

Amendment Tool

v1.6 06 December 2021

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*:	SA001			
Sponsor amendment date* (enter as DD/MM/YY):	13 October 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)*:	<p>Following discussions with the Northwest London primary care research network, we will no longer be using physical posters but rely on the primary care research network to identify and contact eligible patients in the first instance. The rest of the methodology has not changed. Typos in the protocol have been updated and figures of eligible patients updated following a separate discussion with an analyst based in Northwest London (number of eligible patients decreased by half).</p> <p>The PIS has been updated to add a section about randomisation as per a reviewer's comment. The questionnaire has been edited to simplify some questions and to remove others.</p> <p>NIHR PCRN Northwest London has also been added as a research site.</p>			
Project type (select):	Specific study			
	<div>Research tissue bank</div> <div>Research database</div>			
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	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)*:	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 - note that this field will adapt to the amount of text entered):	Physical posters will no longer be placed in GP waiting rooms and in the community. Therefore in the analyses, we have removed any analyses related to physical posters.			
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	
Remove all changes below				

Change 2				
Area of change (select)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource 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)*	The primary care research network in Northwest London will facilitate the identification and contact of eligible patients via GP surgery (practices acting as PIC sites) during the first phase of the project. We will then be approaching the other NIHR CRN (Clinical Research Network) in the following location to set up their preferred arrangement for recruitment: East Midlands, East of England, Greater Manchester, Kent Surrey and Sussex, North East and North Cumbria, North Thames, North West Coast, North West London, South London, South West Peninsula, Thames Valley and South Midlands, Wessex, West Midlands, West of England, and Yorkshire and Humber. They will also facilitate the identification and contact of eligible patients, these networks were not previously identified and named on the Part C of the IRAS form.			
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	
Remove all changes below				

Change 3				
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):	We updated the recruitment target in Northwest London reducing it due to updated information on the size of the eligible population.			
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	
Remove all changes below				

Change 4				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) 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 the PIS, added a section about the randomisation during the trial as per a reviewer's comment. In the questionnaire and the end of survey message, we reviewed and corrected			

in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*		Comment: In the questionnaire and the end of survey message, we reviewed and corrected typos, removed questions, reorganised some answers (e.g., the lists of cancer diagnosis available).			
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	
Remove all changes below					

Change 5					
Area of change (select)*:		Participant Procedures			
Specific change (select - only available when area of change is selected first)*:		Participant procedures - minor change that can be implemented within existing resource 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)*		Imperial College London will be a research site as the participants will be using a College-licensed platform and the participants' data will be collected on Imperial College London grounds.			
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	
Remove all changes below					

Change 6					
Area of change (select)*:		Study Documents			
Specific change (select - only available when area of change is selected first)*:		Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) 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)*		The social media posts have been redesigned to be more modern and include more background pictures. Other social media posts may be created to include Trust logos and/or different pictures. However the text seen by potential participants will unlikely change. Filler posts will be generated as the trial progresses in the future.			
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]*:	James Lloyd
Email address*:	james.lloyd@imperial.ac.uk
Lock for submission <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 style="background-color: #90EE90; padding: 5px 20px; display: inline-block;">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				Y									A
Change 2:	N					(Y)				(Y)									C
Change 3:	N					(Y)				(Y)									A
Change 4:	N					(Y)				(Y)									C
Change 5:	N					(Y)				(Y)									C
Change 6:	Y					Y				Y									C
Overall reviews for the amendment:																			
Full review:	Y					Y				Y									
Notification only:	N					N				N									
Overall amendment type:	Substantial																		
Overall Category:	A																		