HREC Project Number:	**LNR/14/BHSSJOG/28**
Research Project Title:	Sweeter For Everyone: A Ballarat Experience with Oral dextrose gel and its use in Neonatal Hypoglycaemia
Principal Researcher:	Dr Katie van Schilfgaarde, Paediatric Registrar, Ballarat Health Services
Version Number:	3 **Version Date:** 16/11/14

Thank you for taking the time to read this Parent/Guardian Information Statement and Consent Form. We would like to invite your baby to participate in a research project that is explained below. This document is 4 pages long. Please make sure you have all the pages.

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project.

If you would like your child to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this information and consent form to keep.

What is the Research Project about?

Low blood sugars are very common among babies as they go from having a continuous supply of sugar from mum to having to feed themselves. It is important to treat low blood sugars and this project looks at giving babies an extra sugar gel/syrup. This treatment with gel has been used and shown to be effective and safe

Who is funding this research project?

The Ballarat Paediatric Department as part of Ballarat Health Services is funding this project

Why is my child being asked to be in this research project?

Your baby has been identified as either having or being at risk of having low blood sugar. You have received this handout because we are currently undertaking a trial for a new treatment for low blood sugars and would appreciate your participation.

What does participation in this research involve?

As part of usual hospital care your baby will need regular blood tests to monitor the blood sugar. If the sugar level is low we either give babies extra feeds (usually formula) or a drip with sugar water straight into the vein. If you participate in the trial your baby will instead get 1-2.5mls of extra sugar gel/syrup in order to try and avoid extra formula or a drip.

What are my child's alternatives to taking part?

If you choose not to participate, you will continue to receive any required medical treatment through your normal doctor.

Participation in a research project is voluntary. It is your choice to let your child take part in this research. You do not have to agree if you do not want to.

If you give your consent and change your mind, your child can withdraw from the project. You do not need to tell us the reason why you or your child want to stop being in the project. If your child leaves the project we will use any information already collected unless you tell us not to.

Whatever your decision, it will not affect any treatment or care your child gets, or your family's relationship with Ballarat Health Services.

What are the possible benefits for my child and other people in the future?

Participating in the trial is another alternative for the treatment of low blood sugars. Taking part in this study may help doctors in the future to treat babies with low blood sugar levels.

What are the possible risks, side-effects, discomforts and/or inconveniences?

When used in a recent large study in New Zealand there were no reported adverse effects from the use of glucose gel. It is unlikely that there will be any unforeseen side effects from the study.

What will be done to make sure my child's information is confidential?

In this study, we will collect and use personal and health information about your child for research purposes. Any information we collect that can identify your child will be treated as confidential and used only in this project unless otherwise specified. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in the Department Paediatrics, Ballarat Base Hospital.

The following people may access information collected as part of this research project:

- the research team involved with this project
- Ballarat Health Services and St John of God Hospital Ballarat Human Research Ethics Committee

The stored information will be re-identifiable. This means that we will remove identifying information such as your child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so.

We are required to keep information collected as part of a research project for a certain length of time. Because the participants in this project are under 18 years old, we must keep information until a participant turns 25 years old. The research information may be destroyed or kept indefinitely in secure storage after this time.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about your child. Please contact us if you would like to access this information.

At the end of the study, results may be presented at conferences or published in medical journals. This will be done in such a way that your child cannot be identified.

Will we be informed of the results when the research project is finished?

We will send you a summary of the overall project results. The summary will be of the whole group of research study participants, not your child's individual results.

If you would like more information about the study or if you need to contact a study representative, the person to contact is: **Name:** Dr Katherine van Schilfgaarde **Contact telephone:** 5320 4000

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact:
Name: Dr Susan Shea Secretary, Ballarat Health Services and St John of God Hospital Ballarat Human Research Ethics Committee **Phone:** Ph 53204787 **email:** SusanS@bhs.org.au

CONSENT FORM

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Research Project Title: Sweeter For Everyone: A Ballarat Experience with Oral dextrose gel and its use in Neonatal Hypoglycaemia

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- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
  - I understand that this project has been approved by Ballarat Health Services and St John of God Hospital Ballarat Human Research Ethics Committee
- I understand I will receive a copy of this Information Statement and Consent Form.

Child's Name		
Parent/Guardian Name	Parent/Guardian Signature	Date
Name of Witness to Parent/Guardian's Signature	Witness Signature	Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name	Research Team Member Signature	Date

Note: All parties signing the Consent Form must date their own signature.