

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

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*:	Amendment 09			
Sponsor amendment date* (enter as DD/MM/YY):	15 August 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)*:	Reporting the temporary halt and subsequent restart of one study site. Changes made to the protocol to document management of temporary halts and collection of data for patients taken to non-participating hospitals. New documents for patients taken to non-participating hospitals.			
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	
	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	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)*:	Stop or Restart			
Specific change (select - only available when area of change is selected first)*:	Temporary halt of CTIMP			
Date of temporary halt (enter as DD/MM/YY):	09 April 2024			
Recruitment has been stopped:	Yes	No		
Treatment has been stopped:	Yes	No		
Number of participants still receiving treatment in the UK at the time of the temporary halt:	0			
In the further information free text below, briefly describe: - Justification for a temporary halt of the trial - The proposed management of participants receiving treatment at the time of the halt - The consequences of the temporary halt for the evaluation of the results and for the overall risk benefit assessment of the investigational medicinal product - Details of any other trials in the UK that will also be affected by the temporary halt				
Further information (free text - note that this field will adapt to the amount of text entered):	One site (Thames Valley Air Ambulance (TVAA)) was temporarily halted due to an investigation into a serious breach. All other air ambulance services, associated transfusion laboratories and receiving hospitals remained open. TVAA do not carry the IMP (lyophilised plasma) used in this study. Reference: GCP-24-038 Notification of a serious breach: Study of whole blood in frontline trauma (SWiFT) IRAS 300414.			
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)*:	Stop or Restart			
Specific change (select - only available when area of change is selected first)*:	Restart of study following a temporary halt			
Further information (free text - note that this field will adapt to the amount of text entered):	Thames Valley Air Ambulance were restarted on 09/08/2024 following completion of the investigation into a serious breach. A root cause analysis meeting was held on 16th July 2024. Following this meeting the root cause for the incident			
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 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):	Statement added to protocol to document the management of temporary halts of the study or one or more study sites. Clarification on data collection for patients taken to non-participating hospitals.			
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)*:	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: new letter and short study summary sheet for participants taken to non-participating hospitals.			
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:	500 North Bristol Park, Filton, Bristol
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:	Y	Y				(Y)		(Y)		(Y)									B
Change 2:	Y	Y				(Y)		(Y)		(Y)									B
Change 3:	N	N				(Y)		(Y)		(Y)									A
Change 4:	Y	N				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 MHRA office use:																			
This amendment notifies a temporary halt of the trial																			
This amendment requests a restart of the trial																			