Department of **Health**
Government of **Western Australia**

Child and Adolescent Health Service

PARENT/GUARDIAN INFORMATION STATEMENT AND CONSENT FORM

HREC Project Number:

Research Project Title: Stepwise randomised controlled trial of combination adrenaline and dexamethasone in infants with bronchiolitis (DAB trial)

Principal Site Researcher: Dr Simon Erickson, Paediatrician and Intensive Care Consultant Princess Margaret Hospital for Children

Thank you for taking the time to read this Information Statement and Consent form. This document is 4 pages long. Please make sure you have all the pages.

For people who speak languages other than English: If you would also like information about the research and Consent Form in your language, please ask the person explaining this project to you.

Your child is invited to participate in a research project that is explained below.

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 to decide whether or not you would like your child to take part in the research.

Please read this Information Statement carefully. You can ask us questions about anything in it. You may want to talk about the project with your family, friends or health care worker.

Participation in this research project is voluntary. If you don't want your child to take part, you don't have to. You can withdraw your child from the project at any time without explanation and this will not affect their access to the best available treatment options and care from Princess Margaret Hospital for Children.

Once you have understood what the project is about, if you would like your child to take part please sign the consent form at the end of this information statement. You will be given a copy of this information and consent form to keep.

What is this study about?

Bronchiolitis is a common, acute, viral infection of the lower respiratory tract. It's mostly seen in children less than 1 year, but does affect children up to 2 years of age. Each year, an average of 32 children with severe bronchiolitis need admission to the intensive care unit. These children experience significant breathing difficulty and around 50% are ill enough to need help with breathing through a breathing machine called a mechanical ventilator. The normal treatment for these children is to support their breathing, and to give them adequate nutrition and fluids. Dexamethasone and adrenaline nebules are medicines that we know from previous research reduce the number of children admitted to hospital after presenting to the emergency department with bronchiolitis. They are already commonly used medications in respiratory disorders of children such as croup. Dexamethasone is an anti-inflammatory medicine and adrenaline enables inflamed airways that become narrow to re-expand. It is possible that these combined treatments may reduce the duration of intensive care unit stay and respiratory support required for those admitted to the intensive care unit with bronchiolitis. Some doctors use this medicine because they believe it works. Others do not use this medicine because they do not believe it works. The purpose of this research project is to see whether dexamethasone and adrenaline makes a difference in the treatment of children with bronchiolitis. We will compare a group of children who receive the standard treatment for bronchiolitis with a group of children who receive the standard treatment and dexamethasone and adrenaline. We will compare the chance of and duration of mechanical ventilation and the length of intensive care and hospital stay in both groups and aim to study a total of 274 children from 3 hospitals. We will also be conducting this research in other hospitals including Royal Children's Hospital Melbourne, Monash Medical Centre Melbourne, and the Starship and Middlemore Hospitals in New Zealand. The trial is aimed to run from 2013 to 2017

1. Who is funding this research project?

This is an unfunded study being done in paediatric intensive care units in Australia and New Zealand. This study is being coordinated by the research team at Royal Children's Hospital Melbourne.

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

We are asking parents of children aged up to 18 months who have severe bronchiolitis and need intensive care to take part in this study. As your child has bronchiolitis and requires intensive care, you are being asked to give permission for your child to take part in this project

3. What does my child need to do to be in this research project?

Your child will receive the usual management we provide to every child admitted to intensive care with bronchiolitis. The only difference will be that your child will receive either dexamethasone and adrenaline nebulisations or standard care for the time that he or she requires intensive care, to a maximum of 3 days, with observation in intensive care for up to 5 days. Standard care includes the supportive treatment we would normally provide to a child with bronchiolitis. After you have given signed consent, your child will enter into either the dexamethasone/adrenaline group or standard care group. The decision about which treatment your child receives is made by chance and each child has a 50/50 chance of receiving the dexamethasone/adrenaline or standard care alone. If entered into the dexamethasone/adrenaline arm dexamethasone will be given initially through a drip or less commonly an injection into the muscle followed by a repeat administration of a corticosteroid medication like dexamethasone (either methylpredinisolone or prednisolone) every 8 hours. Adrenaline will be administered on 5 occasions through an oxygen mask and

then again every 1 to 4 hourly if required. Both medications will be given for up to 72 hours. There are no tests required in addition to those that are ordinarily performed as part of routine standard care.
We will observe your child very carefully for the entire time they are in intensive care. When your child is well enough to leave intensive care this study will finish. There is no additional time involved in length of Intensive care or hospital stay. Your child's participation in the study is completed when they are well enough to leave the intensive care unit, and hence will be discharged from the research project. There is no need for any future follow-up.

