Amendment Tool

v1.6 06 December 2021

For office use

QC: Yes

Section 1: Project information

Short project title*:	Induction of labour for predicted macrosomia - 'The Big Baby Trial'
IRAS project ID* (or REC reference if no IRAS project ID is available):	229163
Sponsor amendment reference number*:	SA 10
Sponsor amendment date* (enter as DD/MM/YY):	08 February 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)*:	Protocol and related documents updated to allow the trial to stop recruitment into the Cohort group of the trial. Extension of recruitment timelines by a further 6 months.

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**	**Yes**	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	**Yes**	**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 Design
Specific change (select - only available when area of change is selected first)*:	Other significant 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)*	On review of the data available for the Cohort group, it was found that there are sufficient data present in the cohort group to be able to assess generalisability of the trial, and to do a health economic evaluation of c-sections vs induction of labour/standard care. It was decided (with the support of the Trial Steering Committee and Data Monitoring Committee) that collection of further cohort data would not improve the quality of the data. Project documentation (Protocol, Particpant Information Sheet, Trifold leaflet and GP letter) have been updated to allow us to stop recruitment into the Cohort group of the trial. The Cohort Informed Consent forms will be retired. This will not adversly affect resource at site, since we are reducing the number of particpants that will be recruited into the trial.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	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 Design
Specific change (select - only available when area of change is selected first)*:	Extension to study duration 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)*:	Extension to recruitment from 30June2022 (as documented in NSA 40) to 31December2022. This will have resource implications as the research staff within the hospital will be required for a longer period of time to cover the extended recruitment time and corresponding data completion. Removing the Cohort Group from the trial will however reduce the amount of research time needed within the hospitals.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	**Yes**	**Yes**	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]:*	Sonia Kandola
Email address:*	ResearchSponsorship@uhcw.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.

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					C
Change 2:	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																		