

Amendment Tool

v1.6 06 December 2021

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 11			
Sponsor amendment date* (enter as DD/MM/YY):	30 June 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)*:	BigBaby 2 Up process and documentation updates to allow for following up on non-completed questionnaires			
Project type (select):	Specific study			
	<input type="checkbox"/> Research tissue bank <input type="checkbox"/> 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			
	<input type="checkbox"/> 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)?	<input type="checkbox"/> Yes	No		
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	<input type="checkbox"/> Yes	No		
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	<input type="checkbox"/> Yes	No		
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	<input type="checkbox"/> 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?:	<input type="checkbox"/> Yes	No		
Did the study involve adults lacking capacity OR does the amendment introduce this?:	<input type="checkbox"/> Yes	No		
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	<input type="checkbox"/> 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?:	<input type="checkbox"/> Yes	No		
Did the study involve children OR does the amendment introduce this?:	<input type="checkbox"/> 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?:	<input type="checkbox"/> Yes	No		
Lead nation for the study:	England	Wales	Scotland	Northern Ireland
	Yes	<input type="checkbox"/> No	<input type="checkbox"/> No	<input type="checkbox"/> No
Which nations had participating NHS/HSC organisations prior to this amendment?	Yes	Yes	Yes	<input type="checkbox"/> No
Which nations will have participating NHS/HSC organisations after this amendment?	Yes	Yes	Yes	<input type="checkbox"/> 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)*	<p>Additional contacts with participants added:</p> <ul style="list-style-type: none"> •BB2Up Questionnaire introduction message v1.0 12May2022. •BB2Up Questionnaire follow-up message v1.0 12May2022. •BB2Up Questionnaire email address request letter v1.0 12May2022. •BB2Up Questionnaire email address request message v1.0 12May2022. •BB2Up Questionnaire completion request message v1.0 12May2022. 			
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 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 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)*	<p>Updates to the below documentation to allow for extra contact points with participants and other general minor amendments:</p> <ul style="list-style-type: none"> •BigBaby Protocol v11.0 31May2022: <p>Updates to allow for warning the participant of an email to be received, chasing up if questionnaires not completed, and requesting email addresses by post or text if email address is unavailable, or incorrect.</p> <p>Clarification that RCT and Cohort women will be approached, cognitive function will be measured by PARCA-R and that UoW will be contacting the participants.</p> <ul style="list-style-type: none"> •BB2UP Invitation Email v3.0 31May2022: <p>Layout update to make study number clear. Addition of statement explaining how to continue a partially complete questionnaire and a statement clarifying consent is implied upon completing a questionnaire question.</p> <ul style="list-style-type: none"> •BB2UP Participant Information Sheet v3.0 31May2022: <p>Addition of: Title of Big Baby 2UP, Wording to outline what will be asked of the participant, Risk/benefit statement, Indication that EQ5D may be collected by telephone, Complaint section, Details on how to request removal from the trial, Funding section, Links to Qualtrics and UHCW privacy statements & Reference to REC.</p> <p>Amendments: Updated contact email addresses, Clarification that the email is the email that the PIS was attached to and Removal of the link, Clarification on who will have access to personal identifiable data & Clarification that non-identifiable data will be not be retained at the end of the trial.</p> <ul style="list-style-type: none"> •BB2UP Participant Information Sheet v4.0 31May2022: <p>Removal of reference to EQ5D being collected via telephone.</p> <p>Version to be implemented once EQ5D is programmed into the online questionnaire.</p> <ul style="list-style-type: none"> •BB2UP Invitation Letter (CI) v2.0 12May2022: <p>Removal of duplicate sentence.</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	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]*:	Becky Haley
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														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					(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																		
Overall Category:	C																		