

East of England - Essex Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

24 March 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 3
Amendment date:	28 February 2020
IRAS project ID:	260350

Thank you for submitting the above amendment, which was received on 10 March 2020.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
Walton Centre for Neurology and Neurosurgery	Dr Gerald Smith
Kings College Hospital NHS Foundation Trust	Dr Savvas Vlachos

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at <https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant host organisation prior to the study starting at the site.

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.

19/EE/0228**Please quote this number on all correspondence**

Yours sincerely



Vic Strutt
Approvals Officer

Email: Essex.REC@hra.nhs.uk

Copy to: *Professor Gavin Perkins, Heartlands Hospital*
Confidentiality Advise Team