Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	EVIS
IRAS project ID* (or REC reference if no IRAS project ID is available):	307862
Sponsor amendment reference number*:	Substantial Amendment 08
Sponsor amendment date* (enter as DD/MM/YY):	14 February 2024
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). Addition of Aintree University Hospital as a participating site, PI Dr Ben Morton. 2). Removal of Sandwell Hospital, West Bromwich as a participating site, PI Dr Hema Patel. 3). Removal of City Hospital, Birmingham as a participating site, PI Dr Hema Patel. 4). Non-Substantial Changes to the Protocol: A) Administrative updates: versioning. B) Added Appendix H to include further information regarding the imbedded process evaluation. C) Updated the description of the permitted medications to match the updated SpMC for noradrenaline. D) Updated the description of the imbedded process evaluation to match the addition of the new appendix H, to provide further information regarding the imbedded process evaluation sub-study. E) Updated the wording to clarify who will have access to the signed and uploaded informed consent forms. F) Updates to the data linkage description to clarify regarding where the responsibility for submitting the record linkage applications sits. G) Updates to the record retention and archiving arrangements to ensure consistency across study documentation, in relation to the length of time that study documents will be retained. 5). Minor updates to the; Main PIS/ICF, PIS Summary, Welfare Attorney/Guardian, Professional Legal Rep (Scotland & England), Recovered Capacity (Scotland & England) and Personal Legal Rep PIS/ICF's to; A) Update the wording regarding how long the Sponsor and participating sites will be retaining participant information, to ensure consistency across study documentation. B) Updated the wording to clarify who will have access to the signed and uploaded informed consent forms. C) Clarity added to the information provided regarding the duration of treatment and data collection. 6). Submission of a EVIS Consent Form, PIS and Interview Guide for the Qualitative Research in the context of the Early Vasopressors in Sepsis (EVIS) Trial imbedded EVIS Process Evaluation.

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
	No	No	**Yes**	No

Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	**Yes**	No
EudraCT number*:	2021-006886-39	
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**
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**

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	No	No	**Yes**	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)*:	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 (free text - note that this field will adapt to the amount of text entered):	1). Addition of Aintree University Hospital as a participating site, with PI Dr. Ben Morton			
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)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Early closure or withdrawal of research sites			
Further information (free text - note that this field will adapt to the amount of text entered):	2). Removal of Sandwell Hospital, West Bromwich as a participating site, PI Dr Hema Patel.			
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 3	
Area of change (select)*:	Participating Organisations
Specific change (select - only available when area of change is selected first)*:	Early closure or withdrawal of research sites
Further information (free text - note that this field will adapt to the amount of text entered):	3). Removal of City Hospital, Birmingham as a participating site, PI Dr Hema Patel.

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 4	
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 (free text - note that this field will adapt to the amount of text entered):	4). Non-Substantial Changes to the Protocol: A) Administrative updates: versioning. B) Added Appendix H to include further information regarding the imbedded process evaluation. C) Updated the description of the permitted medications to match the updated SpMC for noradrenaline. D) Updated the description of the imbedded process evaluation to match the addition of the new appendix H, to provide further information regarding the imbedded process evaluation sub-study. E) Updated the wording to clarify who will have access to the signed and uploaded informed consent forms. F) Updates to the data linkage description to clarify regarding where the responsibility for submitting the record linkage applications sits. G) Updates to the record retention and archiving arrangements to ensure consistency across study documentation, in relation to the length of time that study documents will be retained.

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)*:	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 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). Minor updates to the; Main PIS/ICF, PIS Summary, Welfare Attorney/Guardian, Professional Legal Rep (Scotland & England), Recovered Capacity (Scotland & England) and Personal Legal Rep PIS/ICF's to; A) Update the wording regarding how long the Sponsor and participating sites will be retaining participant information, to ensure consistency across study documentation. B) Updated the wording to clarify who will have access to the signed and uploaded informed consent forms. C) Clarity added to the information provided regarding the duration of treatment and data

	collection.

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 6	
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 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)*	6). Submission of a EVIS Consent Form, PIS and Interview Guide for the Qualitative Research in the context of the Early Vasopressors in Sepsis (EVIS) Trial imbedded EVIS Process Evaluation.

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

Name [first name and surname]:*	Alison Hamilton
Email address:*	alison.hamilton@ggc.scot.nhs.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:	N					(Y)				(Y)				(Y)					New site

Change 2:	N					(Y)				(Y)				N					B
Change 3:	N					(Y)				(Y)				N					B
Change 4:	N					(Y)				(Y)				(Y)					A
Change 5:	Y					Y				Y				Y					C
Change 6:	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:	A																		