

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*:	NSA 55			
Sponsor amendment date* (enter as DD/MM/YY):	03 July 2023			
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)*:	Addition of the use of thank you vouchers for BigBaby 2 Up invitations. Other minor document updates.			
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		
Is review by a UKECA-recognised Research Ethics Committee (REC) being sought for the first time because of this amendment?:	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.

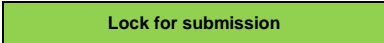
Change 1				
Area of change (select)*:	Study Management			
Specific change (select - only available when area of change is selected first)*:	Funding arrangements - Changes to the payments, benefits or incentives to be received by participants			
Further information (free text - note that this field will adapt to the amount of text entered):	Addition of the use of £10 high street vouchers to be sent with BigBaby 2 Up invitations.			
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)*:	Protocol - Non-substantial changes (e.g. not 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):	Addition of statement regarding the use of thank you vouchers. Update to trial contacts and funder statement to include BB2Up. Other minor updates.			
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 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 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)*	BB2Up Invitation Email v7.0 23Jun2023: addition of statement regarding voucher. BB2Up Paper Questionnaire Cover Letter including Voucher v1.0 23Jun2023: Addition of statement regarding voucher. BB2Up Paper Questionnaire v2.0 23Jun2023: Spelling corrections. BB2Up Participant Information Sheet v7.0 23Jun2023: addition of statement to clarify participants may receive a call from an unknown number.			
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	
<ul style="list-style-type: none"> 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]*:	Claire Finnie
Email address*:	Researchsponsorship@uhcw.nhs.uk

<p>Lock for submission</p> <p>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.</p> <p style="text-align: center;"></p> <p>After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.</p>
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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:	
							roval			function	
											function

	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW App	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating	HSC REC	HSC Data Guardians	Prisons	National coordinating	Category:
Change 1:						(Y)				(Y)				(Y)					A
Change 2:						(Y)				(Y)				(Y)					A
Change 3:						(Y)				(Y)				(Y)					C
Overall reviews for the amendment:																			
Full review:						N				N				N					
Notification only:						Y				Y				Y					
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		