Amendment Tool

v1.4 30 Nov 2020

For office use

QC: No

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 09
Sponsor amendment date* (enter as DD/MM/YY):	27 April 2021
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 major changes reflect the proposed update in process to allow follow-up of the participants at 24 months to assess the impact of pre-term birth on cognitive development. This was thought necessary following the inclusion of possible increase in Special Educational Needs (SEN) identified in the 'NHS England: Saving Babies Lives Version 2' which indicates that early induction of labour could lead to an increase in SEN. This affects the protocol, participant information sheet the creation of new participant information sheets and cover letters and emails to support this change. Furthermore there is the addition of a combined two and six month questionnaire to be sent to participant in the event that the completed 2 month questionnaire was not received before the six month questionnaire becomes due. This is to ensure that data collection is as complete as possible for the trial.

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
	◉	○	○	○
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 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:	◉	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☑	☑	☑	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☑	☑	☑	☐

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, tick 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 (free text - note that this field will adapt to the amount of text entered):	Addition of a 24 month follow-up questionnaire to assess the impact of early induction of labour on SEN. This will be managed from the Warwick Clinical Trials Unit and will not impact staff at site.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☐
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: ☑

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):	The protocol has been updated to reflect the addition of the 24 month questionnaire. Additionally the protocol has been updated to allow the capture of 2 and 6 month questionnaire data in a combined questionnaire, if the participant did not complete the 2 month questionnaire

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☐
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: ☑

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 (free text - note that this field will adapt to the amount of text entered):	The Participant Information Sheet has been updated to support the collection of the combined two- and six-month follow-up data

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☐
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: ☑

Change 4	
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 (free text - note that this field will adapt to the amount of text entered):	24 month questionnaires, cover letters and participant information sheets have been created for use by the Warwick clinical trials unit. These will not be used by the site staff.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☐
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: ☑

Change 5	
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 (free text - note that this field will adapt to the amount of text entered):	Combined 2 and 6 month questionnaires have been created for use by the Warwick Clinical trials unit. These will not be used by the site staff.

Applicability:	England	Wales	Scotland	Northern Ireland

Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☑	☑	☑	☐
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]:*	Becky Haley
Email address:*	R&Dsponsorship@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:	N					(Y)				(Y)				(Y)					C
Change 2:	Y					Y				(Y)				(Y)					A
Change 3:	N					(Y)				(Y)				(Y)					C
Change 4:	N					(Y)				(Y)				(Y)					C
Change 5:	N					(Y)				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:	Y					Y				N				N					
Notification only:	N					N				Y				Y					
Overall amendment type:	Substantial for review																		
Overall Category:	A																		