

East of England - Essex Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

28 May 2020

Mrs Jane Prewett
University of Warwick, Research & Impact Services
University House, Kirby Corner Road
Coventry
CV4 8UW

Dear Mrs Prewett

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 4
Amendment date:	02 April 2020
IRAS project ID:	260350

The above amendment was reviewed on 18 May 2020 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>
Annex 2: Notification of Amendment	Substantial Amendment 4	02 April 2020
Cover Letter		02 April 2020
GP/consultant information sheets or letters [tracked]	2.0	26 February 2020
GP/consultant information sheets or letters [clean]	2.0	26 February 2020
Miscellaneous [follow up reminders]	1.0	03 March 2020

Miscellaneous [Twitter Account Guidance]	1.0	
Participant consent form [Consent form - PerLR post-enrolment - clean]		26 February 2020
Participant consent form [Consent form - PerLR post-enrolment - tracked]		26 February 2020
Participant consent form [PerLR post-enrolment - clean]		26 February 2020
Participant consent form [PerLR post-enrolment - tracked]	2.0	26 February 2020
Participant consent form [ProfLR post-enrolment - clean]	2.0	26 February 2020
Participant consent form [ProfLR post-enrolment - tracked]	2.0	26 February 2020
Participant consent form [Patient post-enrolment - clean]	2.0	26 February 2020
Participant consent form [Patient post-enrolment - tracked]	2.0	26 February 2020
Participant consent form [ProfLR pre-enrolment]	1.0	26 February 2020
Participant information sheet (PIS) [PerLR Pre Enrolment Information Sheet - clean]	4.0	26 February 2020
Participant information sheet (PIS) [PerLR Pre Enrolment Information Sheet - tracked]	4.0	26 February 2020
Participant information sheet (PIS) [ProfLR Post Enrolment Information Sheet - clean]	3.0	26 February 2020
Participant information sheet (PIS) [ProfLR Post Enrolment Information Sheet - tracked]	3.0	26 February 2020
Participant information sheet (PIS) [Patients Information Sheet - clean]	4.0	26 February 2020
Participant information sheet (PIS) [Patients Information Sheet - tracked]	4.0	26 February 2020
Participant information sheet (PIS) [PerLR Post Enrolment Information Sheet - clean]	4.0	26 February 2020
Participant information sheet (PIS) [PerLR Post Enrolment Information Sheet - tracked]	4.0	26 February 2020
Participant information sheet (PIS) [ProfLR Pre Enrolment Information Sheet - tracked]	3.0	26 February 2020
Participant information sheet (PIS) [ProfLR Pre Enrolment Information Sheet - clean]	3.0	26 February 2020
Protocol [clean]	3.0	11 March 2020
Protocol [tracked]	3.0	11 March 2020

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.

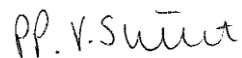
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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



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: Professor Gavin Perkins, Heartlands Hospital Confidentiality Advise Team

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 18 May 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Niki Bannister	Retired Hospital Doctor	Yes	
Dr Gerry Kamstra (Chair)	Retired Solicitor	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Henrietta Phillips	Approvals Administrator