Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	UK-ROX
IRAS project ID* (or REC reference if no IRAS project ID is available):	288506
Sponsor amendment reference number*:	SA004
Sponsor amendment date* (enter as DD/MM/YY):	12 April 2022
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)*:	The proposed amendment introduces a Study Within A Trial (SWAT), to determine the effect of skin tone on the diagnostic accuracy of pulse oximeters. Supporting scientific information and a detailed rationale has been provided as part of this amendment and relevant study documents have been updated accordingly.

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**	
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	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	Yes		**No**	
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		**No**	
Did 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**	**Yes**	No	**Yes**
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	No	**Yes**

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 significant change to study design that will have additional resource implications for participating organisations - Please specify in the free text below			
Further information 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)*:	The proposed amendment introduces a Study Within A Trial (SWAT) called the EXAKT sub-study. This study has received separate funding from the NIHR and aims to determine the effect of skin tone on the diagnostic accuracy of pulse oximeters. Supporting scientific information and a detailed rationale has been provided as part of this amendment (i.e. cover letter and study protocol addendum), and relevant study documents have been updated accordingly. Only selected UK-ROX sites will participate in the EXAKT sub-study.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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)*:	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):	A separate "Protocol Addendum - EXAKT Sub-Study v1.0, 12 April 2022" has been created to provide detailed information about the sub-study. We have also made a minor change to the main UK-ROX protocol through the addition of section 10: 'Exploring pulse oXimeter Accuracy across sKin Tones (EXAKT) sub-study'. This section briefly outlines the sub-study and references the study protocol addendum for further information.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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)*:	Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that will have additional resource implications for participating organisations - Please specify in the free text below
Further information 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)*:	These documents will only be used by sites participating in the EXAKT sub-study. The following documents are additional study documents which make changes to the existing versions of the UK-ROX documents (developed with Patient and Public Involvement). These documents do not supersede the existing UK-ROX documents. The Information Sheets contain the addition of Section 6 'The EXAKT sub-study' and the Consent Forms contain an additional optional field relating to participation in the EXAKT sub-study. - UK-ROX and EXAKT Patient Information Sheet v1.0, 12 April 2022 - UK-ROX and EXAKT Personal Consultee Information Sheet v1.0, 12 April 2022 - UK-ROX and EXAKT Nominated Consultee Information Sheet v1.0, 12 April 2022 - UK-ROX and EXAKT Consent Form v1.0, 12 April 2022 - UK-ROX and EXAKT Telephone Consent Form v1.0, 12 April 2022 - UK-ROX and EXAKT Postal Consent Form v1.0, 12 April 2022

	- UK-ROX and EXAKT Postal Consent Form v1.0, 12 April 2022 - UK-ROX and EXAKT Nominated Consultee Opinion Form v1.0, 12 April 2022 - UK-ROX and EXAKT Personal Consultee Opinion Form v1.0, 12 April 2022 - UK-ROX and EXAKT Enrolment Covering Letter v1.0, 2022 Both Tracked and Clean versions of the documents have been included.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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)*:	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 will have additional resource implications for participating organisations - Please specify in the free text below
Further information 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)*:	These documents will only be used by sites participating in the EXAKT sub-study. The following documents are additional study documents (developed with Patient and Public Involvement), which will be used for patients taking part in the EXAKT sub-study, who were screened but not randomised to the UK-ROX trial. - EXAKT Patient Information Sheet v1.0, 12 April 2022 - EXAKT Personal Consultee Information Sheet v1.0, 12 April 2022 - EXAKT Nominated Consultee Information Sheet v1.0, 12 April 2022 - EXAKT Consent Form v1.0, 12 April 2022 - EXAKT Telephone Consent Form v1.0, 12 April 2022 - EXAKT Postal Consent Form v1.0, 12 April 2022 - EXAKT Nominated Consultee Opinion Form v1.0, 12 April 2022 - EXAKT Personal Consultee Opinion Form v1.0, 12 April 2022 - EXAKT Enrolment Covering Letter v1.0, 12 April 2022

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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 5	
Area of change (select)*:	Study Management
Specific change (select - only available when area of change is selected first)*:	Contract/agreement arrangements
Further information (free text - note that this field will adapt to the amount of text entered):	"Schedule 6 - Variation of CTSA (mNCA) v1.0, 12 April 2022" has been created to add the EXAKT sub-study to existing participating site CTSAs. The following details associated with the sub-study have been included: - Per patient fees - Recruitment target - Equipment arrangements.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	No	**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**

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]:*	Keji Dalemo
Email address:*	keji.dalemo@icnarc.org uk-rox@icnarc.org

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																	
	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	Category:
Change 1:	Y					Y				Y								Y	B
Change 2:	Y					Y				(Y)								(Y)	A
Change 3:	Y					Y				Y								Y	B
Change 4:	Y					Y				Y								Y	B
Change 5:	N					Y				Y								Y	B
Overall reviews for the amendment:																			
Full review:	Y					Y				Y								Y	
Notification only:	N					N				N								N	
Overall amendment type:	Substantial																		
Overall Category:	A																		