Amendment Tool

v1.6 06 December 2021

QC: No

Short project title*:	EVIS				
IRAS project ID* (or REC reference if no IRAS project ID is available):	307862				
Sponsor amendment reference number*:	Substantial Amendm	nent 05			
Sponsor amendment date* (enter as DD/MM/YY):	20 December 2022				
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)*:	 Substantial Chan peripheral vasopress criteria, allowing for p the cases where Ext appendix has been ii (C) Specification of k administration of IMF titration requirements vasopressor adminis Revision to the guida statistics and data ar in a separate statistic sole data controller fi be conducted, which information will be sh 2) Non-Substantial C Clarification regardin to archiving in line wi Updated appendix E 3). Withdrawal of St 4). Withdrawal of Ro 	Sor administration, r peripheral norepine ravasation resulted noserted (Appendix I rey secondary outco s to allow for delay to stration in the event ance for the adminis nalysis section of th cal analysis plan. (H or the purposes of or linkers will be colle nared with. Changes to protocol g CTIMP to Non-CT ith sponsor SOP's. for SOFA score. (F Johns, Edinburgh a	hamely updated s obrine infusion to in temporary tisss B) that includes au omes. (D). Section s for managemen o treatment start that the target <i>M</i> / stration of rescue e protocol, in line) Inclusion that Th data linkage only. cted and which sp : (A) Administrativ TIMP co-enrolmer (D) Updated apper) Standardisation s a participating s	afety information a be restarted at a d ue injury (grade 1 of n extravasation as: n added on concor t of COVID-19. (E) and/or temporary f AP > 65 mmHg is a vasopressors. (G) with the specifics r ie University of Edi Clarification on ho becific NHS depart re updates: version t. (C) Updated ins endix A for dosing g of MAP > 65 mmH ite.	nd stopping ifferent PVC site or 2). (B) A new sessment score. mitant . Revision to dos halt to peripheral achieved. (F). . Updates to the now to be capture inburgh will act at w data linkage w ments this hing. (B) tructions in regar guidance. (E)
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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?:	Y	es		No
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Y	es		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?:	Y	es		No
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Y	es		No
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Y	es		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?:	Y	es		No
Did the study involve children OR does the amendment introduce this?:	Y	es		No
Did the study involve NHS/HSC organisations prior to this amendment?:	Y	es		No
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Y	es		No
	England	Wales	Scotland	Northern Irelan
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?:	Project information
	New site/PI only

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)*:	Protocol - Substantia	l changes (e.g. affe	ecting safety or the	scientific value of	the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	 Substantial Chang peripheral vasopress criteria, allowing for p the cases where Extr appendix has been ir (C) Specification of kk administration of IMP titration requirements vasopressor adminis Revision to the guida statistics and data an in a separate statistic sole data controller for be conducted, which information will be sh 	or administration, i eripheral norepine avasation resulted iserted (Appendix ey secondary outco s with intervention- to allow for delay tration in the event nce for the admini- alysis section of the al analysis plan. (For the purposes of linkers will be colle	namely updated sa phrine infusion to b in temporary tissu B) that includes an omes. (D). Section s for management to treatment start a that the target MA stration of rescue v e protocol, in line v 1). Inclusion that T1 data linkage only. (afety information are be restarted at a di le injury (grade 1 o extravasation ass added on concom of COVID-19. (E). and/or temporary h P > 65 mmHg is a rasopressors. (G). with the specifics n he University of Ed Clarification on how	nd stopping fferent PVC site in r 2). (B) A new essment score. nitant Revision to dose alt to peripheral chieved. (F). Updates to the ow to be captured inburgh will act as v data linkage will
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations locat by this change?*:	ed that will be affected	Yes	No	Yes	No
Will all participating NHS/HSC organisations be affected b some? (please note that this answer may affect the categories change):		ŀ	All	So	ome
				Remove all c	hanges below
Г					
	Change 2				

Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	Protocol - Non-substa	intial changes (e.g	. not affecting safe	ty or the scientific	value of the trial)
Further information (free text - note that this field will adapt to the amount of text entered):	2) Non-Substantial Cl Clarification regarding to archiving in line wit Updated appendix E	CTIMP to Non-C	TIMP co-enrolment (D) Updated appe	t. (C) Updated inst ndix A for dosing g	ructions in regards juidance. (E)
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations locate by this change?*:	ed that will be affected	Yes	No	Yes	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categ change):		A	li	So	ome
				Remove all c	changes below

	Change 3				
Area of change (select)*:	Participating Organisa	ations			
Specific change (select - only available when area of change is selected first)*:	Early closure or withd	rawal of research	sites		
Further information (free text - note that this field will adapt to the amount of text entered):	3). Withdrawal of St J	ohns, Edinburgh a	s a participating si	te.	
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations locate by this change?*:	d that will be affected	No	No	Yes	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categor change):		Ą	All	So	ome
				Remove all c	hanges below

	Change 4				
Area of change (select)*:	Participating Organisa	ations			
Specific change (select - only available when area of change is selected first)*:	Early closure or withd	rawal of research	sites		
Further information (free text - note that this field will adapt to the amount of text entered):	4). Withdrawal of Roy	al Victoria Infirmar	y, Newcastle as a	participating Site.	
Applicability:		England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations locate by this change?*:	ed that will be affected	Yes	No	No	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categ change):		Ą	All	So	ome
				Remove all o	changes below

