

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*:	SA-06			
Sponsor amendment date* (enter as DD/MM/YY):	03 September 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)*:	This amendment makes significant changes to the samples collected as part of the Bioresource sub-study. The changes are designed to increase the scientific value of the study. To better understand how asthma is effected by treatment, we collect 2 new sample types: breath samples and nasal brushings (like a covid test). We are also making changes to the number of existing samples that are collected. New funding stream.			
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	Yes	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		No	
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		No	
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		No	
^ 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		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	
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		No	
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		No	
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	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		No	

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)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Participant procedures - significant change that will have additional resource implications for 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 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)*:	This change relates to samples collected for the Bioresource sub-study. The following new samples will be collected to better understand how the systemic treatments we use for eczema have an impact on asthma: breath samples collected using spirometer, breath samples to measure fraction exhaled Nitrogen Oxide (FeNO) and nasal brushings. A new skin biopsy will be taken in the sub-set of patients donating breath tests and nasal brushings. 3 x biopsies will be taken from this group at week 16. The biopsies will sample skin from an area of active eczema (lesional), skin not affected by eczema (non-lesional) and skin where the eczema has cleared (resolved lesional). The first two samples are currently taken, the last is a new sample. The collection of tape strip samples has also been amended. Previously, non-lesional tape strips were collected from all patients and lesional tape strips were only collected from patients who donated skin punch biopsies. Now, we will collect lesional tape strips from all patients. The number of tape strips has been changed from 8 to a maximum of 10, for each area of skin sampled. The burden for patients donating these samples is extremely small and it will allow flexibility in the research questions that can be answered with these samples. In patient's donating 3 x biopsies, tape strips will be collected from each biopsy site, before the skin biopsy is taken. These changes will increase the time taken to collect samples. The per-patient costs in the OID have been updated to reflect this increased time. There is no additional resource burden for sites as the spirometer and consumables required for sample collection are provided by the central study team. There is no change to the study design as these changes fit within the secondary objective of A-STAR: to establish a collection of biomaterial for molecular and stratification studies.			
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? (please note 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
	The combined patient information sheet and consent forms (PIS-ICF) for adults and the separate PIS-ICF for parents/guardians have been updated to reflect the changes above. In reference to Tape Strip samples, the PIS-ICFs (V3.3) now states that: 'Up to 10 samples will be taken from an area with active eczema and up to 10 will be taken from an area without eczema'. The section titled 'How will we use information about you?' now contains the GDPR template wording. Slight changes have been made in the section titled 'What will happen to my blood and skin samples?' This is to bring the description of a study code & pseudonymisation of data in line with the GDPR wording.

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)*	The PIS-ICF documents have been changed to allow us to share pseudonymised data. Previous versions only allowed sharing of anonymous data. The section titled 'How do I withdraw from the sub-study if I want to?' now includes a caveat that we might not be able to destroy samples if they have already been used. Two optional statements (originally 8 & 9) have been removed from the Adult and Parents/Guardian consent forms as it would not be possible to conduct research without these activities. A new tick box has been inserted to confirm the participant agrees that their '...samples and data may be used as has been set out in this document.' A further tick box has been added to confirm the participant understands there is potential for comercial development in the use of samples. A further PIS-ICF has been included for the sub-group who will donate the additional breath tests, nasal brushings and third skin punch biopsy detailed in Change 1. The documents title is 'A-STAR Adult Biorepository PIS-ICF CHART-AD - V1.0'. Participants in this group will be offered a shopping voucher worth £75 for the inconvenience of participation and to cover reasonable expenses. Optional sections of the Consent form have been removed as it will not be possible to conduct the research without collection of the samples & data detailed in the PIS. The new documents have been based on existing PIS-ICF documents. Email and website contact details have been updated in the patient information sheets.			
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? (please note 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)*:	Protocol - Substantial changes (e.g. affecting safety or the scientific value of the trial)			
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):	The table in page 13 of the protocol has been updated to include the new samples detailed in Change 1. These new samples have been added to the text on pages 22 and 23 of the Protocol. The CHART-AD cohort requires collection of all of the samples listed in the new PIS-ICF detailed in Change 3. This is a change from the original sample collection plan. Wording in page 28 has been added to explain this. The prupose of these test have been described in page 29 on the protocol. The ethical considerations on page 40 of the protocol has been updated with the new CHART-AD tests. The Financial Arrangements section on page 45 has been updated to note that Janssen Research & Development have contributed to funding.			
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? (please note 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	We will attempt to reconsent all patients using the updated consent forms in this amendment. Text in the previous versions of the PIS-ICF do not allow us to share psuedonymised data. This is necessary for the study.

in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*					
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 5					
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 researchers/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):	Additional funding will be directed to sites collecting the new samples detailed in change 1.				
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 6					
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: 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):	Participants in the CHART-AD cohort will be offered a voucher worth £75 per visit.				
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 7					
Area of change (select)*:	Study Documents				
Specific change (select - only available when area of change is selected first)*:	GDPR wording - Accepted wording used verbatim				
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):	The adult patient information sheet and parents/guardians patient information sheet for the main study have been updated using the template GDPR wording. This is to maintain consistency with patient information sheets in the Bioresource sub-study.				
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	
				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]*:

Rachel Fay

Email address*:

rachel.fay4@nhs.net

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.

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:	Y					Y				(Y)				(Y)				(Y)	A
Change 4:	N					(Y)				(Y)				N				N	C
Change 5:	Y					Y				Y				N				N	A
Change 6:	Y					(Y)				(Y)				N				N	A
Change 7:	N					N				N				N				N	N/A
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																		