

Amendment Tool

v1.7 25 March 2025

For office use

QC: No

Section 1: Project information

Short project title*:	Indigo Community			
IRAS project ID* (or REC reference if no IRAS project ID is available):	324034			
Sponsor amendment reference number*:	NSA_03			
Sponsor amendment date* (enter as DD/MM/YY):	22 April 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>With this amendment, we wish to open the study to 3 new sites:</p> <ul style="list-style-type: none"> - Manchester University NHS Foundation Trust, - Worcestershire Acute Hospitals NHS Trust, - Croydon University Hospital. 			
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	
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

	REC	Com	MHR	Com	MHR	ARS	Radi	UKS	REC	CAG	HMP	HRA	REC	PBPI	SPS	Natic	HSC	HSC	Prisc	Natic	Category:
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																				