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*:	NSA_14_23
Sponsor amendment date* (enter as DD/MM/YY):	09 May 2023
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)*:	The following minor changes and clarifications have been made to the mNCA 2022: - The front page has been amended to include additional identifiers and logo. - Study drug has been redefined in the definitions as Investigational Medicinal Product so that this is not misinterpreted when a drug is used in a non-CTIMP. - The definition of Trial Site has been included in the definitions as the contracting body for the site/s. - Clauses 3.9 - 3.12 have been removed as they can never be applicable when the University is the sponsor. Clauses 3.13 and 3.14 have therefore been renumbered 3.9 and 3.10 accordingly. Invoice address updated.

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 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**	
	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**	

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 Management
Specific change (select - only available when area of change is selected first)*:	Contract/agreement arrangements
Further information (free text - note that this field will adapt to the amount of text entered):	The non-commerical agreement has been updated to the UoN version based on the mNCA 2022. Where the previous version (based on the mNCA 2021) has already been sent to sites this will continue to be used, unless sites request otherwise. Sites that have not yet received the LIP will be sent the current version (based on the mNCA 2022). The following minor changes and clarifications have been made to the mNCA 2022: - The front page has been amended to include additional identifiers and logo. - Study drug has been redefined in the definitions as Investigational Medicinal Product so that this is not misinterpreted when a drug is used in a non-CTIMP. - The definition of Trial Site has been included in the definitions as the contracting body for the site/s. - Clauses 3.9 - 3.12 have been removed as they can never be applicable when the University is the sponsor. Clauses 3.13 and 3.14 have therefore been renumbered 3.9 and 3.10 accordingly. Invoice address updated.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	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	

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]:*	Anglea 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:			
	nt Authority Medicines	nt Authority evices		Assurance	overnance	A)			HCRW Approval	IA)		EC)	oordinating function		Guardians		oordinating function

	REC	Competen MHRA - M	Competen MHRA - D	ARSAC	Radiation	UKSW Gc	REC (MC/	CAG	HMPPS	HRA and	REC (AW	PBPP	SPS (RAE	National c	HSC REC	HSC Data	Prisons	National c	Category:
Change 1:						Y				Y				Y					A
Overall reviews for the amendment:																			
Full review:						Y				Y				Y					
Notification only:						N				N				N					
Overall amendment type:	Non-substantial																		
Overall Category:	A																		