**FEED1 – Fluids Exclusively Enteral from Day 1**

**Short Information Flyer – Version 1.0 02 July 2019**

**IRAS Project ID:** 266702

We are inviting you to take part in our research study because you have delivered, or are soon to deliver between 30 and 33 weeks of pregnancy. We want to find out what is the best way to feed babies born between these weeks and to keep them healthy in the long term.

**Why are we conducting the study?**

In the UK around 8% of babies are born early, with around 12% of these born between 30 and 33 weeks. The usual care for these babies is to give small amounts of milk through a tube into their stomach together with additional nutrition through a drip into their veins (intravenously or IV). The amount of milk is slowly increased until they are fully milk fed. For the purpose of this study, we will refer to this method as ‘gradual milk feeds’.

We would like to know if starting babies on full milk feeds only can reduce the need for IV tubes, reduce the risk of infection and therefore reduce the number of days they need to stay in the hospital. We hope that this will allow the mother to have a greater involvement in caring for the baby, increase parent-infant bonding, increase the availability of cots in hospital and reduce the overall costs to parents and to the NHS.

**Why have I been asked to take part?**

You are being asked to take part as you have delivered, or are soon to deliver between 30 and 33 weeks of pregnancy. To help us to answer our research question we are inviting 1,770 mothers with babies born between 30 and 33 weeks gestation to take part in the study. If you have given birth to more than one baby it is you who will be allocated to the group, therefore your babies will be in the same group receiving the same care.

**What will I have to do?**

We are inviting you to give verbal consent now to take part in the study. If you agree to take part your baby will be fed either **(1) full milk feeds (without additional IV nutrition) or (2) gradual milk feeds (with additional IV nutrition).** You will choose the type of milk your baby will be given (breast milk or formula) after talking with the doctors and nurses. If you do take part, we will ask you to sign a consent form within 72 hours of giving birth. We will send you a questionnaire either by post or online for you to complete and return when your child is 6 weeks corrected age and will, with your permission, keep in touch with you until your child is 2 years of age.

**What are the possible benefits of taking part?**

We do not know if taking part in the study will benefit you or your or baby directly. However by doing this study we are hoping it will help to determine the best way of feeding preterm babies and may therefore help to guide the management of preterm infants in the future.

**What are the possible risks of taking part?**

Evidence suggests that in premature babies who are not too poorly, larger milk feeds can be successfully given within 48 hours of birth without increasing the risk of complications, and could reduce the risk of severe infection.

**Do I have to take part?**

It is up to you to decide if you want to join the study or not. If you agree to take part, you are free to withdraw at any time, without giving a reason. If you choose not to take part, your care will continue in the normal way.

**Who has reviewed the study?**

This study has been reviewed and by East Midlands Derby Research Ethics Committee, the Derby and Burton Hospitals NHS Foundation Trust, and the National Institute of Health Research Health Technology Assessment Programme (which funded the study). A Parent Panel (made up of parents of preterm babies) have helped to design the study and have reviewed the study documents.