Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Perioperative Quality Improvement Programme (PQIP)
IRAS project ID* (or REC reference if no IRAS project ID is available):	215928
Sponsor amendment reference number*:	Substantial Amendment SA7
Sponsor amendment date* (enter as DD/MM/YY):	18 August 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 study end date is currently set to '31/10/2023 or 70,000 patients recruited whichever is later'. PQIP is now supporting several randomised clinical trials by acting as a data collection platform. We are therefore updating this to remove the end date, and rephrase: "End date - either when recruitment target of 70,000 patients is reached or at the end of recruitment of linked clinical trials whichever is later" We have clarified that patients presenting for a second procedure can be recruited for a second time to PQIP. And we have added that if a hospital has an electronic consent form within their electronic health record system, that this can be used to evidence consent to participation in PQIP, in addition to our standard REC approved patient consent forms. We removed the day 3 questionnaire in 2021 and some of the study documents still make reference to it, proposed updates to the consent form and protocol will remove wording referencing it. Some sites have reviewed their capacity to continue with the study and have decided to go through the study shutdown process, this amendment will formally remove those sites from the study.

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**	
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**

Which nations had participating non-NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating non-NHS/HSC organisations after this amendment?	**Yes**	No	No	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 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):	Change to study end date.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
			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):	Removal of wording referring to the day 3 questionnaire.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
			Remove all changes below	

Change 3				
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):	Closure of: - The Shrewsbury and Telford Hospital NHS trust - Hampshire Hospitals NHS Foundation Trust			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
			Remove all changes below	

Change 4				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Other significant 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)*	Allowing the recruitment of patients presenting for a second procedure to be recruited for a second time to PQIP. Allowing hospitals to use electronic consent forms as evidence of patient consent to PQIP. Change to end of study definition.			
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	
Where are the participating non-NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
			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]:*	Pushpsen Joshi
Email address:*	pushpsen.joshi1@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																	
	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)	A
Change 3:	N					(Y)				(Y)				(Y)				(Y)	A
Change 4:	Y					Y				Y				Y				Y	C
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