

## Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

Short project title*:	SONAR 1			
IRAS project ID* (or REC reference if no IRAS project ID is available):	265964			
Sponsor amendment reference number*:	NSA01			
Sponsor amendment date* (enter as DD/MM/YY):	16 December 2024			
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)*:	1. Typographic, grammatic and formatting correction changes to CRFs, protocol, patient information sheet, letters to patient and GP and consent form. 2. Shortening of the initial data collection study from 14 days to 7 days. 3. If patients screen or thought to be at risk to their baby or themselves a referral to safeguarding team by the local investigators. 4. Correction of contact information in study documents 5. Addition of funder Central London Patient Safety Research Collaboration to study documents 6. Additional sites			
Project type (select):	<b>Specific study</b>			
	Research tissue bank			
	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>			
	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)?	Yes		<b>No</b>	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	<b>Yes</b>	No	No	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?:	Yes		<b>No</b>	
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?:	Yes		<b>No</b>	
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>	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	<b>Yes</b>	No	No	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 Design			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design 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)*	Shortening of the initial recruitment from 14 to 7 days updates to protocol			
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)*:	Correction of typographical errors			
Further information (free text - note that this field will adapt to the amount of text entered):	Correction of typographical errors, and additional clarification to protocol, patient information sheet, letter to GP, letter to patient, consent form and CRFs			
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)*:	CRF/other study data records - Changes in the documentation used by the research team for recording study data			
Further information (free text - note that this field will adapt to the amount of text entered):	<p>Corrections to the CRFs to aid completion, Typographic, grammatic and formatting correction changes</p> <p>CRF 2 Typographic, grammatic and formatting correction changes Addition of ethnicity and demographic questions corresponding with ONS data Addition of section 2 regarding patients pain experience Reordering of questions Correcting language of final questions regarding communication rating and feedback</p> <p>CRF 3 Typographic, grammatic and formatting correction changes New text- " Mothers who score above 30 are likely to be suffering from PTSD."</p>			
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 4				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Inclusion/exclusion criteria - Minor change unlikely to affect safety or scientific value of study			
Further information (free text - note that this field will adapt to the amount of text entered):	Addition of intrauterine or neonatal demise to the exclusion criteria			
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 5				
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 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)*	addition of translated material for 6 most commonly spoken languages and Welsh to align with NIHR goals of equity in recruitment ability.			
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 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 (free text - note that this field will adapt to the amount of text entered):	<p>Trust Hospital site name</p> <p>Airedale NHS Foundation Trust, Airedale Hospital. Barking, Havering and Redbridge University Hospitals NHS Trust, Queen's Hospital Romford. Barts Health NHS Trust, Newham Hospital, Barts Health NHS Trust, Royal London Hospital. Barts Health NHS Trust, Whipps Cross Hospital. Bedfordshire Hospitals NHS Foundation Trust, Bedford Hospital South Wing. Belfast Health and Social Care Trust, Royal Jubilee</p> <p>Betsi Cadwaladr University Health Board, Glan Clwyd Hospital. Betsi Cadwaladr University Health Board, Wrexham Maelor Hospital, Betsi Cadwaladr University Health Board, Ysbyty Gwynedd</p> <p>Birmingham Women's and Children's NHS Foundation Trust, Birmingham Women's Hospital. Bolton NHS Foundation Trust, Royal Bolton Hospital. Bradford Teaching Hospitals NHS Foundation Trust, Bradford Women's and Newborn Unit, Calderdale and Huddersfield NHS Foundation Trust. Calderdale Royal Hospital. Cambridge University Hospitals NHS Foundation Trust, Rosie Hospital</p> <p>Cardiff and Vale University Health Board, University Hospital of Wales. Chelsea and Westminster Hospital NHS Foundation Trust, Chelsea &amp; Westminster Hospital. Chelsea and Westminster Hospital NHS Foundation Trust, West Middlesex Hospital. County Durham and Darlington NHS Foundation Trust, Darlington Hospital. Croydon Health Services NHS Trust, Croydon University Hospital. Cwm Taf Morgannwg University Health Board Prince Charles Hospital, Cwm Taf Morgannwg University Health Board Princess of Wales, Bridgend. Dorset County Hospital NHS Foundation Trust, Dorset County Hospital Hampshire Hospitals NHS Foundation Trust Royal Hampshire County Hospital Isle of Wight NHS Trust St Marys Hospital University Hospital Southampton NHS Foundation Trust Princess Anne Hospital Dartford and Gravesham NHS Trust Darent Valley Hospital Royal Cornwall Hospitals NHS Trust Trelisk Hospital Aneurin Bevan University Health Board The Grange University Hospital Hywel Dda University Health Board Bronglais Hospital Hywel Dda University Health Board Glangwili Hospital The Dudley Group NHS Foundation Trust Russells Hall Hospital The Royal Wolverhampton NHS Trust New Cross Hospital Walsall Healthcare NHS Trust Walsall Manor</p>

