

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*:	SA_02			
Sponsor amendment date* (enter as DD/MM/YY):	06 September 2024			
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 the pilot study that ran in Northwest London between December 2023 and May 2024, we optimised the questionnaire to improve the enrolment and completion rates (e.g., issues with the consent form, sequencing and wording of questions, typos missed while reviewing the questionnaire). Furthermore, an alternative questionnaire has been added, we wish to get the questionnaire advertised in primary and secondary care services through posters and leaflet, enhance our presence online with more social media posts, and change the main title of the study.</p> <p>The documents affected by these changes are listed in the cover letter (Indigo - cover letter - 2024.10.16_v0.2.docx).</p>			
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	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)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Project identification (e.g. change of title, reference numbers)			
Further information (free text - note that this field will adapt to the amount of text entered):	We wish to change the title of the study, from "Indigo Community" to "Indigo" as it no longer reflects the project ambitions. We wish to simplify the project title to ease the recognition of the work and analyses.			
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)*:	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):	<p>We have worked with companies specialising in online advertisement to promote the digital clinical trial online. Example videos (as per the storyboard "Indigo - Storyboard - 2024.06.20_v4.pptx") and online content were created and more will follow using the same structure, logos, text and/or colour scheme. New contents will be created using a mixture of the structure, logos, text and/or colour schemes already approved by REC/HRA. Set texts will be swapped around in different orders to change the advert that was submitted. Furthermore, posters and leaflets will be made available in primary and secondary care, and health community (e.g., opticians, pharmacists, dentists) locations. These all come following discussions with the PCRN and PPIE input. It became clear that having online and physical content would help to advertise the trial and help with the recruitment rates.</p> <p>Finally, there are communities on WhatsApp that we hope to use to approach participants. This was highlighted by an EAG member who confirmed that community organisations (e.g., faith communities, voluntary groups) have broadcast lists and channels that members can use to keep each other updated. We will be approaching organisations to ask that they use these channels to make their community aware of the research survey. We will not have access to these communities directly or the phone numbers of potential participants. We will share the WhatsApp text template to the people in charge of the WhatsApp channels, and they will send the text message to their communities.</p>			
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 Design			
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study			
Further information (free text - note that this field will adapt to the amount of text entered):	The study was launched in Northwest London with the aim to expand nationally in England so one of the inclusion criteria was "diagnosed and/or treated in England". However, we have had contacts with Wales and other countries in the UK so the inclusion criteria will reflect that expansion.			
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)*:	Participating Organisations								
Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below								
Further information (free text - note that this field will adapt to the amount of text entered):	<p>In October 2024, only 12 CRNs will exist in England, compared to 14 at the moment. Furthermore, they will change their names from Cancer Research Network (CRN) to Research Delivery Network (RDN):</p> <ul style="list-style-type: none"> - North East and North Cumbria - hosted by The Newcastle upon Tyne Hospitals NHS Foundation Trust - Yorkshire and Humber - hosted by Leeds Teaching Hospitals NHS Trust - North West - hosted by Manchester University NHS Foundation Trust - East Midlands - hosted by University Hospitals of Leicester NHS Trust - West Midlands - hosted by The Royal Wolverhampton NHS Trust - East of England - hosted by Norfolk and Norwich University NHS Foundation Trust - North London - hosted by Barts Health NHS Trust - South London - hosted by Guy's & St Thomas' NHS Foundation Trust - South Central - hosted by University Hospital Southampton NHS Foundation Trust - South East - hosted by Royal Surrey NHS Foundation Trust - South West Central - hosted by University Hospitals Bristol and Weston NHS Foundation Trust - South West Peninsula - hosted by Royal Devon University Healthcare NHS Foundation Trust 								
Applicability:	<table border="1"> <tr> <td>England</td> <td>Wales</td> <td>Scotland</td> <td>Northern Ireland</td> </tr> <tr> <td>Yes</td> <td>No</td> <td>No</td> <td>No</td> </tr> </table>	England	Wales	Scotland	Northern Ireland	Yes	No	No	No
England	Wales	Scotland	Northern Ireland						
Yes	No	No	No						
Where are the participating NHS/HSC organisations located that will be affected by this change?*									
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								
Remove all changes below									

