Modification Tool

v2.1 24 April 2026

For office use

QC: No

Section 1: Project information

Short project title*:	PROTECT-DIVERSITY
IRAS project ID* (or REC reference if no IRAS project ID is available):	350756
Sponsor modification reference number*:	Modification of an Important Detail 1
Sponsor modification date* (enter as DD/MM/YY):	20 July 2026
Briefly summarise in lay language the main changes proposed in this modification. Explain the purpose of the changes and their significance for the project. If the modification 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)*:	The following will be changed for the PROTECT-DIVERSITY trial: 1. Addition of two new NHS sites 2. Updated wording in the PROTECT-DIVERSITY appendix 3. Updated wording in the PROTECT-DIVERSITY PIS 4. Change of trial Lead Statistician 5. An extension to the study end date

Project type (select):	**Specific project**			
	Research tissue bank			
	Research database			
Has the project been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this modification?:	**Yes**	No		
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the project based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the project a clinical trial of an investigational medicinal product (CTIMP) OR does the modification make it one?:	Yes		**No**	
Was the project a clinical investigation or other study of a medical device OR does the modification make it one?:	Yes		**No**	
Was the project 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 modification make the project 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 project involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the modification introduce this?:	Yes		**No**	
Did the project involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the modification introduce this?:	Yes		**No**	
Did the project involve adults lacking capacity OR does the modification introduce this?:	Yes		**No**	
Does the project involve access to confidential patient information outside the direct care team without consent OR does the modification introduce this?: (e.g. the project 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 project involve prisoners or young offenders who are in custody or supervised by the probation service OR does the modification introduce this?:	Yes		**No**	
Does the project involve children OR does the modification introduce this?:	Yes		**No**	
Did the study involve NHS/HSC organisations prior to this modification?:	**Yes**	No		
Did the study involve non-NHS/HSC organisations OR does the modification 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 modification?	**Yes**	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this modification?	**Yes**	No	**Yes**	No

Section 2: Summary of change(s)

Please note: Each change being made as part of the modification must be entered separately. For example, if a modification 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 modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Participating organisations			
Specific area of change (select - only available when area of change is selected first)*:	Adding 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 participants/carers (free text - note that this field will adapt to the amount of text entered):	1. Addition of two new NHS sites: a) Sheffield Teaching Hospitals NHS Foundation Trust; PI: Ella Quintela; ella.quintela@nhs.net b) West Hertfordshire Teaching Hospitals NHS Trust; PI: Nidhi Gautam; nidhi.gautam@nhs.net			
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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Protocol - non-significant changes that do not affect safety or the scientific value			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	2. The following updates were made to wording in the protocol: a) Statistician name, address and email updated. b) Addition of Bengali to the translated languages available for the intervention group. c) Removal of wording to say electronic and paper consent are assigned randomly. d) Clarification of statistical design and method of analysis.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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)*:	Project documents			
Specific area of change (select - only available when area of change is selected first)*:	Other non-significant change to project documents that can be implemented within existing resource in place at participating organisations - please specify in the free text below			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers. 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)*	3. The following updates were made to the wording in the PIS: a) Clarification that multi-lingual vs english consent materials are the intervention in the study. b) Updated trial team admin email address. c) Updated study website address.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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)*:	Key project roles			
Specific area of change (select - only available when area of change is selected first)*:	Changes to the research team			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	4. The Lead Statistician for the study was updated to Jo Haviland; j.haviland@qmul.ac.uk			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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)*:	Project design			
Specific area of change (select - only available when area of change is selected first)*:	Change to project duration (no change to project end definition, treatment or interventions, or monitoring arrangements) that will not have any additional resource implications for participating organisations - please specify in the free text below			
Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered):	5. The study end date will now be 01/08/2028, following a no-cost extension to the grant from the British Journal of Anaesthesia.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	**Yes**	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 modification tool
- I confirm that I have been formally authorised by the Sponsor to complete the modification 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 modification tool which must be included in the modification submission. Please ensure that the modification tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the modification online. The "Submission Guidance" tab provides further information about the next steps for the modification.

Section 4: Review bodies for the modification

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 Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	N					(Y)				(Y)				(Y)					New site
Change 2:	N					(Y)				(Y)				(Y)					A
Change 3:	N					(Y)				(Y)				(Y)					C
Change 4:	N					N				N				N					N/A
Change 5:	(Y)					(Y)				(Y)				(Y)					C
Overall reviews for the modification:																			
Full review:	N					N				N				N					
Notification only:	Y					Y				Y				Y					
Overall modification type:	Modification of an Important Detail																		
UKSW Governance:	NHS/HSC review is not required																		
Overall Category:	A																		

Please note: The modification tool has been revised to provide updated classifications in line with the new regulations. However, IRAS has not been updated and will still require you to submit using the old classifications. This section provides guidance on which option to select in order to ensure the modification is processed correctly:

Your modification should be submitted as a **non-substantial, no study-wide review required amendment**