Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Induction of labour for predicted macrosomia 'The Big Baby Trial'
IRAS Project ID:	229163
Sponsor Amendment Notification number:	Non-Substantial Amendment 28
Sponsor Amendment Notification date:	21 May 2020
Details of Chief Investigator:	
Name [first name and surname]	Professor Siobhan Quenby
Address:	University Hospitals Coventry and Warwickshire NHS Trust, Clifford Bridge Road, Coventry.
Postcode:	CV2 2DX
Contact telephone number:	07873416716
Email address:	s.quenby@warwick.ac.uk
Details of Lead Sponsor:	
Name:	University Hospitals Coventry and Warwickshire
Contact email address:	R&DSponsorship@uhcw.nhs.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	N/A
Name of lead R&D office:	University Hospitals Coventry and Warwickshire NHS Trust

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

2. Summary of amendment(s)

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No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	In response to the COVID-19 pandemic, we are currently unable to send postal Follow-up questionnaires to participants in the trial. To allow us to collect follow-up data the Trial Management Group (meeting of 12 May 2020) has confirmed that we should collect the Follow Up data by telephone using the reduced dataset in the 2 and 6 month telephone questionnaires. In addition, it was agreed at this TMG that additional questions should be added to the 2 Month Questionnaires to assess the impact, if any, of COVID-19 on the outcomes. To this effect the Protocol has been updated to clarify how questionnaire data are being collected during the COVID-19 pandemic, and to include the collection of COVID-19 data. The 2 month Follow-Up Questionnaires have been updated to include COVID-19 data collection sections	England Northern Ireland Scotland Wales	All sites or list affected sites All sites or list affected sites All sites or list affected sites All sites or list affected sites	HTA 16/77/02 Protocol HTA 16/77/02 The Big Baby Trial two month telephone questionnaire A HTA 16/77/02 The Big Baby Trial two month questionnaire A HTA 16/77/02 The Big Baby Trial two month questionnaire B	V7.1 21 May 2020 V2.0 20 May 2020 V2.0 20 May 2020 V2.0 20 May 2020	

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: 

Print name: Siobhan Quenby

Date: 21/5/202

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: 

Print name: Becky Haley

Post: R&D Business Development Manager

Organisation: University Hospitals Coventry & Warwickshire

Date: 21.05.2020