Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	PROTECT-AEGIS
IRAS project ID* (or REC reference if no IRAS project ID is available):	1011239
Sponsor amendment reference number*:	Subsatntial amendment 1
Sponsor amendment date* (enter as DD/MM/YY):	29 July 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)*:	1. Update to the reference safety information for ibuprofen 400mg solution for infusion 2. Minor changes to the PROTECT-AEGIS appendix including: i. Sections 7.2, 11.1, 13.8, 11.2, 11.3, 11.4, and section 14. 3. Changes to the PROTECT-AEGIS Informed Consent Form and econsent form 4. PROTECT MAster protocol, PIS and ICF have also been updated and included for information only.

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	
EudraCT number* (if the study has a EudraCT number enter it here. If the study does not have a EudraCT number enter "N/A"):	N/A			
Was this clinical trial of an investigational medicinal product (CTIMP) processed under the CTIMP combined review service (formerly known as the Combined Ways of Working (CWoW) pilot)?:	**Yes**		No	
Did the study receive Pharmacy Assurance?:	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
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	**Yes**	No

Section 2: Summary of change(s)

What do you want to update?:	Chief Investigator Sponsor Group Administrative **Project information**

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)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	IB, SmPC - Substantial changes (e.g. affecting the risk/benefit assessment; changing Reference Safety Information)			
Where a substantial change is being made to the IB or SmPC (e.g. affecting the risk/benefit assessment), it would normally be expected that this would be accompanied by a significant change to study documents (e.g. information sheets) to notify participants about the updated risk/benefit assessment. Please enter a separate change in the amendment tool for a significant change to study documents or provide a justification in the free text below setting out why the study documents are not being updated:				
Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered)*:	1. Update to the reference safety information (section 4.8) for Ibuprofen 400 mg solution for infusion. The version dated 09/02/2024 will now be used to monitor any adverse reactions for participants administered ibuprofen intravenously. The following sections were updated: Section 4.2 - Posology and method of administration Section 4.4 - Special warnings and precautions for use Section 4.8 - Undesirable effects			
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 2				
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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered):	2.Changes to the PROTECT-AEGIS appendix including: i.Section 7.2 and 11.1, updated in accordance to the MHRA notice of acceptance of amended request letter. ii.Section 13.8 requirement for the PI or a medical delegate to prescribe the trial IMP. iii.Clarification to wording in randomisation sections 11.2 and 11.3 iv.Removal of some study assessments from the PROTECT-AEGIS comparison as they are already captured under the PROTECT Master protocol v.Clarifications to the pharmacovigilance section which include changes to the wording.			
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)*:	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: explain what the change is, why the	

Further information: explain what the change is, why the change is being made and any possible impact on study 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. Changes to the PROTECT-AEGIS consent form: i. Removal of email address field as this is already captured as part of the PROTECT consent form. ii. The econsent module has also been updated to bring this in line with the above changes.

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 amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Applicant identification:	**Sponsor** Legal representative of the sponsor Person or organisation authorised by the sponsor
Organisation:	Queen Mary University of London
Name [first name and surname]:*	Mays Jawad
Address:	
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	
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, amendments to trials processed under the combined review service should be made using the new part of IRAS. Further information can be found on the "Submission Guidance" tab.

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 Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:		Y				(Y)				(Y)				(Y)					C
Change 2:		N				(Y)				(Y)				(Y)					A
Change 3:		N				(Y)				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:		Y				N				N				N					
Notification only:		N				Y				Y				Y					
Overall amendment type:	Substantial for information																		

Overall Category:	A