

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**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**

<b>Full title of study:</b>	Induction of labour for predicted macrosomia 'The Big Baby Trial'
<b>IRAS Project ID:</b>	229163
<b>Sponsor Amendment Notification number:</b>	Non-Substantial Amendment 19
<b>Sponsor Amendment Notification date:</b>	26/09/2019
<b>Details of Chief Investigator:</b>	
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
<b>Details of Lead Sponsor:</b>	

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Name:	University Hospitals Coventry and Warwickshire
Contact email address:	R&DSponsorship@uhcw.nhs.uk
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	N/A
<b>Name of lead R&amp;D office:</b>	University Hospitals Coventry and Warwickshire NHS Trust

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**2. Summary of amendment(s)**

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No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>		R&D category of amendment <i>(category A, B, C) For office use only</i>
		Nation	Sites	Document	Version	
1	Addition of new site: West Hertfordshire Hospitals NHS Trust	England	All sites or list affected sites	N/A		
		Northern Ireland	All sites or list affected sites			
		Scotland	All sites or list affected sites			
		Wales	All sites or list affected sites			
2	Addition of new site: Northern Lincolnshire And Goole NHS Foundation Trust			N/A		
3	Addition of new site: Milton Keynes University Hospital NHS Foundation Trust			N/A		
4	Addition of new site: East Suffolk and North Essex NHS Foundation Trust			N/A		

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**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:* 02/10/2019**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:* Ceri Jones*Post:* Head of Research & Development*Organisation:* University Hospitals Coventry & Warwickshire*Date:* 02/10/2019