

East of England - Essex Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

07 January 2020

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 02
Amendment date: 06 January 2020
IRAS project ID: 260350

Thank you for submitting the above amendment, which was received on 06 January 2020.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
Wessex Neurological Centre	Mr Diederik Butlers
Derriford Hospital	Dr Jessie Welbourne
Royal Victoria Hospital	Professor Danny McAuley
The Walton Centre NHS Foundation Trust	Ms Catherine McMahon
St George's University Hospitals NHS Foundation Trust	Dr Andrew Hitchings
Nottingham University Hospitals NHS Trust	Dr Paul Candler
NHS Grampian	Dr Callum Kaye
Barts Health NHS Trust	Mr Christopher Uff
University Hospitals of North Midlands NHS Trust	Dr Felicity Clark
University Hospital Coventry & Warwickshire NHS Trust	Dr Christopher Bassford

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,



Katie Arnold
Approvals Administrator

Email: NRESCCommittee.EastofEngland-Essex@nhs.net

Copy to: *Mrs Jane PrewettConfidentiality Advise Team*