## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

**Please enter a short title for this project** (maximum 70 characters)
The 'Big Baby Trial'

**1. Is your project research?**

(●) Yes ( ) No

**2. Select one category from the list below:**

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

**If your work does not fit any of these categories, select the option below:**

( ) Other study

**2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?**

( ) Yes (●) No

**2b. Please answer the following question(s):**

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

**3. In which countries of the UK will the research sites be located?***(Tick all that apply)*

- [x] England
- [x] Scotland
- [x] Wales
- [x] Northern Ireland

**3a. In which country of the UK will the lead NHS R&D office be located:**

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

**4. Which applications do you require?**

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

**5. Will any research sites in this study be NHS organisations?**

(•) Yes ( ) No

**5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?**

**Please see information button for further details.**

( ) Yes (•) No

***Please see information button for further details.***

**5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?**

**Please see information button for further details.**

(•) Yes ( ) No

*The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".*

*If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.*

**6. Do you plan to include any participants who are children?**

◉ Yes ○ No

**7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?**

○ Yes ◉ No

*Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.*

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?**

○ Yes ◉ No

**9. Is the study or any part of it being undertaken as an educational project?**

○ Yes ◉ No

**10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?**

○ Yes ◉ No

**11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?**

○ Yes ◉ No

**NOTICE OF SUBSTANTIAL AMENDMENT**

*Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).*
*The form should be completed by the Chief Investigator using language comprehensible to a lay person.*

**Details of Chief Investigator:**


| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Professor | Siobhan | Quenby |
| Work Address | Clifford Bridge Road, Coventry | | |
| PostCode | CV2 2DX | | |
| Email | s.quenby@warwick.ac.uk | | |
| Telephone | 07873416716 | | |
| Fax | | | |


**For guidance on this section of the form refer to the guidance**

| | |
|---|---|
| **Full title of study:** | Induction of labour for predicted macrosomia |
| **Lead sponsor:** | University Hospitals Coventry and Warwickshire NHS Trust |
| **Name of REC:** | South West-Exeter Research Ethics Committee |
| **REC reference number:** | 18/SW/0039 |

| | |
|---|---|
| **International Standard Randomised Controlled Trial Number (ISRCTN):** | ISRCTN18229892 |
| **ClinicalTrials.gov Identifier (NCT number):** | |

**Additional reference number(s):**

| Ref.Number Description | Reference Number |
|---|---|

| | |
|---|---|
| **Name of lead R&D office:** | University Hospitals Coventry & Warwickshire |
| **Date study commenced:** | 1st January 2018 |
| **Protocol reference (if applicable), current version and date:** | V4.0 30/10/18 |
| **Amendment number and date:** | AM04 17th December 2018 |

**Type of amendment**

*(a) Amendment to information previously given in IRAS*

○ Yes ◉ No

*If yes, please refer to relevant sections of IRAS in the "summary of changes" below.*

*(b) Amendment to the protocol*

◉ Yes ○ No

*If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.*

*(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

◉ Yes ○ No

*If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.*

**Is this a modified version of an amendment previously notified and not approved?**

○ Yes ◉ No

**Summary of changes**

*Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.*
*If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.*
*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.*

The protocol has been amended to make the following changes:
1. The risk tables have been amendeded for each mode of delivery in-line with the participant information sheet and based on the best available evidence.
2. Clarification has been made that eligibility must be confirmed by a medically qualified doctor delegated to do so and that trial discussion and obtaining informed consent must be taken by a medically qualified doctor or research midwife delegated to do so. It was felt that other members of research staff such as nurses may not possess the required level of clinical knowledge and experience of the obstetric pathway and associated risks/benefits of each mode of delivery to support discussion and consent process.
3. The text has been amended to reflect that the trial database will now be developed by Warwick clinical trials unit.
4. Text has been added to explain the process for when the obstetrician cannot provide written obstetric confirmation prior to randomisation.
5. It has been stated that participants will be contacted to chase core missing data items
6. Further minor clarifications have been made throughout the document
7. Typographical corrections throughout the document

The participant information sheet has been amended to make the following changes:
1. To improve the flow of the information provided to women so it can be delivered and read in a more logical way.
2. Clarifications have been made throughout the document with regards to the clinical aspect of the information and provide further explanation of the uncertainty surrounding the risk of experiencing shoulder dystocia

Update to the urgent safely measure notified to the REC as part of SA03:
All women who were awaiting delivery at the time of implementation of the urgent safety measure have been informed of the updated risk information and were verbally re-consented. Where women have asked to withdraw from the study we have requested consent to continue to collect their follow-up data as usual.
In the previous amendment we outlined our proposal to informing women who had already delivered. Following discussion with obstetric clinicians, medical ethicists, PPI and also NHS legal representatives we have agreed the

following approach:
1. Women who have delivered without shoulder dystocia:
a. Women will be contacted via telephone or by letter, at the discretion of the local PI. Where contact is via a letter this will be sent alongside their 2 or 6 month postal questionnaire (depending on progress in the trial). The letter will outline that the risk of shoulder dystocia had been presented for all vaginal deliveries and did not reflect that of women with big babies. A corrected version of the participant information sheet will be provided, alongside contact details for the site study team should they wish to discuss this further via telephone or face to face. Communication with the women, regardless of the approach taken, will be documented in the patients' medical record.

Please find enclosed with this amendment the shoulder dystocia risk letter v1.0, dated 19.12.2018.

2. Women who have delivered and shoulder dystocia or other complications have been documented:
a. The Chief Investigator will discuss each case with the Principle Investigator and/or obstetrician responsible for their care and arrangements made to contact the women to provide by telephone to explain that the risk had not been presented for women with big babies. Following this discussion the shoulder dystocia risk letter will be sent to the woman alongside an updated version of the participant information sheet. All communication with the women will be documented in the patients' medical record.

**Any other relevant information**

*Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.*

**List of enclosed documents**

| *Document* | *Version* | *Date* |
|---|---|---|
| Protocol-Tracked | 5.0 | 19/12/2018 |
| Participant Information Sheet-Tracked | 5.0 | 17/12/2018 |
| Shoulder Dystocia Risk Letter | 1.0 | 19/12/2018 |
| Cover Letter | | |

**Declaration by Chief Investigator**

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

This section was signed electronically by Professor Siobhan Quenby on 20/12/2018 08:31.

| | |
|---|---|
| Job Title/Post: | Prof os Obstetrics |
| Organisation: | University of Warwick |
| Email: | s.quenby@warwick.ac.uk |

**Declaration by the sponsor's representative**

*I confirm the sponsor's support for this substantial amendment.*

This section was signed electronically by Mrs Becky Haley on 19/12/2018 14:53.

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|---|---|
| Job Title/Post: | R&D Business Development Manager |
| Organisation: | University Hospitals Coventry & warwickshire NHS Trust |
| Email: | becky.haley@uhcw.nhs.uk |