

**Project Title:** 'Salt or Sugar trial: Hyperosmolar therapy in traumatic brain injury (SOS Trial)'

**Chief Investigator:** Professor Gavin Perkins

**Sponsor's Office Ref:** SOC.14/18-19

**Amendment Number:** Non-substantial amendment 1

**Sponsor Approval Date:** 29/07/2020

This letter is to confirm that the above referenced non-substantial amendment was approved by the University of Warwick as trial sponsor of 'Salt or Sugar trial: Hyperosmolar therapy in traumatic brain injury (SOS Trial) (SOC.14/18-19)' on the above date.

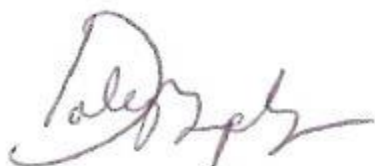
This amendment has been categorised as category C and does not require HRA/HCRW Approval or R&D agreement. As such, this amendment will be implemented immediately.

Details of the amendment are as follows:

In order to enable the SOS trial to resume recruitment during the COVID-19 pandemic, non-substantial changes have been made to approved documents to help avoid the risk of infection transmission, as detailed below:

- Whilst travel restrictions and visiting restrictions at sites are in place, monitoring activities will be conducted remotely instead of on-site.
- If there are practical difficulties posting out follow up questionnaires, for example due to office access restrictions, the trial team will collect follow up data from patients/legal representatives over the phone instead of via postal questionnaire.
- If it is not feasible to obtain written informed consent from personal legal representatives or patients, witnessed verbal consent will be obtained instead. For example, if the personal legal representative is unable to attend the hospital due to visiting restrictions or if the patient tests positive for COVID-19.

Kind regards,



**Dale Topley**

**Research Governance & Quality Assurance Manager**

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