

# Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	PARAMEDIC-3			
IRAS project ID* (or REC reference if no IRAS project ID is available):	298182			
Sponsor amendment reference number*:	Substantial Amendment One			
Sponsor amendment date* (enter as DD/MM/YY):	29 November 2021			
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)*:	Changes to the protocol that reflects our plan to co-enrol between the PARAMEDIC-3 and POSED studies, and the implications of this on our strategy to informing relatives of study participants who have died.			
Project type (select):	<input checked="" type="radio"/> Specific study <input type="radio"/> Research tissue bank <input type="radio"/> Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<input checked="" type="radio"/> NHS/HSC REC <input type="radio"/> Ministry of Defence (MoDREC)			
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)?	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> 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?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve prisoners OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve children OR does the amendment introduce this?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Did the study involve NHS/HSC organisations prior to this amendment?:	<input checked="" type="radio"/> Yes		<input type="radio"/> No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	<input type="radio"/> Yes		<input checked="" type="radio"/> No	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Which nations had participating NHS/HSC organisations prior to this amendment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Which nations will have participating NHS/HSC organisations after this amendment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 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, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design that will have additional resource implications for participating organisations - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	Plan to co-enrol between the PARAMEDIC-3 and POSED and differing approach to informing relatives of trial participants when the individual has been enrolled in both POSED and PARAMEDIC-3.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

Change 2				
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):	<p>Page 2- Amend trial manager name/ contact email address</p> <p>Page 6- Addition of Professor Stephen Brett as member of data monitoring committee</p> <p>Section 1.5- Minor text amendment to clarify that a passive information approach may not be used across all trial participants</p> <p>Figure one- Clarification on how national data opt-out will be captured in the CONOSRT flow chart</p> <p>Section 2.7.3- Addition of text to clarify our approach to informing relatives of trial participants when the individual has been enrolled in both POSED and PARAMEDIC-3.</p> <p>Section 2.9.2- Minor text amendment to ensure consistency between section 2.9.1 and 2.9.2</p> <p>Table two-</p> <ul style="list-style-type: none"> <li>•Clarification that health resource use information will be collection</li> <li>•Clarification of need to check regarding national data opt-out</li> </ul> <p>Section 3.2- Text amendment to clarify the different ways in which follow-up questionnaires can be completed</p> <p>Section 5- Addition of text to confirm need to check regarding national data opt-out, and process which should then be followed</p> <p>Section 6.1- Addition of text to confirm that individuals randomised but whose data cannot be used due to the national data opt-out will not be counted for the purposes of the sample size</p>			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> 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]*:	Mathew Gane
Email address*:	sponsorship@warwick.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:	N					(Y)				(Y)									A
Change 2:	Y					Y				(Y)									A
Overall reviews for the amendment:																			
Full review:	Y					Y				N									
Notification only:	N					N				Y									
Overall amendment type:	Substantial																		
Overall Category:	A																		