

Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	PhEAST			
IRAS project ID* (or REC reference if no IRAS project ID is available):	304658			
Sponsor amendment reference number*:	SA_04_22			
Sponsor amendment date* (enter as DD/MM/YY):	15 September 2022			
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 introduces that participants in the PhEAST trial may need additional chest X-Rays performed, if they are randomised to the PES treatment. This has been given radiation assurance by the HRA, having had a CRE and an MPE review the new documents to ensure the correct risk assessment statements are in place. Further to this, this amendment introduces the collection of protocol deviations, and some additional sentences for clarification regarding threshold levels, and the use of catheters.			
Project type (select):	Specific study			
	<input type="checkbox"/> Research tissue bank <input type="checkbox"/> 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			
	<input type="checkbox"/> 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)?	<input type="checkbox"/> Yes	No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<input type="checkbox"/> Yes	No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		<input type="checkbox"/> No	
Does this clinical investigation or other study of a medical device require a Notice of No Objection from MHRA Devices?:	<input type="checkbox"/> Yes		No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	<input type="checkbox"/> 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		<input type="checkbox"/> No	
Did the study have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?:	<input type="checkbox"/> Yes		<input type="checkbox"/> No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		<input type="checkbox"/> No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	<input type="checkbox"/> 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?:	<input type="checkbox"/> Yes		No	
Did the study involve children OR does the amendment introduce this?:	<input type="checkbox"/> Yes		No	
Did the study involve NHS/HSC organisations prior to this amendment?:	Yes		<input type="checkbox"/> No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	<input type="checkbox"/> Yes		No	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	Yes	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> 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)

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)*:	Ionising radiation exposure not involving Radioactive Substances			
Specific change (select - only available when area of change is selected first)*:	Addition or removal of a procedure involving research exposures			
Further information (free text - note that this field will adapt to the amount of text entered):	Participants randomised to receive the PES treatment may need additional chest X-Rays. The protocol has been updated to reflect this, as well as the participant information sheets.			
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	
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 - 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):	Two sentences added for clarification: Sentence added on page 19 for clarification ' or if the difference between threshold and tolerance is less than 8mA'. Sentence on page 21 added for clarification ' If sites have their own catheters, these may also be used in the trial in line with the trial protocol.' Introduction of the collection of protocol deviations.			
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	
Remove all changes below				

Change 3				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	CRF/other study data records - Changes in the documentation used by the research team for recording study data			
Further information (free text - note that this field will adapt to the amount of text entered):	Introduction of the collection of protocol deviations.			
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	
Remove all changes below				

Change 4				
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):	Addition of potential need for x-rays for NG tube/PES placement.			
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	
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 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)*	Participant and consultee information sheets amended to include the potential of ionising radiation exposure and the relevant risk statements.			
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

Name [first name and surname]*:	Angela Shone
Email address*:	sponsor@nottingham.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	HMP/PS	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					Y	A
Change 2:	N				N	(Y)			(Y)				(Y)					(Y)	A
Change 3:	N				N	(Y)			(Y)				(Y)					(Y)	A
Change 4:	Y				N	Y			(Y)				(Y)					(Y)	A
Change 5:	Y				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																
Overall Category:	A																