Amendment Tool

v1.2 11 Jun 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 08
Sponsor amendment date* (enter as DD/MM/YY):	30/06/2020
Summary of amendment including justification*:	Change to recruitment procedures due to COVID-19: Addition of possibility for discussion of Participant Information Sheet over the telephone and for verbal informed consent to allow recruitment during COVID-19 as many face-to-face consultations have been moved to telephone calls and partners do not accompany women to their consultations. Corresponding updates and additions to Trial documents. Update to timelines following Variation to Contract. Other minor administarative changes.

Project type:	◉ 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?:	◉ 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?	○ 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 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 Changes" tab. To add another change, tick the "Add another change" box.

Change 1	
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 (free text):	Protocol amended section 2.14 to allow the Participant Information Sheet to be sent by email/post. This is required as the number of face-to-face visits in hospitals has decreased during COVID-19, creating difficulties in giving the women enough time to consider the trial. Partners are not visiting with the women, so discussions involving them are difficult. Recruitment window for Big Baby is very tight and with the current COVID-19 restrictions women are unlikley to have a further hospital visit after the scan confirming eligibility until they go into labour.

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?:	◉ All		○ Some	

Add another change: ☑

Change 2	
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 (free text):	Protocol amended section 2.14.1 to allow verbal Informed consent. This is required as the number of face-to-face visits in hospitals has decreased during the COVID-19 outbreak, and partners are not visiting with the women. Without remote informed consent, recruitment will be challenging.

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?:	◉ 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 significant document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text):	Creation of verbal Informed Consent forms to support the changes outlined in section 2.14.1 of the protocol

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?:	◉ 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 significant document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below

Further information (free text):	Creation of a cover letter to use when sending the Participant Information Sheet and Informed Consent forms to the potential participant by post or email.

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?:	◉ All		○ Some	

Add another change: ☑

Change 5	
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 (free text):	Protocol section 7.6 table 15 - Recruitment has been extended by a further 18 months. This impacts the sites as instead of recruitment stopping in June 2020, research staff will be required to recruit into the trial until December 2021.

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?:	◉ All		○ Some	

Add another change: ☑

Change 6	
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):	Protocol section 2.9.2.3 - clarification that if the participant is consented into the trial verbally, that the PI or designee will collect the baseline questionnaire data over the telephone/videoconference. Protocol section 5.5 - clarification that if further trials are planned in the future where we would like to contact the participants, the children will be conatcted at 16 years of age to consent for us to retain their contact details. Protocol sectioni 6.1 - minor change to the way non-compliance analysis will be performed.

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?:	◉ All		○ Some	

Add another change: ☑

Change 7	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below

Further information (free text):	Written Informed Consent forms updated to include the Data Controller in the text and to clarify that HES-ONS will be accessed if the six-month questionnaire is not completed. Update to the GP letter to instruct GP to return the letter to site if they no longer have the participant on their books. Creation of a separate cover letter to be sent ot participants if they have Follow-Up questionnaire B rather then Questionnaire A

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?:	◉ All		○ Some	

Add another change: ☑

Change 8	
Area of change (select)*:	Study Documents
Specific change (select - only available when area of change is selected first)*:	GDPR wording - Unaccepted alternative wording used
Further information (free text):	Clarification added to Participant Information sheet detailing that Warwick Clinical Trials Unit will be a data processor and wording updated to allow verbal informed consent. Clarificaton on which data will be collected, when it may be collected, and what it is used for. Sections updated to allow verbal informed consent.

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?:	◉ All		○ Some	

Add another change: ☑

Change 9	
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):	Protocol section 2.3 - clarification on the definition of the primary outcome in reference to the cohort group. Protocol section 2.7 - update to the number of proposed trusts to be in the trial.

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?:	◉ All		○ Some	

Add another change: ☑

Change 10	
Area of change (select)*:	Administrative details for the project
Specific change (select - only available when area of change is selected first)*:	Contact details - CI or other project staff

Further information (free text):	Updates to Trial Management Group and TSC contact details.

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?:	◉ 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]:*	Becky Haley
Email address:*	becky.haley@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 PDF copy of the completed amendment tool that can 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, refer to the "Submission Guidance" tab for 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					A
Change 2:	Y					Y				Y				Y					A
Change 3:	Y					Y				Y				Y					C
Change 4:	Y					Y				Y				Y					C
Change 5:	N					(Y)				(Y)				(Y)					A
Change 6:	N					(Y)				(Y)				(Y)					C
Change 7:	N					(Y)				(Y)				(Y)					C
Change 8:	N					Y				Y				Y					C
Change 9:	N					(Y)				(Y)				(Y)					C
Change 10:	(Y)					Y				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:	Y					Y				Y				Y					
Notification only:	N					N				N				N					

Overall amendment type:	Substantial for review
Overall Category:	A

For office use:	
Update HARP:	This amendment may involve an update to contact details or other project details. Ensure that HARP is updated with the current details. If this is the only change, no further study-wide review is required.