

East of England - Essex Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

06 October 2020

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 06 / 19/EE/0228/AM07
Amendment date: 23 September 2020
IRAS project ID: 260350

Thank you for submitting the above amendment, which was received on 30 September 2020.

Research site	Principal Investigator / Local Collaborator	
Cardiff and Vale University Health Board	Matt Wise	
University Hospitals Birmingham NHS Foundation Trust	Nick Murphy	

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

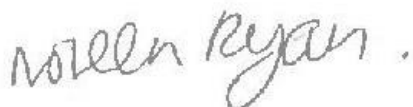
This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

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.

IRAS Project ID: 260350**Please quote this number on all correspondence**

Yours sincerely

**Noreen Ryan**

Email: Essex.REC@hra.nhs.uk

Copy to:

Professor Gavin Perkins, Heartlands Hospital
Mrs Jane Prewett Confidentiality Advise Team

