professor Gavin Perkins,

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: Substantial Amendment 01
Amendment date: 29 October 2019
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>
Covering letter on headed paper [Cover Letter]		25 October 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UHB Sponsorship Confirmation Letter]		04 June 2019
Notice of Substantial Amendment (CTIMP)	Substantial Amendment 01	29 October 2019

Participant information sheet (PIS) [SOS ProfLR Pre Enrolment Information Sheet, Tracked]	V2.0, Tracked	22 October 2019
Participant information sheet (PIS) [SOS PerLR Pre Enrolment Information Sheet, Tracked]	V3.0, Tracked	22 October 2019
Participant information sheet (PIS) [SOS Patients Information Sheet, Tracked]	V3.0, Tracked	22 October 2019
Participant information sheet (PIS) [SOS PerLR Post Enrolment Information Sheet, Tracked]	V3.0, Tracked	22 October 2019
Participant information sheet (PIS) [SOS ProfLR Post Enrolment Information Sheet, Tracked]	V2.0, Tracked	22 October 2019

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.

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/>

19/EE/0228:	Please quote this number on all correspondence
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Yours sincerely,



P.P
Dr Niki Bannister
Chair

E-mail: NRESCCommittee.EastofEngland-Essex@nhs.net

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 via Correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Dr Niki Bannister (Chair)	Retired Hospital Doctor	Yes
Dr Nkiruka Umaru	Pharmacist	Yes

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Katie Arnold	Approvals Administrator