

# Amendment Tool

v1.2 11 Jun 2020

For office use

QC: No

## Section 1: Project information

Short project title*:	Perioperative Quality Improvement Programme: Patient Study			
IRAS project ID* (or REC reference if no IRAS project ID is available):	215928			
Sponsor amendment reference number*:	SA6			
Sponsor amendment date* (enter as DD/MM/YY):	17 August 2020			
Summary of amendment including justification*:	<p>COVID 19 created an unprecedented public health emergency. Many sites had to suspend recruitment due to redeployment of staff or re-prioritised resources.</p> <p>The amendment will allow to</p> <ol style="list-style-type: none"> <li>1. Reduce face-to-face contact and risk of transmission between patients and research staff</li> <li>2. Include NHS patients who are having their surgery within the private sector</li> </ol>			
Project type:	<input checked="" type="radio"/> Specific study <input type="radio"/> Research tissue bank <input type="radio"/> Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable?:	<input type="radio"/> NHS/HSC REC <input checked="" type="radio"/> <input type="radio"/> Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment?	<input type="radio"/> Yes		<input type="radio"/> No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> 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?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve access to confidential patient information without consent OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve prisoners OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve NHS/HSC organisations prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Which nations had participating NHS/HSC organisations prior to this amendment?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Which nations will have participating NHS/HSC organisations after this amendment?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

## 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 Changes" tab. To add another change, tick 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)*:	Addition of sites undertaking the same activities as existing sites			
Further information (free text):	In some regions NHS cancer work has been delegated to private hospitals as a result of re-allocation of resources for COVID. It is important we include this cohort in PQIP to follow up these NHS patients and evaluate their outcomes in comparison to similar patients receiving care in NHS insititutions			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input type="radio"/> All		<input type="radio"/> Some	
Add <input type="checkbox"/> other change: <input checked="" type="checkbox"/>				

Change 2				
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):	Sites will be able to distribute the PIS either in person, by post or electronically. Research teams will approach the patient over the telephone/video call/ in person to explain the study. Patients will continue to have atleast one hour to consider the study. Consent will then be gained over the telephone/video call or in person depending on site preference			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	
Add <input type="checkbox"/> other change: <input checked="" type="checkbox"/>				

Change 3				
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 (free text):	Additional research question to investigate the impact on processes and outcomes of major surgery. The PQIP study recruited almost 30,000 patients pre-COVID19 we propose to compare processes and outcomes of care before and after the pandemic surge to evaluate the impact of changes in structures and processes of care due to COVID 19.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	
Add <input type="checkbox"/> other change: <input checked="" type="checkbox"/>				

Change 4				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			

Further information (free text):	Changes to the protocol, patient invitation letter and organisational information document reflecting above changes			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input checked="" type="radio"/> All		<input type="radio"/> Some	
Add <input type="checkbox"/> other change: <input checked="" type="checkbox"/>				

Change 5				
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):	Change of PI at Bristol Royal Infirmary. The new PI will be Dr Elizabeth Hood			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input type="radio"/> All		<input checked="" type="radio"/> Some	
Add <input type="checkbox"/> other change: <input checked="" type="checkbox"/>				

Change 6				
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):	Addition of new site - Addenbrookes Hospital. The PI will be Dr Elisa Masoni			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will all participating NHS/HSC organisations be affected by this change, or only some?:	<input type="radio"/> All		<input checked="" type="radio"/> Some	
Add <input type="checkbox"/> other change: <input type="checkbox"/>				

**Section 3: Declaration(s) and lock for submission**

<b>Declaration by the Sponsor or authorised delegate</b>	
<ul style="list-style-type: none"> <li>I confirm that the Sponsor takes responsibility for the completed amendment tool</li> <li>I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf</li> </ul>	
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 PDF copy of the completed amendment tool that can 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, refer to the "Submission Guidance" tab for 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:	N					(Y)				(Y)				(Y)				(Y)	New site
Change 2:	Y					Y				Y				Y				Y	A
Change 3:	N					(Y)				(Y)				(Y)				(Y)	C
Change 4:	N					(Y)				(Y)				(Y)				(Y)	C
Change 5:	N					(Y)				(Y)				N				N	A
Change 6:	N					(Y)				(Y)				N				N	New site
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y				Y	
Notification only:	N					N				N				N				N	
Overall amendment type:	Substantial for review																		
Overall Category:	A																		