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_01_22
Sponsor amendment date* (enter as DD/MM/YY):	25 February 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 comprises of updates to the inclusion and exlcusion criteria, regarding the conciousness levels of potential participants (NIHSS score added for clarification of which participants can be recruited); the disposition of the participant at day 14 primary outcome (participants need to be in treating organisation for this) and a change to the oxygen levels in the exclusion criteria (up to 35 litres deemed safe with the use of PES). This amendment also comprises of various administrative changes; namely a protocol version table has been added, the WHO ID added to the front page, and sentences throughout the protocol added for clarification. This amendment also extends the Serious Adverse Event Collection from days 0-7 to days 0-9 to account for the change in the participant treatment schedule, whereby participants can have three days of treatment followed by a 1 or 2 day break, followed by another three days of treatment, to ensure sites that do not operate at weekends can recruit and treat eligible patients. Finally, an appendix has been added at the behest of the Austrian ethics committee, to outline their consent procedure that will be approved and followed in Austrian sites.

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	
Does this clinical investigation or other study of a medical device require a Notice of No Objection from MHRA Devices?:	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**	**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)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Significant change (e.g. to age range) likely to affect safety or scientific value of study			
Further information (free text - note that this field will adapt to the amount of text entered):	Inclusion criteria updated to include 'NIHSS item 1a score of 0, 1 or 2 (where the patient requires repeated stimulation to arouse).' Exclusion criteria updated to include 'NIHSS item 1a score of 2 (where the patient only responds to pain) or NIHSS item 1a score of 3.' Exclusion criteria updated to include 'Patient expected to be repatriated to a separate organisation.' Exclusion criteria updated to include 'Patient expected to be rehabilitated at a separate organisation.'Exclusion criteria updated to include 'Patient not likely to be in the treating hospital for at least 14 days.' Exclusion criteria updated to state 'Need for >35 litres of oxygen' instead of 'Need for >2 litres of oxygen'.			
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 Design			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design 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)*	Updated SAE collection time points. SAEs to be collected from 0-9 days, fatal SAEs to be collected from 10-90 days.			
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)*:	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):	Protocol version control table added. Inserted sentence on pg 18 for clarification, 'If sites already have a Phagenyx® base station, this may be used in the trial in line with the trial protocol.'Inserted sentence on pg 21 for clarification, ' The use of fibreoptic endoscopic evaluation of swallowing (FEES) or videofluoroscopy (VFS) is not mandatory, but if they are carried out the penetration aspiration scale score and date will be recorded via the eCRF.' Sentence added on pg 25 for clarification 'Co-enrolment between certain trials is allowed, an up to date list of trials which PhEAST can co-enrol with, and at which time points, will be available on the trial website.' Sentence added on pg 28 for clarification 'The process for informed consent in both Germany and Denmark will be the same. The process for informed consent in Austria is outlined in Appendix L.' Sentence added of pg 31 for clarification 'The treatment cycle should be 6 consecutive days. If this is not possible, a treatment cycle should not be less than 3 consecutive days.' Wording change on pg 39 '…with stratification on country and minimisation on site characteristics (prior PES experience and stroke volume).			
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)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource 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)*	Treatment schedule table added. Participants no longer need to have six consecutive days of treatment, this can be split to allow for staffing levels / weekends etc.			
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)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Project identification (e.g. change of title, reference numbers)			
Further information (free text - note that this field will adapt to the amount of text entered):	WHO ID added on to front page U1111-1273-9942.			
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 6				
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 (free text - note that this field will adapt to the amount of text entered):	The consent process for Austria is slightly different to that of the UK, Germany and Austria. This will be passed through Austrian ethics and an appendix has been added (Appendix L) to outline the process.			
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																	
	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)				(Y)				(Y)	A
Change 2:	N					(Y)				(Y)				(Y)				(Y)	C
Change 3:	Y					Y				(Y)				(Y)				(Y)	A
Change 4:	N					(Y)				(Y)				(Y)				(Y)	C
Change 5:	(Y)					Y				(Y)				(Y)				(Y)	C
Change 6:	Y					Y				Y				Y				Y	A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y				Y	
Notification only:	N					N				N				N				N	
Overall amendment type:	Substantial																		
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.