

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.

21 November 2022

Professor Gavin Perkins
Heartlands Hospital
Bordesley Green East
Birmingham
B9 5SS

Dear Professor 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: SA 10
Amendment date: 31 October 2022
IRAS project ID: 260350

The above amendment was reviewed 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 [260350_SA 10_locked amendment	1.0	31 October 2022

tool]		
Cover Letter [REC Cover Letter - SA10]	1.0	08 November 2022
Cover Letter [ProfLR SOS_QuestionnaireCoverLetter_without voucher_v1.0_08Nov2022]	1.0	08 November 2022
Cover Letter [ProfLR SOS_QuestionnaireCoverLetter_with voucher_v1.0_08Nov2022]	1.0	08 November 2022
GP/consultant information sheets or letters [SOS_ GP letter_GOS-E_v3.0_08Nov2022]	3.0	08 November 2022
GP/consultant information sheets or letters [SOS_ GP letter_GOS-E_v3.0_08Nov2022_tracked]	3.0	08 November 2022
Other [MHRA correspondence re. ACCP assessment of eligibility]	1.0	16 April 2021
Other [Summary of changes_SA10]	1.0	08 November 2022
Other [SOS_ApologyLetter_27Jul22_v1.0]	1.0	27 July 2022
Other [SOS_ApologyLetterWithdrawnPpt_27Jul22_v1.0]	1.0	27 July 2022
Research protocol or project proposal [SOS_Protocol_v6.0_08Nov2022]	6.0	08 November 2022
Research protocol or project proposal [SOS_Protocol_v6.0_08Nov2022_tracked]	6.0	08 November 2022

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

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

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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 Niki Bannister (Chair)	Retired Hospital Doctor	Yes	
Miss Rachael Bass	Assistant Psychologist	Yes	

Also in attendance:

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