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| **Participant consent form – Consent to take part in the Big Baby Trial –**  **Induction of labour for predicted macrosomia**  (‘Macrosomia’ refers to babies who appear to be bigger than expected for their dates.)  **Remote consent form**  The University Hospitals Coventry and Warwickshire NHS Trust, is the data controller for this trial. |
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**Please read each statement to the participant and, if they agree, put your initials and the date in the box next to it.**

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| 1. The participant has read and understood the **Participant Information Sheet** version ……… dated…………….. for the Big Baby Trial. | Please initial here |
| 1. The participant has had time to think about the information they have been given about the Big Baby Trial and ask questions, and they are satisfied with the answers they have been given. | Please initial here |
| 1. The participant understands that they do not have to take part and that they can withdraw from the trial at any time, without giving a reason and without their medical care or legal rights being affected. | Please initial here |
| 1. The participant understands that the hospital research team will collect information relevant to them taking part in the trial from their NHS hospital records. The participant gives the hospital research team permission to collect this information. | Please initial here |
| 1. The participant understands that the hospital research team will collect information relevant to their child taking part in the trial from their NHS hospital records and GP records. The participant gives the hospital research team permission to collect this information. | Please initial here |
| 1. The participant understands that the trial team (members of the Big Baby Trial team at the Warwick Clinical Trials Unit (WCTU) and the Perinatal Institute) may look at relevant sections of their medical records if this is relevant to them taking part in this trial.  The participant also understands that representatives from WCTU, and the local hospital trust may have access to their medical records to monitor the trial they are agreeing to take part in.  The participant gives permission for these people to have direct access to their records. | Please initial here |
| 1. The participant understands that the trial team may look at relevant sections of their child’s NHS hospital records and GP records if this is relevant to them taking part in this trial.  The participant also understands that representatives from WCTU and the local hospital trust may have access to their medical records to monitor the trial they are agreeing to take part in. The participant gives permission for these people to have direct access to their records. | Please initial here |
| 1. The participant understands that if their baby is not born in this hospital, the hospital research team will contact the relevant hospital trust to collect medical details from their NHS hospital records and their child’s NHS hospital records if this is relevant to them taking part in this trial. The participant gives the research team permission to access these records. | Please initial here |
| 1. The participant understands that if they are treated at another hospital, the hospital research team will contact the relevant hospital trust to collect details from their NHS hospital records if this is relevant to them taking part in this research. The participant gives the research team permission to access these records. | Please initial here |

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**Study number**

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| 1. The participant understands that if their child is treated at another hospital, the hospital research team will contact the relevant hospital trust to collect details from their NHS hospital records if this is relevant to them taking part in this research. The participant gives the research team permission to access these records. | Please initial here |
| 1. The participant agrees to the trial team holding contact details for them (address, email address, phone numbers) so the trial team can send them reminders and follow-up questionnaires, or contact them if they need them to explain anything in the follow-up questionnaires and to ask about their and their baby’s health. | Please initial here |
| 1. The participant agrees to the hospital research team accessing their child’s NHS hospital records before sending them reminders for the two- or six-month follow-up questionnaires. | Please initial here |
| 1. The participant agrees to the trial team accessing linked information from Hospital Episode Statistics (HES) and the Office for National Statistics (ONS) about their child from NHS Digital to check that their child is alive at six months old and, if their child has died, to assess the cause of their death. | Please initial here |
| 1. The participant agrees to the trial team accessing linked information from Hospital Episode Statistics (HES) and the Office for National Statistics (ONS) about them from NHS Digital to check that they are alive six months after their child’s birth and, if they have died, to assess the cause of their death. | Please initial here |
| 1. The participant understands that any information the trial team collect for this trial will be kept confidential and stored in line with UK data-protection laws. | Please initial here |
| 1. **Optional:** The participant understands that the trial team may contact them in the future and invite them to take part in studies that are relevant to their child. In order to do this the trial team will use information about them to access Hospital Episode Statistics (HES) from NHS Digital. The participant understands that they do not have to agree to take part in these studies | Please initial here |
| 1. **Optional:** The participant understands that the trial team may contact them or their child in the future and invite them to take part in studies that are relevant to their child. In order to do this the trial team will use information about their child to access Hospital Episode Statistics (HES) from NHS Digital. The participant understands that they do not have to agree to take part in these studies. | Please initial here |
| 1. **Optional:** The participant agrees to the trial team contacting them to invite them to an interview about their experiences of taking part in the Big Baby Trial. | Please initial here |
| 1. The participant agrees to take part in this randomised controlled trial. | Please initial here |
| 1. The participant agrees to the hospital research team telling their GP that they are taking part in this trial. | Please initial here |

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| **Person obtaining informed consent** (to be filled in by the person taking the participants consent)   |  |  | | --- | --- | | **Name** Please print **Signature** Please sign **Date** dd/mm/yyyy **Time** hh:mm  **Witness from recruiting site** (to be filled in by the person witnessing the taking of the participants consent) | | | **Name** Please print **Signature** Please sign **Date** dd/mm/yyyy **Time** hh:mm  **Please make three copies:** Keep the original in the Big Baby Trial investigator site file, give a copy to the participant, and put a copy in the participant’s medical notes. Funded by National Institute for Health Research-HTA 16/77/02. | | |
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