

# Amendment Tool

v1.8 30 April 2025

For office use

QC: No

## Section 1: Project information

Short project title*:	SepTIC		
IRAS project ID* (or REC reference if no IRAS project ID is available):	1005848		
Sponsor amendment reference number*:	AM011		
Sponsor amendment date* (enter as DD/MM/YY):	15 December 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)*:	<p>We would like to make the following changes to the trial:-</p> <ol style="list-style-type: none"> <li>1. Add new sites</li> <li>2. Change the name of one site</li> <li>3. Change a PI at one site</li> <li>4. Make slight changes to the patient information sheets and consent forms.</li> <li>5. Added stipulation that ACCPs can assess eligibility of Diagnostic and Fluid patients.</li> </ol>		
Project type (select):	<b>Specific study</b>		
	<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?:	<b>Yes</b>	No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	<b>NHS/HSC REC</b>		
	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)?	Yes	<b>No</b>	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland
	<b>Yes</b>	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<b>Yes</b>	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)?:	<b>Yes</b>	No	
Did the study receive Pharmacy Assurance?:	Yes	<b>No</b>	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes	<b>No</b>	
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	<b>No</b>	
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	<b>No</b>	
^ 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	<b>No</b>	
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	<b>No</b>	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<b>Yes</b>	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	<b>No</b>	
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	<b>No</b>	

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	Yes	Yes	Yes
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	Yes	Yes	Yes

## 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)*:	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: 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):	<p>1. We would like to add the following new sites and Principal Investigators:-</p> <ul style="list-style-type: none"> <li>-Morrison Hospital – PI Dr Rowenna Morris Clarke</li> <li>-Queen Elizabeth Hospital (Woolwich) - PI Dr Nicholas Beaumont</li> <li>-University Hospital Lewisham – PI Dr Nicholas Beaumont</li> <li>-Doncaster Royal Infirmary – PI Dr Ahjit Chowdhury</li> <li>-Princess Alexandra Hospital – Dr Khalid Abdelrahman</li> <li>-West Middlesex Hospital - Dr Theodora Christodouloupoulou</li> </ul> <p>2. We would like to change the name of the following site:-</p> <ul style="list-style-type: none"> <li>-Change site name from Queen Elizabeth Hospital Birmingham to University Hospitals Birmingham NHS Foundation Trust (PI remains the same as Dr Dhruv Parekh)</li> </ul>			
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? ( <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)*:	Researchers
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or temporary arrangements to cover the absence of a PI
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):	<p>3. We would like to change the following Principal Investigator</p> <ul style="list-style-type: none"> <li>-Southampton General – change of PI from Dr Cusack to Prof. Kordo Saeed</li> </ul>

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? ( <b>please note</b> 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 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: 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)*	4. We would like to make a slight amendment to our patient facing consent forms (full information sheet and consent form, the information sheet summary and consent form, the full retrospective information sheet and consent form and the retrospective information sheet summary and consent form. The change is to include an option for patients to 'tick' the consent boxes, as an alternative to including initials. As our population are admitted to ICU we have received feedback that most of these patients have a rather weak hand once they regain capacity and they would find ticking boxes easier than initialling each box. The requirement to print and sign their name still remains. If a patient does not agree to a consent statements they are instructed to mark an X in the relevant box.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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 4				
Area of change (select)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Participant procedures - minor change that can be implemented within existing resource 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 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)*	5. The CI would like to stipulate that ACCPs (Advanced Critical Care Practitioners) are able to assess eligibility for patients in SepTiC for the Diagnostic and Fluid part of the trial only. Medically qualified doctors will continue to be able to assess eligibility of patients in all parts of the SepTiC Trial. The ACCPs must be adequately trained in GCP and the protocol and are listed on the delegation log. ACCPs are highly experienced and educated healthcare professionals who work within a critical care team, assessing, diagnosing, and managing critically ill patients. They provide a crucial level of advanced care by performing diagnostic and therapeutic procedures, managing patient care plans, and performing invasive interventions under a consultant-led service. Therefore, ACCPs are well suited to access eligibility of these patients. Overall oversight will still be maintained by the PI and is agreed by the CI and Sponsor.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	No	No	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]*:	Amalia Ndoutoumou
Email address*:	rgit.ctimp.team@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, 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																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)								(Y)	New site
Change 2:	N					(Y)				(Y)								N	B
Change 3:	Y					Y				Y								Y	C
Change 4:	N					(Y)				(Y)								(Y)	C
Overall reviews for the amendment:																			
Full review:	Y					Y				Y								Y	
Notification only:	N					N				N								N	
Overall amendment type:	Substantial for review																		
Overall Category:	B/C																		