4. What are my child's alternatives to taking part in this project?

The alternative option is you can decline to enter and your child will receive the standard treatment that the Intensive Care Unit uses for Bronchiolitis. Declining to enter will not make any difference to the other treatments or the quality of care that your child receives.

5. What are the possible benefits for my child?

Dexamethasone and adrenaline are medicines already used for different respiratory disorders in childhood. In bronchiolitis these medications could reduce your child's need for respiratory support with mechanical ventilation and the duration of intensive care stay. Mechanical ventilation requires that a tube be placed in the opening of the airway and is then attached to a machine to assist with breathing. We cannot guarantee that improvement will occur. This is the reason for the study.

6. What are the benefits for other people in the future?

The results of this study will indicate whether these medications are helpful in reducing the need for and duration of mechanical ventilation for children with bronchiolitis who are admitted to the intensive care unit

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

All medications have associated risks of side effects. Adrenaline is a medication that also works on the heart to make it beat faster and harder when given in a vein through a drip. In this study adrenaline will be nebulised into the airway and lungs through the mouth and nose. Adrenaline can be absorbed into the blood stream and increase the heart rate. When monitoring the heart rate we will not administer adrenaline if the resting heart rate is higher than 180 beats per minute.

Dexamethasone is commonly used in conditions such as croup (an infection of the upper airway). Belonging to the group of medications called steroids, dexamethasone can cause some agitation but is usually well tolerated for a short period of time such as 3 days.

8. What are the possible inconveniences?

Wearing a face mask for the administration of nebulised adrenaline will be required. A nebulisation often takes 3-5 minutes. The dose is likely to be repeated every 30 minutes for 5 hours and then between 1-4 hourly depending on the response for up to 3 days. The mask is removed after doses. Adrenaline and steroid medication can give a feeling of agitation but so to does respiratory distress of bronchiolitis.

Dexamethasone is administered by intravenous or intramuscular injection. Often an intravenous drip is already in place for the purpose of supportive care for bronchiolitis in the intensive care unit. No additional drips will be placed in this instance.

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

We will use study numbers for all data collection and analysis. The code will only be available to the research team and will be kept in strict confidentiality. No information regarding your child's name or address will bea made public. Information collected from your child will be stored in a locked file cabinet in the intensive care offices. A code protected computer database will also be maintained with all the information collected. The only people with access to the information will be the investigators involved in the research project

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

Information on the results of this study will be available to parents at the end of the project. We plan to send a letter to notify parents that a summary of results is available. You can contact us to receive a copy of the summary results of the study.

11. What happens if my child is injured during the project?

In the unlikely event that your child suffers an injury as a result of taking part in this project, hospital care and treatment will be provided by the public health service at no cost to you.

12. Will my child be able to claim any compensation if injured?

In the unlikely event of injury, standard medico legal procedures can be pursued in accordance with routine hospital care

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

Name: Simon Erickson 08 93408447

Intensive Care Unit

Princess Margaret Hospital

If you have any concerns about the project or the way it is being conducted, and would like to speak to someone independent of the project, please contact:

Dr. Mark Salmon
Medical Director
Princess Margaret Hospital for Children
Telephone: (08) 9340 8245.

CONSENT FORM

HREC Project Number:

Research Project Title: Stepwise randomised controlled trial of combination adrenaline and dexamethasone in infants with bronchiolitis (DAB trial)

Version Number: 2 **Version Date:** 9/05/2012

- I voluntarily consent for my child to take part in this research project.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this 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 Princess Margaret Hospital Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Parent/Guardian 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

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.