

Amendment Tool

v1.6 06 December 2021

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*:	Non-Substantial Amendment 22			
Sponsor amendment date* (enter as DD/MM/YY):	12 July 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)*:	Addition of new PI's. Addition of new Site's.			
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

Section 2: Summary of change(s)

215928_Non-Substantial Amendment 22_12Jul2022_Locked08Aug22_140328.pdf Page 1 of 3

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)*:	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):	North Tees and Hartlepool NHS Foundation Trust - University hospital of North Tees NHS Ayrshire and Arran - University Hospital Crosshouse North Middlesex University Hospital NHS Trust - North Middlesex University Hospital NHS Tayside - Ninewells Hospital NHS Golden Jubilee (National Waiting Times Centre)			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	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	
				Remove all changes below

Change 2				
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):	New PI's: James Wight - Maidstone hospital Matthew Evans - Royal Surrey Suehana Rahman - Royal Free Hospital Geetanjali Verma - North Cumbria Kostas Miltios - Whittington Hospital Christopher Bailey - Betsi Cadwaladr Owen Lewis - Aneurin Bevan University Health Board Danny Wong - St Thomas' Hospital Matthew Jackson - Stockport NHS foundation trust Verma Geetanjali - North Cumbria Integrated Care 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	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	
<ul style="list-style-type: none"> • 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

215928_Non-Substantial Amendment 22_12Jul2022_Locked08Aug22_140328.pdf Page 2 of 3

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

England and Wales:

UK wide: Northern Ireland:

Scotland:

(This area contains a very faint, low-resolution grid of characters, likely a placeholder for a table or data that is illegible in the provided image.)



Category:

Change 1: New site (Y) (Y) (Y)

Change 2:

(Y) (Y) (Y)

B

Overall reviews for the amendment:

Full review:

N N N

Notification only:

Y Y Y

Overall amendment type: Non-substantial, no study-wide review required

Overall Category: B