

Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	A-STAR			
IRAS project ID* (or REC reference if no IRAS project ID is available):	237309			
Sponsor amendment reference number*:	Substantial Amendment 2 (SA2)			
Sponsor amendment date* (enter as DD/MM/YY):	09 August 2021			
<p>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>	<p>Biorepository sub-study reimbursements: Participants of the biorepository sub-study will be offered a voucher to the value of £10 per visit to cover reasonable expenses during the course of the sub-study.</p> <p>Sample clarification: Protocol, Adult Biorepository Patient Information Sheet, Parent/guardian Biorepository Patient Information Sheet and Young Person Biorepository Patient Information Sheet all updated to inform the participants about this.</p> <p>Addition of nine new sites.</p> <p>Staff and site changes: > Dublin and Dundee have been taken off the Biorepository section in the protocol as they will no longer be taking part in the biorepository part. > Other staff changes made throughout protocol to reflect changes.</p> <p>Schedule of Events correction: > In the protocol, "Schedule of Events," there is no, "C," annotated assessment. Therefore other appendices have been rearranged to reflect this. > For the Baseline 2 (3, 4 etc.) there is no need for the patient to re-sign a Consent Form so the, "X" has been removed from the Informed Consent row. > Further clarification was entered if patients either switch therapy or re-start the same therapy after a break in treatment.</p> <p>Protocol: > In, "Section 7.2 - Baseline visit," for the, "e. physical examination," section, the Study Steering Committee decided that all adequately trained team members can conduct the skin assessments. > In, "Section 12 - Data Capture and Data Management," in exceptional circumstances where a face-to-face visit cannot be arranged at site, data collection can be carried out over the phone, via video calls/virtual visits and also by mail/email.</p>			
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 modified amendment (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 type="radio"/>	<input checked="" 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 type="radio"/> Yes	<input checked="" 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 checked="" type="radio"/> Yes	<input 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		
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Which nations will have participating NHS/HSC organisations after this amendment?	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" 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 Management			
Specific change (select - only available when area of change is selected first)*:	Funding arrangements - Changes to the payments, benefits or incentives to be received by participants			
Further information (free text - note that this field will adapt to the amount of text entered):	Participants of the biorepository sub-study will be offered a voucher to the value of £10 per visit to cover reasonable expenses during the course of the sub-study.			
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 checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input type="radio"/> All		<input checked="" type="radio"/> Some	
Add another change: <input checked="" type="checkbox"/>				

Change 2				
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 (free text - note that this field will adapt to the amount of text entered):	> Collection of "Skin microbiome samples," corrected to, "skin swab samples." > Collection of, "metabolites," confirmed. > Collection of, "biological molecules," confirmed.			
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 checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input type="radio"/> All		<input checked="" type="radio"/> Some	
Add another change: <input checked="" type="checkbox"/>				

Change 3	
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):	Addition of nine new sites: > Harrogate and District NHS Foundation Trust - Principal Investigator: Professor Alison Layton > North Tees and Hartlepool NHS Foundation Trust - Principal Investigator: Dr Sharmela Darne > Liverpool University Hospitals NHS Foundation Trust - Principal Investigator: Dr Richard Parslew > Walsall Healthcare NHS Trust - Principal Investigator: Dr Aaron Wernham > Princess of Wales Hospital - Principal Investigator: Dr Jenny Hughes > Bradford Teaching Hospitals NHS Foundation Trust - Principal Investigator: Professor Andrew Wright > Nottingham University Hospitals NHS Trust - Principal Investigator: Jo Llewellyn > Countess of Chester Hospital - Principal Investigator: Dr Evelyn Davies > The James Cook University Hospital NHS Trust - Principal Investigator: Dr Sharmela Darne			
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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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):	<input type="radio"/> All		<input checked="" type="radio"/> Some	

Add another change:

Change 4				
Area of change (select)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Other - Please specify in the free text below			
Further information (free text - note that this field will adapt to the amount of text entered):	> Dublin and Dundee have been taken off the Biorepository section in the protocol as they will no longer be taking part in the biorepository part. > Other staff changes made throughout protocol to reflect local changes.			
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 checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input type="radio"/> All		<input checked="" type="radio"/> Some	

Add another change:

Change 5				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Correction of typographical errors			
Further information (free text - note that this field will adapt to the amount of text entered):	In the protocol, "Schedule of Events," there is no, "C," annotated assessment. Therefore other appendices have been rearranged to reflect this.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

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 (free text - note that this field will adapt to the amount of text entered):	Protocol, Adult Biorepository Patient Information Sheet, Parent/guardian Biorepository Patient Information Sheet and Young Person Biorepository Patient Information Sheet have all been updated to reflect the changes of this amendment.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

Change 7				
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 (free text - note that this field will adapt to the amount of text entered):	In the protocol, "Schedule of Events," for the Baseline 2 (3, 4 etc.) procedures there is no need for the patient to re-sign a consent form so the, "X" has been removed from the Informed Consent row.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

Change 8				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Data collection, transfer or processing of identifiable participant information - Changes in arrangements or organisations involved (other than the addition of new participating organisations)			
Further information (free text - note that this field will adapt to the amount of text entered):	Further clarification was entered if patients either switch therapy or re-start the same therapy after a break in treatment. On both occasions, a further baseline assessment is required. This has also been clarified in, "Schedule of Events," and, "Section 7.2 - Baseline visit," of the protocol.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

Change 9				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Data collection, transfer or processing of identifiable participant information - Changes in arrangements or organisations involved (other than the addition of new participating organisations)			
Further information (free text - note that this field will adapt to the amount of text entered):	In, "Section 7.2 - Baseline visit," for the, "e. physical examination," section, the Study Steering Committee decided that all adequately trained team members can conduct the skin assessments.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

Add another change:

Change 10				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Data collection, transfer or processing of identifiable participant information - Changes in arrangements or organisations involved (other than the addition of new participating organisations)			
Further information (free text - note that this field will adapt to the amount of text entered):	In, "Section 12 - Data Capture and Data Management," in exceptional circumstances where a face-to-face visit cannot be arranged at site, data collection can be carried out over the phone, via video calls/virtual visits and also by mail/email.			
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 checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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):	<input checked="" type="radio"/> All		<input type="radio"/> Some	

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]*:	p.p Matthew Osmond/ Rachel Fay
Email address*:	reza.razavi@kcl.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.



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:	Y					(Y)				(Y)				(Y)					B
Change 2:	N					(Y)				(Y)				(Y)					C
Change 3:	N					(Y)				(Y)				(Y)					New site
Change 4:	Y					Y				Y				Y					B
Change 5:	N					N				N				N					N/A
Change 6:	N					(Y)				(Y)				(Y)					C
Change 7:	N					(Y)				(Y)				(Y)					C
Change 8:	N					Y				Y				Y					A
Change 9:	N					Y				Y				Y					A
Change 10:	N					Y				Y				Y					A
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y					
Notification only:	N					N				N				N					
Overall amendment type:	Substantial																		
Overall Category:	A																		