

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	SOS Trial: Hyperosmolar therpay in traumatic brain injury			
IRAS project ID* (or REC reference if no IRAS project ID is available):	260350			
Sponsor amendment reference number*:	NSA09			
Sponsor amendment date* (enter as DD/MM/YY):	31 July 2024			
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	There are two site closures, Oxford and Southampton due to equipoise issues and staffing capacity, there were no safety concerns relating to their closure. John Radcliffe Hospital Oxford – Closed on 02/04/2024 and Wessex Neurological Centre Southampton, University Hospital Southampton NHS Foundation Trust – Closed on 14/06/2024. The sites have closed to recruitment but will continue to collect data.			
Project type (select):	Specific study			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	Yes		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	NHS/HSC REC			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		No	
EudraCT number*:	2019-001688-66			
Was this clinical trial of an investigational medicinal product (CTIMP) processed under the CTIMP combined review service (formerly known as the Combined Ways of Working (CWoW) pilot)?:	Yes		No	
Did the study receive Pharmacy Assurance?:	Yes		No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		No	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		No	
Did the study involve children OR does the amendment introduce this?:	Yes		No	
Did the study involve NHS/HSC organisations prior to this amendment?:	Yes		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	Yes	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	Yes	Yes	Yes

Section 2: Summary of change(s)

What do you want to update?:

Project information

New site/PI only

**Please note:** Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1

Area of change (select)\*:

Participating Organisations

Specific change (select - only available when area of change is selected first)\*:

Early closure or withdrawal of research sites

Further information (free text - note that this field will adapt to the amount of text entered):

There were staff capacity and equipoise issues with both sites resulting in their early closure. John Radcliffe Hospital Oxford – Closed on 02/04/2024 and Wessex Neurological Centre Southampton, University Hospital Southampton NHS Foundation Trust – Closed on 14/06/2024. The sites have closed to recruitment but will continue to collect data.

Applicability:

England

Wales

Scotland

Northern Ireland

Where are the participating NHS/HSC organisations located that will be affected by this change?\*

Yes

No

No

No

Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):

All

Some

Add another change

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

I confirm that the Sponsor takes responsibility for the completed amendment tool

I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]\*:

Mathew Gane

Email address\*:

sponsorship@warwick.ac.uk; sostrial@warwick.ac.uk

Lock for submission

**Please note:** This button will only become available when all mandatory (\*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, [proceed to submit the amendment online](#). The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

**Please note:** This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies

UK wide:

England and Wales:

Scotland:

Northern Ireland:

REC

Competent Authority MHRA - Medicines

Competent Authority MHRA - Devices

ARSAC

Radiation Assurance

UKSW Governance

REC (MCA)

CAG

HMPPS

HRA and HCRW Approval

REC (AWIA)

PBPP

SPS (RAEC)

National coordinating function

HSC REC

HSC Data Guardians

Prisons

National coordinating function

Category:

Change 1:

(Y)

(Y)

B

Overall reviews for the amendment:

Full review:

Notification only:

N

Y

N

Y

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Overall amendment type:	Non-substantial, no study-wide review required
Overall Category:	B