BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor Scott & White Medical Center- McKinney
McKinney, Texas

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: The Feasibility of Prolact CR for Neonatal Hypoglycemia

PRINCIPAL INVESTIGATOR ("PI"): Karen Stanzo, PhD, RN, IBCLC, NEA-BC

TELEPHONE NUMBER: 469-764-6282

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

Key Information

1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this research study because your baby is at risk for hypoglycemia (low blood sugar).

2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to find out what effects (good and bad) that Prolact CR (cream from donated and pasteurized human milk) has on your baby and others with neonatal hypoglycemia (low blood sugar in a newborn baby).

We think that your baby will be in the study for less than 48 hours.

3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?

If you decide to take part in this study, you will continue to breastfeed your baby normally and your baby will be fed Prolact CR up to 3 times by the nurses if they have low blood sugar.

4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to your baby. We hope that the information learned from this study will benefit other patients with this disease in the future.

The possible benefits of taking part in this study are the same as receiving oral glucose gel without being in this study. Oral glucose gel is a sugar gel that is gently rubbed into a baby's mouth to help their blood sugar go up.

5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?

Though Prolact CR is approved by the U.S. Food and Drug Administration (FDA) and has been used in premature infants in Neonatal Intensive Care Units without reports of problems, it has not been studied in well, full-term babies with neonatal hypoglycemia. The researchers do not know all of the effects that could happen, but they could include intolerance like spitting up or gas.

For a complete description of known risks, refer to the Detailed Information section of the consent form and privacy authorization.

6. WHAT OTHER OPTIONS ARE THERE?

You may choose not to take part in this study. Your baby will then receive oral glucose gel instead of Prolact CR if they have low blood sugar. Your baby will not receive Prolact CR if they do not participate in the study.

Please talk to your regular doctor about these and other options.

7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?

There is no additional cost to you or your insurance if your baby takes part in this study and subjects will not receive any payment for their participation.

Detailed Information Section

What is the Status of the Drugs Involved in This Study?

Prolact CR is not a drug, but a nutritional product. It is approved by the US Food and Drug Administration for other treatments, but is not approved for neonatal hypoglycemia, so it is considered investigational in this study.

Oral glucose gel, which is used for those not participating in the study, is an over-the-counter sugar gel that is not required to be FDA-approved and is routinely used for the treatment of neonatal hypoglycemia.

How Many People Will Take Part In This Study?

About 75 people will take part at this location.

What Will I Be Asked To Do?

Whether or not you choose to participate in this study, your baby will have heel stick blood tests to test their blood sugar and these will be performed before every feeding for at least 12 hours. If your baby continues to have low blood sugar, this testing may go on for about 24 hours. If a baby who is participating in the study has low blood sugar, nurses will feed them Prolact CR, the cream from donor-pasteurized human milk. If a baby who is not participating in the study has low blood sugar, nurses will rub glucose gel into the inside of their cheek.

After you are finished with this study, the study doctor, Prolacta Bioscience (the maker of Prolacta CR), and the institution will not continue to provide Prolact CR to you.

Your Responsibilities as a Research Subject:

Commitment: While you always have the right to change your mind and leave this study, you should enter this study only if you think you will want to be in it until it ends.

Problems: You will let the research staff know immediately if any problems occur while your baby is involved in this study. You will also let the research doctor/staff know if you have to go to an emergency room, doctor's office, or a hospital.

Medicines: You will let the research doctor/staff know about any changes in your baby's prescription medicines, over-the-counter medicines, and all vitamins or supplements that s/he takes.

Other studies*:* Your baby will not take part in any other study at the same time you are in this study (unless you are given permission by both PI's).

How Long Will I Be In This Study?

Your baby will be in this study for about 48 hours.

The researcher may decide to take your baby off this study if any of the following occur:

- The baby does not tolerate Prolact CR well.
- They feel that it is in the baby's medical best interest.
- The baby's condition worsens.
- New information becomes available.

You can stop taking part in this study at any time. However, if you decide to stop taking part in this study, we encourage you to talk to the researcher and your regular doctor first.

What Are The Risks of This Study?

While in this study, your baby is at risk for intolerance (spitting up or gas). You should discuss these with the researcher and/or your regular doctor. There also may be other reactions that we cannot predict. Other medicines may be given to make this reaction less serious and uncomfortable.

Conflict of Interest

Your doctor and nurse may be investigators in this study. If so, they are interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor or nurse who is not associated with this research project. You are not under any obligation to take part in any research study offered by your doctor or nurse.

What About Confidentiality?

You have a right to privacy. This means that all the information about your baby from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute ("BSWRI") and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively, "Your Health Care Providers") get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Board), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 3434 Live Oak, Dallas TX 75204. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your study-related health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

Additional Financial Information
Prolacta Biosciences, the sponsor of the study will pay for:

- Prolact CR

You or your insurance company will pay for:

- Your hospital stay
- Some of the lab tests that may be done for the study, but that you would need to pay for even if you were not in the study

You will not be paid for being in this study. There is no additional cost to you or your insurance if your baby takes part in this study.

What if I am Injured or Become Ill While Taking part in this Study?
The people doing this research project will do everything they can to make sure your baby does not get hurt during the project. If they do get hurt, there are some things that you need to know:

- Baylor Scott and White Health, Baylor Scott and White Research Institute and Baylor Scott & White – McKinney have not set funds aside to pay you money if you are hurt.
- If your baby has an emergency illness during the project, the people working with you will provide emergency care. You or your insurance company may need to pay for the emergency care if that happens.
- You have not given up any of your legal rights by signing this form.

What are My Rights As a Subject?
Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason. Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact Karen Stanzo at 469-764-6282 or 469-764-6940.
For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 254-215-9697.

Statement of Person Obtaining Consent:

I have explained to _____(printed name of parent/legal representative) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this study. You will be asked to give your written consent if you want your baby to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission for your baby to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, my baby is not in any other medical research. Therefore, I consent for my baby to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____ _____ _____
Signature of Parent/Legal Guardian Date Time

_____
Relationship to Subject