

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	TICH-3			
IRAS project ID* (or REC reference if no IRAS project ID is available):	IRAS Project ID: 297457			
Sponsor amendment reference number*:	MA_24_24			
Sponsor amendment date* (enter as DD/MM/YY):	25 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)*:	This amendment is to correct typographical errors in the recently approved protocol Final v3.0 28/02/2024.			
Project type (select):	Specific study			
	<div style="text-align: center;">Research tissue bank</div> <div style="text-align: center;">Research database</div>			
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*:	2021-001050-62			
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 have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?:	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	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)*:	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):	<p>Amended typographical errors in protocol Final v3.0 28/02/2024 to become Final v3.1 25/04/2024.</p> <p>1. As per MHRA guidance within email dated 25/04/2024 we have corrected the accidental deletion of the VAS scale from 'Table 1. Summary of data collection at which timepoint'</p> <p>2. As per MHRA notice of acceptance of amendment letter for SA_06_24 dated 22/04/2024 we have actioned the 60ml +/- typographical errors</p> <p>> this has also been actioned in the approved eligibility checklist and enrolment form final v1.0 28/02/2024 to become final v1.1 25/04/2024</p> <p>Added definition of spontaneous ICH to protocol and eligibility checklist and enrolment form and prescribing guidance to eligibility checklist and enrolment form.</p>			
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	
<ul style="list-style-type: none"> 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]*:	Alison Thorpe
Email address*:	sponsor@nottingham.ac.uk

<p>Lock for submission</p> <p>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.</p> <div style="text-align: center; margin: 10px 0;"> <div style="background-color: #90EE90; padding: 5px 20px; display: inline-block; border: 1px solid black;">Lock for submission</div> </div> <p>After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.</p>

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:		
Authority medicines	Authority devices	Assurance	overance	(A)			HCRW Approval	(A)		(C)	coordinating function	Guardians	coordinating function

	REC	Compete MHRA - I	Compete MHRA - D	ARSAC	Radiation	UKSW Gc	REC (MC)	CAG	HMPPS	HRA and I	REC (AW)	PBPP	SPS (RAE)	National c	HSC REC	HSC Data	Prisons	National c	Category:
Change 1:						(Y)				(Y)				(Y)				(Y)	A
Overall reviews for the amendment:																			
Full review:						N				N				N				N	
Notification only:						Y				Y				Y				Y	
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		