Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	Spinal Immobilisation Study SIS
IRAS project ID* (or REC reference if no IRAS project ID is available):	316755
Sponsor amendment reference number*:	SA002
Sponsor amendment date* (enter as DD/MM/YY):	19 May 2025
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)*:	1) Change in sample size from 8316 down to 2010 2) Change in consent process to add in a 'Opt-out' consent model 3) Change to the protocol v7.0, 16May2025 for the following reasons: Following completion of the pilot extension phase and DMC/TSC meetings with discussions with funder there are now 3 main changes in the study 1. Change in sample size for main study (now 2010 previously 8316) 2. Change in the FIM-score cut-off from 2 point to 3 points for analysis. 3. Change in Consent process - Now utlising an opt out consent procedure detailed for those patients who are lost at discharge similar to other emergency care trials (non-contactable for consent depsite 3 contact attempt phone calls). 4) Other minor change to study documents (See change 4 for details) - SIS Young Person PIS V2.0, 16May2025 - SIS Adult PIS V3.0, 16May2025 - SIS Parent Guardian PIS V3.0, 16May2025 Minor updates to consent wording (See change 4 for details) - SIS Consultee Declaration Form V3.0, 16May2025 - SIS ParentGuardianDeclarationForm_v2.0, 16May2025 - SIS PatientConsentForm_v4.0, 16May2025 5)Other significant change to study documents (New form created) - SIS-Opt-Out Form V1.0, 16May2025

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 **modified amendment** (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**		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	**No**		
Was the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	**No**		
Does the amendment make the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	**No**		

^ IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination

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	
Does the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: (e.g. the study relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality)	Yes		**No**	
Does 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**	
Does 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**	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	No	No

Section 2: Summary of change(s)

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 Design			
Specific change (select - only available when area of change is selected first)*:	Participant numbers - Significant change to sample size			
Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	After reviewing the data from the pilot extension stage of the study and following discussions with DMC/TSC groups and funder meetings, a reduction in sample size has been proposed for the main study recruitment. New sample size target is 2010 individuals agreed by NIHR - (8316 prior)			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	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	
			Remove all changes below	

Change 2	
Area of change (select)*:	Participant Procedures
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of participants
Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt	Proposing an opt out consent process just for those patients who are discharged early before being approached for consent .During the pilot phase of the study, it became clear that due to the nature of their condition many patients are admitted late in an evening, have their c-spine cleared and are discharged before they can be consented (sometimes on the same day as admission). This has made it difficult for site staff to get consent from these patients for trial participation even with pre-existing measures in place (x3 telephone call consent).The study will continue in the same way as the pilot, with verbal agreement (assent) at the time of randomisation in the pre-hospital phase by paramedics. In hospital site staff must attempt to gain consent in person as usual and try to get telephone consent when this has not occurred.For any patients discharged on the same day and/or not contactable by trial staff members (i.e. post 3 calls attempt) to explain the study, the PIS will be sent via post/email with

participants/carers (free text - note that this field will adapt to the amount of text entered):	members (i.e. post 3 calls attempt) to explain the study, the PIS will be sent via post/email with an opt out consent form attached. Patients can fill in the opt out form or contact sites directly via phone or email about their decision to opt out, post discharge. This will also be recorded in the notes. If this is not returned, we will assume consent for the period of hospitalisation and the data from this (e.g. that their c-spine was cleared, and they returned home neurologically the same i.e. the FIM score was unchanged) will be included in the study. At each subsequent follow up timepoint post discharge (30, 90 and 180 days) where survival and PROMs data is collected site staff will continue to attempt to contact the patient to collect these if contact is successful and remind the participant of their right to opt out at each timepoint. (explained in the Protocol - Section 2.7)

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	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	
			Remove all changes below	

Change 3	
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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	Change to the protocol v7.0, 16May2025 for the following reasons: Following completion of the pilot extension phase and DMC/TSC meetings with discussions with funder there are now 3 main changes in the study 1. Change in sample size for main study (now 2010 previously 8316) 2. Change in the FIM-score cut-off from 2 point to 3 points for analysis. 3. Change in Consent process - Now utlising an opt out consent procedure detailed for those patients who are lost at discharge similar to other emergency care trials (non-contactable for consent depsite 3 contact attempt phone calls).

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	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	
			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: explain what the change is, why the change is being made and any possible impact on study participants/carers. 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)*	Minor wording changes added to all PIS versions informing of the opt-out consent process. Update to the sections 'What will you do with my information?' to re order the text to make clearer and delete duplication. Name change of The Trauma Audit Research Network (TARN) to the National Major Trauma Registry (NMTR) - SIS Young Person PIS V2.0, 16May2025 - SIS Adult PIS V3.0, 16May2025 - SIS Parent Guardian PIS V3.0, 16May2025 Minor updates to the consent forms to ensure they are consistent with each other and appropriate for the person providing consent. Name change of The Trauma Audit Research Network (TARN) to the National Major Trauma Registry (NMTR) - SIS Consultee Declaration Form V3.0, 16May2025 - SIS ParentGuardianDeclarationForm_v2.0, 16May2025 - SIS PatientConsentForm_v4.0, 16May2025

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	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
		Remove all changes below

Change 5				
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: explain what the change is, why the change is being made and any possible impact on study participants/carers. 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 Form for Opt Out Consent created - SIS-Opt-Out Form V1.0, 16May2025			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	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]:*	cheuk fung wong
Email address:*	cheuk-fung.wong@imperial.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)				(Y)									A
Change 2:	Y					Y				Y									A
Change 3:	Y					Y				(Y)									A

Change 4:	N					(Y)				(Y)									C
Change 5:	Y					Y				Y									C
Overall reviews for the amendment:																			
Full review:	Y					Y				Y									
Notification only:	N					N				N									
Overall amendment type:	Substantial																		
Overall Category:	A																		