Hospital Barnsley Hospital NHS Foundation Trust Barnsley District General Hospital				
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 7				
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):	<p>East and North Hertfordshire NHS Trust Lister Hospital East Kent Hospitals University NHS Foundation Trust Queen Elizabeth the Queen Mother Hospital Margate East Kent Hospitals University NHS Foundation Trust William Harvey Hospital East Lancashire Hospitals NHS Trust Burnley General Teaching Hospital East Sussex Healthcare NHS Trust Conquest Hospital Epsom and St Helier University Hospitals NHS Trust Epsom Hospital Epsom and St Helier University Hospitals NHS Trust St Heliers Hospital Frimley Health NHS Foundation Trust Frimley Park Hospital Frimley Health NHS Foundation Trust Wexham Park Hospital Gateshead Health NHS Foundation Trust Queen Elizabeth Hospital, Gateshead George Eliot Hospital NHS Trust George Eliot Hospital Gloucestershire Hospitals NHS Foundation Trust Gloucestershire Royal Hospital Great Western Hospitals NHS Foundation Trust Great Western Hospital Guy's and St Thomas' NHS Foundation Trust St Thomas' Hospital Homerton Healthcare NHS Foundation Trust Homerton Hospital Imperial College Healthcare NHS Trust Queen Charlotte's Imperial College Healthcare NHS Trust St Mary's Hospital Kettering General Hospital NHS Foundation Trust Kettering General Hospital King's College Hospital NHS Foundation Trust Princess Royal University Hospital King's College Hospital NHS Foundation Trust King's College Hospital, Denmark Hill Site Kingston and Richmond NHS Foundation Trust Kingston Hospital Lancashire Teaching Hospitals NHS Foundation Trust Royal Preston Hospital Leeds Teaching Hospitals NHS Trust St James University Hospital Lewisham and Greenwich NHS Trust University Hospital Lewisham Lewisham and Greenwich NHS Trust Queen Elizabeth Hospital Liverpool Women's NHS Foundation Trust Liverpool Womens' London North West University Healthcare NHS Trust Northwick Park Maidstone and Tunbridge Wells NHS Trust Tunbridge Wells Hospital Manchester University NHS Foundation Trust North Manchester General Hospital Manchester University NHS Foundation Trust St Mary's Hospital Medway NHS Foundation Trust Medway Hospital Mid and South Essex NHS Foundation Trust Southend Hospital Mid and South Essex NHS Foundation Trust Basildon Hospital Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust Bassetlaw District General Hospital Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust Doncaster Royal Infirmary Harrogate and District NHS Foundation Trust Harrogate District Hospital Maternity Unit Hull University Teaching Hospitals NHS Trust Hull Royal Infirmary Leeds Teaching Hospitals NHS Trust Leeds General Infirmary North Bristol NHS Trust Southmead Hospital</p>			
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 8				
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			
	<p>Mid and South Essex NHS Foundation Trust Broomfield Hospital Mid Cheshire Hospitals NHS Foundation Trust Leighton Hospital Mid Yorkshire Hospitals NHS Trust Pinderfields Hospital NHS Ayrshire and Arran University Hospital Crosshouse NHS Borders Borders General Hospital NHS Dumfries and Galloway Dumfries and Galloway Royal Infirmary NHS Fife Victoria Hospital, Kirkcaldy NHS Forth Valley Forth Valley Royal Hospital NHS Grampian Royal Infirmary of Aberdeen NHS Greater Glasgow and Hyde Glasgow Royal Infirmary NHS Greater Glasgow and Hyde Queen Elizabeth University Hospital NHS Greater Glasgow and Hyde Royal Alexandra Hospital NHS Highland Raigmore Hospital NHS Lanarkshire University Hospital Wishaw NHS Lothian St Johns Hospital NHS Lothian The Royal Infirmary of Edinburgh NHS Tayside Ninewells Hospital Norfolk and Norwich University Hospitals NHS Foundation Trust Norfolk and Norwich North Bristol NHS Trust Southmead Hospital North Middlesex University Hospital NHS Trust North Middlesex Hospital North Tees and Hartlepool NHS Foundation Trust University Hospital of North Tees North West Anglia NHS Foundation Trust Peterborough</p>			

