**FEED1 Trial**

**Informed Consent Form**

Version 1.2 23 February 2021

**Section A: Written Informed Consent**

**Name of Principal Investigator**:

**IRAS Project ID:** 266702

**Participant Trial ID:**

(To be completed after randomisation)

|  |  |  |
| --- | --- | --- |
|  | | **Please initial box** |
|  | I confirm that I have read and understand the Participant Information Sheet, Version <insert current PIS version number and date > for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
|  | I understand that my participation is voluntary and that I am free to withdraw my baby/babies at any time, without giving any reason, and without my own or my baby’s/babies’ medical care or legal rights being affected. I understand that should I withdraw, then the information collected so far cannot be deleted and that this information may still be used in the trial analysis. |  |
|  | I understand that relevant sections of medical notes and data collected in the trial may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (University of Nottingham), the Sponsor (University Hospitals of Derby and Burton NHS Foundation Trust), NHS bodies, the trial research group and regulatory authorities where it is relevant to my taking part in this trial. I give permission for these individuals to have access to these records and for a copy of this signed consent form to be sent to the Nottingham Clinical Trials Unit. |  |
|  | I give permission for the Nottingham Clinical Trials Unit, the Sponsor and the trial research group to collect, store, analyse and publish information obtained from me and my baby/babies participation in this trial. I understand that our personal details will be kept confidential. |  |
|  | I understand that the Nottingham Clinical Trials Unit and the trial research group will be provided with our personal details to contact me in order to assist with any trial related queries and/or trial data collection. I give my permission for this information to be kept and for these individuals to contact me to see how my baby/babies is/are getting on when they reach 6 weeks corrected age. I understand that members of the research group may also contact me when my baby reaches 2 years of age for follow-up of children in early childhood and for later educational outcomes. |  |
|  | I agree for my baby/babies NHS number to be used to access the National Neonatal Research Database, NHS Digital and other central UK NHS bodies to provide information about the health status of myself and my baby/babies. |  |
|  | I understand that the anonymised information collected about us may be used to support other research closely related to this study in the future and may be shared with other researchers. |  |
|  | I agree for my baby/babies to be fed either:   1. Full milk feeds – a minimum of 60ml/kg/day of milk only without the use of any supplementary fluids. 2. Gradual milk feeds (usual care) – a maximum of 30ml/kg/day of milk with supplementary fluids. |  |
|  | I agree to take part in the above trial. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Yes** | **No** |
|  | **Optional** | **Please initial either box** | |
|  | I would like to receive a copy of the results at the end of the study. |  |  |
|  | I agree to be contacted and informed about participating in future studies. I understand that there would be no obligation to participate. |  |  |
|  | I agree for my baby/babies NHS number to be used for contacting me for follow-up of children in early childhood and for later educational outcomes. |  |  |

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Name of mother Date Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person taking consent Date Signature of person taking consent

(You must be on the delegation log)

*Original signed ICF to be kept in the Investigator Site File (unless storage of such is not appropriate for instance where the participant has tested positive for COVID, the original will be photographed, and a printed copy kept in the Investigator Site File). 3 copies: 1 for participant, 1 for the medical notes and 1 to be sent to the Nottingham Clinical Trials Unit.*

**Section B: Oral Assent**

***This section is ONLY to be used for women who are approached in labour or postnatally. Please ensure that Written Informed Consent (section A) is completed within 72 hours of birth.***

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Name of woman

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_:\_\_\_\_\_\_

Name of person taking **oral** assent Date Time (24 hour)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person taking oral assent

Oral assent given ⃞ Yes

⃞ No

If yes, mother was given (tick all that apply):

⃞ Short Information Flyer

⃞ Patient Information Leaflet

⃞ Verbal information

**Witness signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**