

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	United Kingdom Adult ITP Registry			
IRAS project ID* (or REC reference if no IRAS project ID is available):	IRAS Project ID: 92703. REC reference: 07/H0718/57			
Sponsor amendment reference number*:	Substantial amendment 8			
Sponsor amendment date* (enter as DD/MM/YY):	21 September 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)*:	Change of Study CI and updates to relevant study documents			
Project type (select):	<div>Specific study</div> <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):	<div>NHS/HSC REC</div> <div>Ministry of Defence (MoDREC)</div>			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (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?:	<div>England</div> <div>Yes</div>	<div>Wales</div> <div>No</div>	<div>Scotland</div> <div>No</div>	<div>Northern Ireland</div> <div>No</div>
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		
Lead nation for the study:	<div>England</div> <div>Yes</div>	<div>Wales</div> <div>No</div>	<div>Scotland</div> <div>No</div>	<div>Northern Ireland</div> <div>No</div>
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)

**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)*:	Researchers			
Specific change (select - only available when area of change is selected first)*:	CI - New CI, or temporary arrangements to cover the absence of a CI			
Further information (free text - note that this field will adapt to the amount of text entered):	Dr Vickie McDonald is stepping down as the CI for the study. Dr Frederick Chen will be taking over as the new study CI. The protocol, patient information sheets, consent forms and study proformas have all been amended to reflect this change.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):	All		Some	
			Remove all changes below	

  

Change 2				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Correction of typographical errors			
Further information (free text - note that this field will adapt to the amount of text entered):	Updating the addressee details relating to where samples need to be delivered in the protocol and correcting errors in the proformas. Point 3 of the informed consent agreement is being amended to match the wording with HRA templates, enabling sponsor representatives and regulatory authorities to review participant medical records as required for the research study. Study invitation letters are being amended so that they may be used for all ITP cases.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	Yes
Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> 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)*:	Mays Jawad
Email address*:	research.amendments@qmul.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											
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 Appl	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating	HSC REC	HSC Data Guardians	Prisons	National coordinating	Category:
Change 1:	Y					Y				(Y)				(Y)				(Y)	C
Change 2:	N					N				N				N				N	N/A
Overall reviews for the amendment:																			
Full review:	Y					Y				N				N				N	
Notification only:	N					N				Y				Y				Y	
Overall amendment type:	Substantial																		
Overall Category:	C																		
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.																		