Change 5									
Area of change (select)*:	Study Design								
Specific change (select - only available when area of change is selected first)*:	New arm - Addition of a study arm or placebo/control group								
Further information (free text - note that this field will adapt to the amount of text entered):	<p>Following the preliminary analyses, we wish to include a new questionnaire to be compared to EQ-5D-5L (i.e., the baseline questionnaire) and the other questionnaires offered as part of the randomisation. This new validated questionnaire, Quality of Life in Adult Cancer Survivors (QLACS), was suggested by a member of our Expert Advisory Group (EAG). The randomisation will vary between 1:2 to 1:4 (i.e., EORTC QLQ-C30, PGI, SDI, QLACS) and depending on the results, and we will adjust the questionnaires depending on the ongoing analyses.</p> <p>We shall use the latest version of the SDI comprising 24 questions instead of 21 as we have used in the pilot study.</p> <p>Furthermore, there will be a sub-randomisation 1:2 for QLACS to explore the people's preferences on how the new questionnaire is displayed (i.e., using radio buttons or dropdown lists).</p> <p>These changes are reflected in the documents "Indigo - full initial questionnaire - 2024.11.10_v1.6.pdf", "Indigo - Comparison of the two versions of the Indigo - 2024.10.11_v1.1.pptx" and "Indigo - survey flow - 2024.10.11_v1.2.pptx".</p>								
Applicability:	<table border="1"> <tr> <td>England</td> <td>Wales</td> <td>Scotland</td> <td>Northern Ireland</td> </tr> <tr> <td>Yes</td> <td>No</td> <td>No</td> <td>No</td> </tr> </table>	England	Wales	Scotland	Northern Ireland	Yes	No	No	No
England	Wales	Scotland	Northern Ireland						
Yes	No	No	No						
Where are the participating NHS/HSC organisations located that will be affected by this change?*									
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								
Remove all changes below									

Change 6				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Protocol - Substantial changes (e.g. 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):	The protocol reflects the changes mentioned above, and correction of typos throughout the document.			
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 7				
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)*	<p>- Following the new template designed and written by Imperial College London, we updated our consent by merging the first and eighth question. We also reflected a discussion with our sponsor regarding the conditions on the consent and how participants can still take part even though they disagree with some questions. The consent form was also reviewed and approved by our PPIE groups.</p> <p>- The transparency notice was already reviewed by the FOM-GDPR team, and the amendment does not impact the transparency notice. On the PIS, it is shown as a hyperlink to download the document on the participant's personal device.</p> <p>- The patient information sheet (PIS) and the sequence of questions in the survey have also</p>			
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 8				
Area of change (select)*:	Administrative details for the project			
Specific change (select - only available when area of change is selected first)*:	Contact details - Funder			
Further information (free text - note that this field will adapt to the amount of text entered):	Macmillan has agreed to fund this study, with a grant of £100,000. Imperial Health Charity has also agreed to fund this study with a grant of £38,000.			
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 9	
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):	Patients may be made aware of the study by seeing physical media (posters, leaflets) in primary and secondary care locations. They may also be approached by mail out following database (e.g., EMIS, SystmOne) searches conducted by organisations. These searches will map to the eligibility criteria for the trial and take account of research opt out and contact preferences

Further information (free text - note that this field will adapt to the amount of text entered):

preferences.

As per our agreement process, detailed above, with the CRNs and practices, the following practices have been asked to be added:

- Hampshire and Isle of Wight Healthcare NHS Foundation Trust,
- North Cumbria Integrated Care NHS Foundation Trust,
- Kent Community Health 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	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

- 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]*:	becky.ward@imperial.ac.uk
Email address*:	becky.ward@imperial.ac.uk

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

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																		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)									C
Change 2:	Y					Y				Y									A
Change 3:	N					(Y)				(Y)									A
Change 4:	Y					Y				Y									A
Change 5:	Y					(Y)				(Y)									A
Change 6:	Y					Y				(Y)									A
Change 7:	Y					Y				Y									C
Change 8:	N					(Y)				(Y)									C
Change 9:	N					(Y)				(Y)									New site
Overall reviews for the amendment:																			

Full review:	Y					Y				Y									
Notification only:	N					N				N									
Overall amendment type:	Substantial																		
Overall Category:	A																		
For national coordinating function office use:																			
Update HARP:	This amendment may involve an update to contact details, project end date, or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.																		