

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	SOS Trial: Hyperosmolar therapy in traumatic brain injury			
IRAS project ID* (or REC reference if no IRAS project ID is available):	260350			
Sponsor amendment reference number*:	SA 11			
Sponsor amendment date* (enter as DD/MM/YY):	21 February 2023			
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)*:	See appended summary of changes document for full details: Introduction of electronic questionnaires for collection of GOS-E score follow-up data using Qualtrics, included in the protocol and patient information sheets.			
Project type (select):	<b>Specific study</b>			
	<div>Research tissue bank</div> <div>Research database</div>			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<b>Yes</b>		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<b>NHS/HSC REC</b>			
	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		<b>No</b>	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<b>Yes</b>		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		<b>No</b>	
Did the study receive Pharmacy Assurance?:	Yes		<b>No</b>	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		<b>No</b>	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<b>Yes</b>		No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		<b>No</b>	
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		<b>No</b>	
Did the study involve children OR does the amendment introduce this?:	Yes		<b>No</b>	
Did the study involve NHS/HSC organisations prior to this amendment?:	<b>Yes</b>		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		<b>No</b>	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<b>Yes</b>	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Which nations will have participating NHS/HSC organisations after this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

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)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)			
Further information (free text - note that this field will adapt to the amount of text entered):	Typographical corrections in the protocol where necessary			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
				Remove all changes below

Change 2				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Protocol - Substantial changes (e.g. affecting safety or the scientific value of the trial)			
Further information (free text - note that this field will adapt to the amount of text entered):	Electronic online questionnaires will be used to collect follow-up data using Qualtrics in order to improve follow-up return rates. Contents of questionnaires is unchanged.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
				Remove all changes below

Change 3				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	Text message template document has been updated to include template texts for sending participants/relatives with the link to Qualtrics to complete the follow-up questions.  Patient information sheets have been updated to include reference to the electronic questionnaires alongside an update to the University GDPR statement and storage requirements. Patient information sheets and consent forms have been updated to have the new NIHR abbreviation and NHS digital replaced with the new name NHS England  PDF copies of the electronic questionnaire has been developed as well as shortened questionnaires which do not contain the GOS-E questions (to avoid duplication for patients that only complete the mandatory GOS-E questions on the electronic questionnaire)			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	Yes	Yes
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
				Remove all changes below

Change 4				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	New cover letter developed based on existing cover letters - to be sent alongside voucher to patients who receive a text message link to the online questionnaires			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
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

Applicant identification:

Sponsor

Legal representative of the sponsor

Person or organisation authorised by the sponsor

Organisation:

University of Warwick

Name [first name and surname]\*:

Mathew Gane

Address:

Telephone number:

Fax number:

Purchase Order (PO) number for MHRA invoicing:

Email address\*:

sppnsorship@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															Category:			
	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
Change 1:	N	N				(Y)				(Y)				(Y)				(Y)	A
Change 2:	Y	Y				Y				(Y)				(Y)				(Y)	A

Change 3:	Y	N				Y				Y				Y				Y	C
Change 4:	N	N				(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:	Y	Y				Y				Y				Y				Y	
Notification only:	N	N				N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		