

Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

Section 1: Project information

Short project title*:	Study of whole blood in frontline trauma			
IRAS project ID* (or REC reference if no IRAS project ID is available):	300414			
Sponsor amendment reference number*:	Substantial Amendment 06			
Sponsor amendment date* (enter as DD/MM/YY):	29 April 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)*:	Change to Protocol v2.0 12/03/2024, specific changes are: Update to study contacts; change to collect day 30 data at "day 30, death or discharge (whichever is sooner)" to reduce burden on research teams; clarification of processes on consent; provision of injury data from Hospital Trusts until availability of this data from TARN is restored; addition of transfusion definitions for paediatric participants; addition of air ambulance pocket cards and air ambulance care records as source data; clarification of data deletion process if requested by participants or legal representative on withdrawal; participants taken to non-participating hospitals will have pre-hospital care data entered by a member of NHSBT CTU not involved in the study; new professional information sheet for professional legal representatives, new letters for participants who have not been approached in hospital before discharge; new letter for participants who were enrolled but were not eligible.			
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	
EudraCT number*:	2021-006876-18			
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	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No

Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		No	
Which nations had participating non-NHS/HSC organisations prior to this amendment?	Yes	No	No	No
Which nations will have participating non-NHS/HSC organisations after this amendment?	Yes	No	No	No

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):	Change to Protocol v2.0 12/03/2024, specific changes are: Update to study contacts; change to collect day 30 data at "day 30, death or discharge (whichever is sooner)" to reduce burden on research teams; clarification of processes on consent; provision of injury data from Hospital Trusts until availability of this data from TARN is restored; addition of transfusion definitions for paediatric participants; addition of air ambulance pocket cards and air ambulance care records as source data; clarification of data deletion process if requested by participants or legal representative on withdrawal; participants taken to non-participating hospitals will have pre-hospital care data entered by a member of NHSBT CTU not involved in the study.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
Remove all changes below				

Change 2				
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)*	New documents provided to sites: new information sheet for professional legal representatives; new letters for participants (or personal legal representatives or parents/guardians) who have not been approached in hospital before discharge; new letter for participants (or personal legal representatives or parents/guardians) who were enrolled but were not eligible who have not been approached before discharge.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
Remove all changes below				

Change 3	
Area of change (select)*:	Study Management

Specific change (select - only available when area of change is selected first)*:	Funding arrangements - Changes to the payments, benefits or incentives to be received by researchers/sites			
Further information (free text - note that this field will adapt to the amount of text entered):	Inclusion of excess treatment costs for this study that have been fully approved by NIHR.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
				Remove all changes below

Change 4				
Area of change (select)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Contact details - CI or other project staff			
Further information (free text - note that this field will adapt to the amount of text entered):	Changes listed in the protocol to changes of key contacts, due to NHSBT CTU staff changes.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	No
				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:	NHS Blood and Transplant
Name [first name and surname]*:	Oluwayomi Adegbaaju
Address:	
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	
Email address*:	research.office@nhsbt.nhs.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)									A
Change 2:	Y	N				Y		(Y)		Y									C
Change 3:	Y	N				Y		(Y)		Y									A
Change 4:	(Y)	Y				Y		(Y)		(Y)									C
Overall reviews for the amendment:																			
Full review:	Y	Y				Y		N		Y									
Notification only:	N	N				N		Y		N									
Overall amendment type:	Substantial for review																		
Overall Category:	A																		
For national coordinating function office use:																			
Update HARP:	This amendment may involve an update to contact details, project end date, or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.																		