

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	The POPPY Study			
IRAS project ID* (or REC reference if no IRAS project ID is available):	321740			
Sponsor amendment reference number*:	NSA 03			
Sponsor amendment date* (enter as DD/MM/YY):	30 November 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)*:	Withdrawal of one site. Addition of multiple sites. Multiple PI changes and updated qualifications. Correction of typographical error. Removing unplanned readmission within 7 days from withdrawal criteria. Further specifying that overnight stay is an exclusion criteria only if on day 0 overnight from surgery. Changed EU GDPR to UK GDPR. Addition of more stringent monitoring requirements as required by sponsor. Changes to make the poster easier to understand.			
Project type (select):	<b>Specific study</b>			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<b>Yes</b>	No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<b>NHS/HSC REC</b>			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes	<b>No</b>		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes	<b>No</b>		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	<b>No</b>		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes	<b>No</b>		
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	<b>No</b>		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes	<b>No</b>		
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	<b>No</b>		
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	<b>No</b>		
Did the study involve children OR does the amendment introduce this?:	Yes	<b>No</b>		
Did the study involve NHS/HSC organisations prior to this amendment?:	<b>Yes</b>	No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	<b>No</b>		
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Which nations will have participating NHS/HSC organisations after this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

## 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)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Early closure or withdrawal of research sites			
Further information (free text - note that this field will adapt to the amount of text entered):	Withdrawal of: ANEURIN BEVAN UNIVERSITY LHB, PI Dr Tamas Szakmany. Prior to the undertaking of any research activities.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	No	Yes	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 2				
Area of change (select)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites			
Further information (free text - note that this field will adapt to the amount of text entered):	Addition of sites, outlined in appendix 1			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 3				
Area of change (select)*:	Researchers			
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI			
Further information (free text - note that this field will adapt to the amount of text entered):	Updates to PIs and qualifications, outlined in appendix 1			
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? ( <b>please note</b> 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)*:	Correction of typographical errors			
Further information (free text - note that this field will adapt to the amount of text entered):	Page 48 - typographical error corrected. See tracked changed in protocol v1.3			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 5				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study			
Further information (free text - note that this field will adapt to the amount of text entered):	Further clarifying that overnight stay is an exclusion criteria if on day 0 overnight from surgery (tracked change p9 protocol v1.3). Removing unplanned readmission within 7 days from withdrawal criteria (tracked changed p21 of protocol v1.3).			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 6				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	GDPR wording - Unaccepted alternative wording used			
Further information (free text - note that this field will adapt to the amount of text entered):	Changed EU GDPR to UK GDPR page 32 protocol v1.3			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 7				
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)*	Addition of more stringent monitoring requirements as required by sponsor. Page 35 and 36 of protocol v1.3 with tracked changes.			
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? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
Remove all changes below				

Change 8				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor 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)*	Simplified wording and removed phrase "pseudo-anonymised" to make it easier to understand for patients. Poster POPPY 1.2 - changes in orange.			
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? ( <b>please note</b> 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]*:	Victoria Carrington Yates
Email address*:	victoriayates@nhs.net

**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)				N				N	B
Change 2:						(Y)				(Y)				(Y)				(Y)	New site
Change 3:						(Y)				(Y)				(Y)				(Y)	B
Change 4:						N				N				N				N	N/A
Change 5:						(Y)				(Y)				(Y)				(Y)	A
Change 6:						Y				Y				Y				Y	C
Change 7:						(Y)				(Y)				(Y)				(Y)	C
Change 8:						(Y)				(Y)				(Y)				(Y)	C
Overall reviews for the amendment:																			
Full review:						Y				Y				Y				Y	
Notification only:						N				N				N				N	
Overall amendment type:	Non-substantial																		
Overall Category:	A																		