

Amendment Tool

v1.8 30 April 2025

For office use

QC: No

Section 1: Project information

Short project title*:	SAFE-D			
IRAS project ID* (or REC reference if no IRAS project ID is available):	326332			
Sponsor amendment reference number*:	Amendment 2			
Sponsor amendment date* (enter as DD/MM/YY):	13 August 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)*:	In this amendment we have; *made some minor changes to the protocol (i.e. clarified one point of the exclusion criteria, inclusion of social media). *made minor changes to the following study documents: ICF, Recruitment Poster, GP letters, Participant letters. *added more PIC sites and research sites. *added a telephone recording to enable the Southampton CTU team to respond more efficiently to queries from participants and/or reserach sites *added documents to aid recruitment (infographic, social media reel/carousel, newsletter)			
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
	Yes	No	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	
[^] 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 have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?:	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	
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	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)*:	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: 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):	<p>The following updates have been made:</p> <ul style="list-style-type: none"> •Clarification to include self-referral option in Section 5.1 •Addition of social media to the self-referral path in Section 7.2 •Changed wording to using secure transfer system, rather than specifically SafeSend in Section 5.2, 7.6.2 and 7.6.4 •Clarified Exclusion criteria to also include confirmed pancreatic cancer or cyst in Section 5.4. •Addition of SAFE-D website address in Section 7.2 •Addition of data collection for participants who opt in to future health questionnaire related research in Section 7.6.1 and 7.6.4 •Clarification that the clinical study team may contact participants by phone to inform of a detected result in Section 7.6.4 			
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)*:	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: 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 Informed Consent Form has been updated with a specific email address to send the copy of the ICF to SCTU team. Additionally the box for the tracking sticker has been removed, and in point 5 statement - NHS number has been added to information collected from participant to align with the PIS.			
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)*:	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: 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)*	<p>Addition of SAFE-D website address to the following documents:</p> <ul style="list-style-type: none"> - Patient letter for repeat blood test - SAFE-D Informing GP of Participant - SAFE-D Informing GP of Detected result <p>Addition of the study specific QR code to the study Recruitment Poster.</p>			

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)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	PICs - Addition of Participant Identification Centres undertaking the same activities as existing PICs			
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):	<p>Addition of PICs from the following:</p> <ul style="list-style-type: none"> - RRDN East Midlands - RRDN South Central - Central Bournemouth PCN - Poole Bay and Bournemouth PCN - Christchurch PCN - Wimborne & Ferndown PCN - The Vale PCN - Weymouth & Portland PCN - Poole North PCN - South Coast Medical Group PCN - Mid Dorset PCN - Purbeck PCN - Bournemouth East Collaboration PCN 			
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)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Other - 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 (free text - note that this field will adapt to the amount of text entered):	Telephone recording has been created for participants trying to reach the Southampton CTU SAFE-D team via telephone. The recording will be heard as a voice recording. The system will record the message from the participant which will be emailed directly to the participant dedicated SAFE-D study inbox.			
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)*:	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: 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):	<p>Addition of the following research sites:</p> <ul style="list-style-type: none"> - RRDN East Midlands - RRDN South Central 			
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)*:	Participant Procedures			
Specific change (select - only available when area of change is selected first)*:	Recruitment - Change in identification, approach, recruitment or consent of 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):	<p>We have added documents to aid recruitment.</p> <p>*Infographic: the infographic will be placed on the SAFE-D website as an visual/audio aid to communicate study information.</p> <p>*Carousel: To increase awareness of the study and consequently recruitment, parts of the Infographic has been made into a reel/carousel which we would like to post on paid-for social media such as Facebook and Instagram.</p> <p>*Newsletter and new poster: For the same purpose, we have made newsletter and a new poster based on the infographic which we would like our participating reserach sites to distribute locally.</p> <p>All these recruitment aids are directing people to our already existing study website for more information and ability to book an appointment.</p>			
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	
<ul style="list-style-type: none"> 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]*:	Sharon Davies-Dear
Email address*:	sharon.davies-dear@uhs.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.
<div style="background-color: #90EE90; padding: 5px; display: inline-block; border: 1px solid black;">Lock for submission</div>
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.

Change 1:	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
N					(Y)				(Y)									A

