**Participant Information Sheet**

# Study title

Feasibility of cue-based feeding compared to scheduled feeding for babies in neonatal units

# Study Researcher

[Alison Findlay] [Elizabeth Bailey] [Louise Rattenbury]

**We invite you to take part in this research study**

Before you decide whether or not to participate, we need to be sure that you understand why we are doing the study and what you would need to do if you agreed to take part. This information will help you decide if you would like to take part, or not. Please take time to read it carefully, ask any questions, and, if you want, discuss it with others. We will do our best to answer any questions you have, now or later on. You do not have to make a decision straight away.

This study is supported by the University of Dundee and NHS Tayside. It is being funded by the National Institute for Health Research. The study has been organised by Dr Alison McFadden, Senior Research Fellow at the University of Dundee.

# What is this research about?

We know that feeding babies when they show signs that they are hungry (cue- based) is best for full term babies. Some research has shown that feeding premature babies when they show signs they are hungry might be good for them and their parents too. Feeding babies when they show signs they are hungry may allow parents to better understand the needs of their baby and become more involved in their baby’s care. Babies who are fed when they show signs they are hungry, instead of at set times (schedule), may be discharged from hospital earlier too.

# Why are we doing this research?

We want to develop a plan to help parents and staff to feed premature babies in neonatal units when they show signs that they are hungry instead of at set times. The plan will include training for staff and information for parents. We then want to find out if the plan is useful, if parents and staff find it helpful and if it could be tested in a future study comparing the two different ways of feeding premature babies in neonatal units.

# Why am I being invited to take part?

We want to talk to about 18 parents of babies in three neonatal units to find out what it was like feeding their babies at the time when they were changing from being fed through a tube to feeding by mouth. We are inviting you to take part because you have had this experience while your baby was in a neonatal unit. We would also like to know your views on feeding babies when they show signs they are hungry instead of at set times. This will help the study team to develop a plan so that it’s helpful for babies, parents and staff. We will also be talking to staff in three neonatal units, and visiting units that already feed babies when they show signs they are hungry instead of at set times. All of this information will help us to design a plan.

# What does taking part involve?

We would like to talk to you in a small group of about 6 parents, or if you prefer, on your own. The conversation will last about one hour and we will organise it at a time and place that is easy for you to attend. We would like to record the conversation. Your name will not be linked in any way to anything you say during the discussion. Before starting the discussion, we will ask you to sign a form to confirm that you understand the information in this leaflet and that you agree to take part.

# Do I have to take part?

It is up to you to decide. Taking part in this study is your choice and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason. Whether you take part or will not affect your baby’s care or your relationship with medical or nursing staff.

# What are the possible benefits of taking part?

The information that you provide will be used by the study team to design a plan that could benefit babies, their parents, and staff in neonatal units in the future. If you want, we can tell you what the study found when it is finished.

# What are the possible disadvantages and risks of taking part?

We do not think there are any risks to you from taking part in this research. We understand that talking about your experiences of neonatal care might be difficult and we will support you as best we can. We will not expect you to share any information you are not comfortable sharing with us. If you become upset during the interview the researcher will be able to support you, and if you would like, give you information about local services that may be able to offer you more support.

# Will my personal information be kept confidential?

The information you give us during the study, and any information that could identify you will be stored locally and named members of the research team will have access to this information

The information we collect, about you will be securely stored on a password-protected computer in the University of Dundee. Only named members of the research team will be able to see your personal information.

The information you give us will be stored securely for five years after the end of study, after which time it will be destroyed. Personal information about you will not be published or otherwise shared. Information that you give us that does not identify you, may be shared with other researchers in the UK.

# What if something goes wrong?

If you have any worries about taking part in the study you have the right to talk about this with someone from the research team.

If you have a complaint about taking part in the study, you should first talk to a researcher involved in the study. However you have the right to make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for [NHS Tayside].

Complaints and Feedback Team

NHS Tayside

Ninewells Hospital

Dundee DD1 9SY

Freephone: 0800 027 5507

Email: feedback.tayside@nhs.net]

In the event that you think you have suffered harm as a result of your participation in the study there are no automatic financial compensation arrangements.  However, you may have the right to make a claim for compensation. If you wish to make a claim, you should consider seeking independent legal advice but you may have to pay for your legal costs.

# Insurance

The University of Dundee and Tayside Health Board are co-sponsoring the study. The University of Dundee maintains a policy of public liability insurance which provides legal liability cover in respect of damages, costs and expenses arising out of claims.

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which provides legal liability cover of NHS Tayside in relation to the study.

As the study involves University of Dundee staff undertaking clinical research on NHS Tayside patients, such staff hold honorary contracts with Tayside Health Board which means they will have cover under Tayside’s membership of the CNORIS scheme.]

[NHS Health Trusts in England are participating as study sites and those NHS organisations will maintain membership of a scheme similar to CNORIS via the NHS Litigation Authority (NLA)].

# Who has reviewed this study?

The East of Scotland Research Ethics Service REC 1, which has responsibility for reviewing all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from University of Dundee and Tayside Health Board, whose role is to check that research is properly conducted and the interests of those taking part are protected. The baby charity Bliss is involved with this study.

The parents’ charity BLISS is involved in designing and conducting this study.

# Contact details for further information.

Dr. Alison McFadden (Chief Investigator) or Bronagh Raftery (Project Manager)

Dr Alison McFadden

E: nursing-health-CUBSstudy@dundee.ac.uk

T: 01382 388735 (Alison) or 01382 884963 (Bronagh)

Thank you for taking time to read this information and for considering participating in this study.

If you would like more information or want to ask questions about the study please contact the study team using the contact details above.

You can contact us Monday – Friday between 09:00-17:00