**Participant Information Sheet for staff**

# 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 would like to 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 firstly why we are doing the study and secondly what it would involve if you agreed to take part. We are therefore providing you with this information. Please take time to read it carefully, ask any questions, and, if you want, discuss it with others. We will do our best to explain and provide any further information you may ask for now or later. You do not have to make an immediate decision

This study is being sponsored 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 already known?

We know that feeding babies according to their feeding cues is best for full term babies. Some research has shown that feeding preterm babies when they show they are hungry might be beneficial for them and their parents. For example babies may be discharged from hospital earlier. Cue-based feeding may also allow parents to better understand the needs of their baby and become more involved in providing care.

# Why are we doing this research?

We want to develop an intervention to help parents and staff to feed preterm babies in neonatal units according to their feeding cues instead of according to a strict schedule. We then want to find out if the intervention is practical and acceptable to parents and staff and if the intervention could be tested in a future study comparing cue-based with scheduled feeding for preterm babies in neonatal units.

# Why am I being invited to take part?

We want to talk to about 24 staff in three neonatal units to find out your views and experiences of feeding babies who are ready to transition from tube to oral feeding in your unit. We particularly want to know what you understand by cue-based feeding and how you would feel about this being introduced in your unit. This will help the study team to develop an intervention that is effective, practical and acceptable to parents and staff. We will also be conducting focus groups/ interviews with parents in three neonatal units, and visiting units that are using cue-based feeding. All of this information will help us to design the intervention.

# Do I have to take part?

It is up to you to decide. Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason.

# What does taking part involve?

We would like to invite you to participate in a focus group discussion with some of your colleagues. The discussion will probably last about one hour and will take place at a time and venue that is convenient for you. Before starting the discussion, we will ask you to sign a consent form to indicate that you understand the information in this sheet and to confirm that you consent to participate in the research. If you are unable to attend the focus group discussion or if you prefer we can arrange an individual telephone interview instead. We would like to record the focus group discussion or telephone interview. Nothing that you say during the focus group will be attributed to either you or the neonatal unit where you work.

# What are the possible benefits of taking part?

The information that you provide will be used by the study team to inform development of an intervention that could benefit future babies and their parents, and staff in neonatal units. You will be informed of the findings on completion of the study.

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

There are no particular risks to taking part in this research.

# Will my personal information be kept confidential?

Identifiable information about you and your collected study data will be stored locally and designated members of the research team will have access to this information.

For data management purposes, your anonymised coded study data will also be securely stored on a password-protected database in the University of Dundee. Specified members of the data management team will also have access to your identifiable information.

Your data will be archived securely for five years after the end of study, after which it will be destroyed. Any Identifiable information about you will not be published or otherwise shared.

# What if something goes wrong?

If you have any concerns about your participation in the study you have the right to raise these with a researcher involved in conducting the study.

If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However you have the right to raise 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 scrutinising 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 adequately protected.’ Contact details for further information.

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

Chief Investigator:

Dr Alison McFadden

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

T: 01382388735 (Alison) or 01382 884963 (Bronagh)

[site researcher’s contact details]

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