	Change 5				
Area of change (select)*:	Participating Organis	ations			
Specific change (select - only available when area of change is selected first)*:	Addition of sites unde	ertaking the same a	activities as existing	g sites	
Further information (free text - note that this field will adapt to the amount of text entered):	5). Addition of Peters	borough City Hosp	ital as a participati	ng site, PI Dr. Chri	istopher Edmunds
Applicability:	·	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations locate by this change?*:	ed that will be affected	Yes	No	No	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categories of the categorie	, , ,	ļ	All	So	ome

	Change 6				
Area of change (select)*:	Researchers				
Specific change (select - only available when area of change is selected first)*:	PI - New PI, or tempo	rary arrangements	to cover the abse	nce of a Pl	
Further information (free text - note that this field will adapt to the amount of text entered):	6). Change of PI at pa Ravindra Pochiraju.	articipating site 26.	Leicester Royal Ir	firmary from Dr. S	cott Knapp to Dr
Applicability:		England	Wales	Scotland	Northern Irelan
Where are the participating NHS/HSC organisations locate by this change?*:	d that will be affected	Yes	No	No	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the catego change):		A	II	S	ome
				Remove all o	changes below
	Change 7				
Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	Other significant char questionnaires, letters organisations - Please	s) that will have ad	ditional resource in		
Further information In particular, please describe the additional resource arrangements that participating organisations will need to have in place to implement this change (free text - note that this field will adapt to the amount of text entered)*:	 Substantial update information on data lin conducted). Correctio completion of the heat 	nkage, data contro in of a previous err	ship for data linka or, from 180 day f	ge purpose and he ollow up to 90 day	ow it will be
Applicability:		England	Wales	Scotland	Northern Irelan
Where are the participating NHS/HSC organisations locate by this change?*:	d that will be affected	Yes	No	Yes	No
Will all participating NHS/HSC organisations be affected by some? (please note that this answer may affect the categor change):		Α	II	S	ome
				Remove all o	changes below
	Change 8				
Area of change (select)*:	Change 8 Study Documents				
Area of change (select)*: Specific change (select - only available when area of change is selected first)*:	·	s) that can be imple	emented within ex	sting resource in p	
Specific change (select - only available when area of	Study Documents Other minor change t questionnaires, letters	s) that can be imple tions - Please spec he clinical informat	emented within ex bify in the free text ion sheets for the	sting resource in p below	blace at
Specific change (select - only available when area of change is selected first)*: 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	Study Documents Other minor change t questionnaires, letters participating organisa 8). Minor updates to t	s) that can be imple tions - Please spec he clinical informat	emented within ex bify in the free text ion sheets for the	sting resource in p below	blace at
Specific change (select - only available when area of change is selected first)*: 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)*	Study Documents Other minor change t questionnaires, letters participating organisa 8). Minor updates to t arms, to match the up	s) that can be imple tions - Please spec he clinical informat dated protocol wo	emented within ex ify in the free text ion sheets for the rding.	sting resource in p below intervention and s	tandard of care
Specific change (select - only available when area of change is selected first)*: 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)* Applicability: Where are the participating NHS/HSC organisations locate	Study Documents Other minor change t questionnaires, letters participating organisa 8). Minor updates to t arms, to match the up d that will be affected this change, or only	s) that can be imple tions - Please spec he clinical informat odated protocol wo England	emented within ex ify in the free text ion sheets for the rding. Wales No	sting resource in p below intervention and s Scotland Yes	tandard of care

Section 3: Declaration(s) and lock for submiss	sion				
Declaration by the Sponsor or authorised delegate					
 I confirm that the Sponsor takes responsibities I confirm that I have been formally authorised 	lity for the completed amendment tool ed by the Sponsor to complete the amendment tool on their behalf				
	Sponsor				
Applicant identification:	Legal representative of the sponsor				
	Person or organisation authorised by the sponsor				

Organisation:	R&I NHS GG&C
Name [first name and surname]*:	Pamela Sandu
Address:	Ward 11, Dykebar Hospital, Grahamston Road
Telephone number:	
Fax number:	
Purchase Order (PO) number for MHRA invoicing:	
Email address*:	pamela.sandu@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, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Z Z - Competent Authority MHRA - Medicines Competent Authority	MHRA - Devices	ARSAC	Radiation Assurance	(3) ≺ UKSW Governance	REC (MCA)		Review and Wa		REC (AWIA)	Scot	Iand:	S S National coordinating function	HSC REC	HSC Data Guardians	suosiju	National coordinating function	Category A
Z - Competent Authority MHRA - Medicines Competent Authority	JIIIY		Radiation Assurance	Y				G HRA and HCRW Approval	REC (AWIA)			(Y)	REC	Data Guardians		-	A
Y N	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	Y	REC (MCA)	CAG	SHAMH	(Y)	REC (AWIA)	РВРР	SPS (RAEC)	(Y)	HSC REC	Data	Prisons	National coordinating function	A
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