Further information (free text - note that this field will adapt to the amount of text entered):	Hospital Northampton General Hospital NHS Trust Northampton General Northern Health and Social Care Trust Antrim Area Hospital Northumbria Healthcare NHS Foundation Trust Northumbria Hospital Nottingham University Hospitals NHS Trust City Hospital Nottingham Nottingham University Hospitals NHS Trust Queen's Medical Centre, Nottingham Portsmouth Hospitals University NHS Trust Queen Alexandra Hospital Royal Berkshire NHS Foundation Trust Royal Berkshire Hospital Royal Devon University Healthcare NHS Foundation Trust North Devon District Hospital Royal Devon University Healthcare NHS Foundation Trust Royal Devon and Exeter Royal Free London NHS Foundation Trust Royal Free Hospital Royal Surrey NHS Foundation Trust Royal Surrey Hospital Royal United Hospitals Bath NHS Foundation Trust Royal United Hospital, Bath Salisbury NHS Foundation Trust Salisbury Hospital Sandwell and West Birmingham Hospitals NHS Trust Midland Metropolitan University Hospital Sheffield Teaching Hospitals NHS Foundation Trust Royal Hallamshire, Jessop Wing Sherwood Forest Hospitals NHS Foundation Trust King's Mill Hospital Somerset NHS Foundation Trust Musgrove Park Hospital South Eastern Health and Social Care Trust Ulster Hospital South Tees Hospitals NHS Foundation Trust James Cook University Hospital South Tyneside And Sunderland NHS Foundation Trust Sunderland Royal Hospital South Warwickshire NHS Foundation Trust Warwick Hospital Southern Health and Social Care Trust Craigavon Area Hospital Southern Health and Social Care Trust DaisyHill Hospital St George's University Hospitals NHS Foundation Trust St George's Hospital.			
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 9				
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):	<p>Surrey and Sussex Healthcare NHS Trust East Surrey Hospital Swansea Bay University Health Board Singleton Hospital The Hillingdon Hospitals NHS Foundation Trust Hillingdon Hospital The Newcastle Upon Tyne Hospitals NHS Foundation Trust Royal Victoria Infirmary The Princess Alexandra Hospital NHS Trust Princess Alexandra Hospital The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust Queen Elizabeth Hospital, King's Lynn, The Rotherham NHS Foundation Trust The Rotherham Maternity Unit The Shrewsbury and Telford Hospital NHS Trust The Royal Shrewsbury Hospital Torbay and South Devon NHS Foundation Trust Torbay Hospital University College London Hospitals NHS Foundation Trust University College Hospital University Hospitals Birmingham NHS Foundation Trust Birmingham Heartlands Hospital University Hospitals Bristol and Weston NHS Foundation Trust St Michael's Hospital University Hospitals Bristol and Weston NHS Foundation Trust St Michael's Hospital University Hospitals Coventry and Warwickshire NHS Trust University Hospital Coventry University Hospitals of Derby and Burton NHS Foundation Trust Queen's Hospital Burton University Hospitals of Derby and Burton NHS Foundation Trust Royal Derby Hospital University Hospitals of Leicester NHS Trust Leicester General Hospital University Hospitals of Leicester NHS Trust Leicester Royal Infirmary University Hospitals of Morecambe Bay NHS Foundation Trust Furness Hospital University Hospitals of Morecambe Bay NHS Foundation Trust Royal Lancaster Infirmary University Hospitals of North Midlands NHS Trust Royal Stoke University Hospital University Hospitals Plymouth NHS Trust Derriford Hospital University Hospitals Sussex NHS Foundation Trust Princess Royal Hospital, Haywards Heath University Hospitals Sussex NHS Foundation Trust Royal Sussex County Hospital, Brighton University Hospitals Sussex NHS Foundation Trust St Richards Hospital University Hospitals Sussex NHS Foundation Trust Worthing Hospital Warrington and Halton Teaching Hospitals NHS Foundation Trust Warrington Hospital West Hertfordshire Teaching Hospitals NHS Trust Watford Hospital West Suffolk NHS Foundation Trust West Suffolk Hospital Western Health and Social Care Trust Altnagelvin Area Hospital Whittington Health NHS Trust Whittington Hospital Wirral University Teaching Hospital NHS Foundation Trust Arrows Park Hospital Worcestershire Acute Hospitals NHS Trust Worcestershire Royal Hospital Warrington, Wigan and Leigh NHS Foundation Trust Royal Albert Edward Infirmary Wye Valley NHS Trust Hereford County Hospital York and Scarborough Teaching Hospitals NHS Foundation Trust Scarborough Hospital York and Scarborough Teaching Hospitals NHS Foundation Trust York Hospital</p>			
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 10				
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 (free text - note that this field will adapt to the amount of text entered):	Non substantial changes to the study protocol, with correction/ clarification of the protocol in the event of screening positive for depression and storage of data			
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	

**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]*:	Pushpsen Joshi
Email address*:	pushpsen.joshi1@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)	C
Change 2:						N				N				N				N	N/A
Change 3:						(Y)				(Y)				(Y)				(Y)	A
Change 4:						(Y)				(Y)				(Y)				(Y)	A
Change 5:						(Y)				(Y)				(Y)				(Y)	C
Change 6:						(Y)				(Y)				(Y)				(Y)	New site
Change 7:						(Y)				(Y)				(Y)				(Y)	New site
Change 8:						(Y)				(Y)				(Y)				(Y)	New site
Change 9:						(Y)				(Y)				(Y)				(Y)	New site

Change 10:						(Y)					(Y)					(Y)				(Y)	A
Overall reviews for the amendment:																					
Full review:						N					N					N					N
Notification only:						Y					Y					Y					Y
Overall amendment type:	Non-substantial, no study-wide review required																				
Overall Category:	A																				