

Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	Indigo		
IRAS project ID* (or REC reference if no IRAS project ID is available):	324024		
Sponsor amendment reference number*:	NSA_08		
Sponsor amendment date* (enter as DD/MM/YY):	01 August 2025		
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)*:	<p>The following practices have asked to be added:</p> <ul style="list-style-type: none"> - Blackpool Teaching Hospitals NHS Foundation Trust, - Whittington Health NHS Trust, - The Royal Marsden NHS Foundation Trust, - Royal Devon University Healthcare NHS Foundation Trust, - East and North Hertfordshire Teaching NHS Trust, - The Clatterbridge Cancer Centre NHS Foundation Trust, - Andover War Memorial Hospital as part of Hampshire Hospitals NHS Foundation Trust, - Basingstoke and North Hampshire Hospital as part of Hampshire Hospitals NHS Foundation Trust, - Royal Hampshire County Hospital, Winchester as part of Hampshire Hospitals NHS Foundation Trust 		
Project type (select):	Specific study		
	<p>Research tissue bank</p> <p>Research database</p>		
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
	Yes	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	
Was the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device [^] (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	No	
Does the amendment make the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device [^] (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:	Yes	No	
[^] IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination			
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	
Does the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: (e.g. the study relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality)	Yes	No	
Does 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	
Does 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)*:	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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	<p>The following practices have asked to be added:</p> <ul style="list-style-type: none"> - Blackpool Teaching Hospitals NHS Foundation Trust (PI: Preston, Stephen; Research Nurse) - Whittington Health NHS Trust (PI: Hughes, Peta ; Lead Nurse, Acute Oncology Service), - The Royal Marsden NHS Foundation Trust (PI: Droney, Joanne; Consultant in Palliative Medicine), - Royal Devon University Healthcare NHS Foundation Trust (PI: Sr Mooney, Matthew; Clinical Oncology Consultant), - East and North Hertfordshire Teaching NHS Trust (PI: Duncan, Julia; Lead research nurse), - The Clatterbridge Cancer Centre NHS Foundation Trust (PI: Appleton, Lynda; Research Nurse), - Andover War Memorial Hospital as part of Hampshire Hospitals NHS Foundation Trust (PI: Paisey, Sangeeta; Clinical oncologist), - Basingstoke and North Hampshire Hospital as part of Hampshire Hospitals NHS Foundation Trust (PI: Paisey, Sangeeta; Clinical oncologist), - Royal Hampshire County Hospital, Winchester as part of Hampshire Hospitals NHS Foundation Trust (PI: Paisey, Sangeeta; Clinical oncologist) 			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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]*:	Eleanor Izzard
Email address*:	e.izzard@imperial.ac.uk

<p>Lock for submission</p> <p>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.</p> <div style="text-align: center;"> <div>Lock for submission</div> </div> <p>After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.</p>

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)										New site
Overall reviews for the amendment:																			
Full review:					N				N										
Notification only:					Y				Y										
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	New site																		