

## 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 12
<b>Sponsor Amendment Notification date:</b>	12 February 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>	
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

**Partner Organisations:**

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

**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	Baseline Questionnaire amended <ul style="list-style-type: none"> <li>To include the scoring asterisks on the Edinburgh Postnatal depression Scale</li> </ul>	England  Northern Ireland	All sites or list affected sites  All sites or list affected sites	Big Baby Baseline Questionnaire	V1.3 14/01/19	
2	Two Month Follow-Up Questionnaire A amended <ul style="list-style-type: none"> <li>To include the woman's date of birth for identification purposes. Women's date of birth is already collected in other trial documentation.</li> <li>Name if the form amended to clarify that this is a form for mother and baby use</li> <li>'Hospital admissions' changed to 'Hospital visits' in sections 5 and 11 for hospital out-patient visits</li> </ul>	As above	All sites or list affected sites All sites or list affected sites	Two Month Follow-up Questionnaire (Mother and Baby)	V1.3 28/01/19	
3	Two Month Follow-Up Questionnaire B amended <ul style="list-style-type: none"> <li>To include the woman's date of birth for identification purposes. To include the woman's date of birth for identification purposes. Women's date of birth is already collected in other trial documentation.</li> </ul>	As above		Two Month Follow-up Questionnaire (Mother)	V1.3 28/01/19	

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	<ul style="list-style-type: none"> <li>Name if the form amended to clarify that this is a form for mother's use only</li> <li>'Hospital admissions' changed to 'Hospital visits' in section 4 for hospital out-patient visits</li> </ul>				
<p>Six Month Follow-Up Questionnaire A amended</p> <ul style="list-style-type: none"> <li>To include the woman's date of birth for identification purposes. To include the woman's date of birth for identification purposes. Women's date of birth is already collected in other trial documentation.</li> <li>Name if the form amended to clarify that this is a form for mother and baby use</li> <li>'Hospital admissions' changed to 'Hospital visits' in sections 5 and 10 for hospital out-patient visits</li> </ul>	As above		Six Month Follow-up Questionnaire (Mother and Baby)	V1.3 28/01/19	
<p>Six Month Follow-Up Questionnaire B amended</p> <ul style="list-style-type: none"> <li>To include the woman's date of birth for identification purposes. To include the woman's date of birth for identification purposes. Women's date of birth is already collected in other trial documentation.</li> <li>Name if the form amended to clarify that this is a form for mother's use only</li> <li>'Hospital admissions' changed to 'Hospital visits' in section 3 for hospital out-patient visits</li> </ul>	As above		Six Month Follow-up Questionnaire (Mother)	V1.3 28/01/19	

**Partner Organisations:**

Health Research Authority, England

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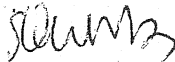
NISCHR Permissions Co-ordinating Unit, Wales

**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:

12/2/2014

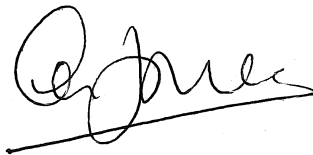
**Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)**

*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  
Head of Research  
& Development

Post:

Organisation: UHCW NHS TRUST

Date:

6<sup>th</sup> March 2014