

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	The GenOMICC Study			
IRAS project ID* (or REC reference if no IRAS project ID is available):	189676 (Scotland) 269326 (Rest of UK)			
Sponsor amendment reference number*:	SA14_Scotland SA_011 (rest of UK) - MODIFIED			
Sponsor amendment date* (enter as DD/MM/YY):	17 January 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)*:	We propose to expand our objectives, by widening our inclusion criteria and introducing a sub-study, ACUTE. ACUTE follows the exact methodology of GenOMICC but requires a small amount of additional blood. We have also modernised the font within the protocol and made minor edits both within the protocol and across the study documents, including clarifying the withdrawal process and defining the role of the consultee in the telephone script. The changes are defined in the summary of changes attachment.			
Project type (select):	<b>Specific study</b>			
	<input type="checkbox"/> Research tissue bank <input type="checkbox"/> Research database			
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>			
	<input type="checkbox"/> 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)?	<b>Yes</b>	No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	No	No	<b>Yes</b>	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	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>		
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		
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes	<b>No</b>		
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	<b>No</b>		
Did the study involve children OR does the amendment introduce this?:	<b>Yes</b>	No		
Did the study involve NHS/HSC organisations prior to this amendment?:	<b>Yes</b>	No		
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes	<b>No</b>		
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	No	No	<b>Yes</b>	No
Which nations had participating NHS/HSC organisations prior to this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Which nations will have participating NHS/HSC organisations after this amendment?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>

## 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, 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 - 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):	Changes to the inclusion criteria to include all infections, introduced GenOMICC Acute and other minor font improvements and edits, including additional sampling options.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	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 2				
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)*	New study documents for the Acute sub study - only applies to a limited number of sites and is not study wide. The GenOMICC study team will be in touch with participating locations			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	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 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 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)*	Minor updates to existing documents to clarify withdrawal process, improve flow and simplify information where possible and a QR code for patients to easily access our video			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*	Yes	Yes	Yes	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

<b>Declaration by the Sponsor or authorised delegate</b>	
<ul style="list-style-type: none"> <li>• I confirm that the Sponsor takes responsibility for the completed amendment tool</li> <li>• I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf</li> </ul>	
Name [first name and surname]*:	Jo-Anne Robertson
Email address*:	genomicc@roslin.ed.ac.uk and jo-anne.robertson@ed.ac.uk

<p><b>Lock for submission</b></p> <p><b>Please note:</b> 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.</p> <p style="text-align: center;"><b>Lock for submission</b></p> <p>After locking the tool, <a href="#">proceed to submit the amendment online</a>. The "Submission Guidance" tab provides further information about the next steps for the amendment.</p>
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**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:	Y					Y			(Y)				(Y)					(Y)	A
Change 2:	Y					Y			Y				Y					Y	C
Change 3:	N					(Y)			(Y)				(Y)					(Y)	C
Overall reviews for the amendment:																			
Full review:	Y					Y			Y				Y					Y	
Notification only:	N					N			N				N					N	
Overall amendment type:	Substantial																		
Overall Category:	A																		

**Please note:** This amendment should **not** be processed via online submission. Please contact the REC directly to submit this amendment. See the "Submission Guidance" tab for further information.