Pregnancy Partner Informed Consent to Participate in Research

BMT CTN 2001

A Multi-Center, Phase 2 Gene Transfer Study Inducing Fetal Hemoglobin

in Sickle Cell Disease

Your Name: _____

Principal Investigator:

Insert local PI information

Sponsor: This study is sponsored by the National Institutes of Health the National Institutes of Health, through the Blood and Marrow Transplant Clinical Trials Network

The ethics of this study have been reviewed and approved by [name of IRB].

A study doctor or nurse will review this **Consent Form** with you, including:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Other options available to you
- ✓ Your rights if you join the study

1. Study Overview

You are being asked to provide information on your pregnancy, and on the birth and health of your newborn child, because the biological father of your child is/was participating in a clinical research study titled "A Multi-Center, Phase 2 Gene Transfer Study Inducing Fetal Hemoglobin in Sickle Cell Disease".

The main purpose of the clinical research study the biological father of your child is/was participating in is to learn whether a new treatment called gene therapy can be used safely, and whether it improves or eliminates the symptoms of sickle cell disease (SCD). Gene therapy is a new treatment created from the biological father's own blood-forming cells. The study he is participating on will look at whether gene therapy can be used in place of a stem cell transplant to improve symptoms of SCD.

You have become pregnant within 30 days from the biological father's receipt of gene therapy cells. The purpose of this consent is to allow collection of information about your pregnancy and newborn by the National Heart, Lung and Blood Institute (NHLBI), who is conducting the research your partner is/was a part of. Connell & O'Reilly Families Cell Manipulation Core Facility, Dana-Farber Cancer Institute and California Institute for Regenerative Medicine (CIRM) are also involved in sponsoring this study. You nor your child will not be given any experimental drug if you agree to this consent. We will just collect information from you or your doctor. This information is important to the overall safety evaluation of the gene therapy.

If you agree, you may provide this information yourself or give permission to your health care provider and/or obstetrician/gynecologist to release it directly to the biological father's study doctor. If you agree to participate and allow your information to be used and analyzed, you will be asked to sign and date this form.

If you agree:

- You or your health care provider will answer questions about your health and your pregnancy.
- We'll collect information about your health, your pregnancy, and the result of your pregnancy, such as childbirth.

Some possible risks and benefits of joining the study include:

Possible Risks: There is a small risk your confidentiality could be lost. The study team will do everything it can to keep your information confidential.

Possible Benefits: None.

If you do **not** join the study, you can continue your usual health care.

Key points:

- Providing data for any research study is your choice.
- Knowledge gained from your pregnancy and/or newborn's medical information may help others.
- If you agree to provide medical information, you can change your mind at any time. If you decide to no longer provide information, it will not affect you or your newborn's care.
- Ask the study staff questions about anything you do not understand, or if you would like more information. You can ask questions now or at any time.
- Take time to talk about whether you want to provide medical information with your doctor, study staff, and your family and friends. It is **your** choice to provide medical information. If you decide to provide medical information, please sign the end of this Consent Form. You'll get a copy to keep. No one can force you to agree.

2. Study Purpose

We are doing the study the biological father is/was a part of to test a new possible treatment for Sickle Cell Disease (SCD). SCD is a disease that causes the oxygen carrying blood cells, called hemoglobin, to sickle, preventing those cells from carrying oxygen and causes other issues in the veins based on the change from a circular cell to a sickled cell. SCD is usually treated with medicines to manage the symptoms of SCD. Currently, the only treatment that has the potential to cure SCD is hematopoietic stem cell transplantation (HSCT), also called bone marrow transplant.

Gene therapy is a treatment made of the biological father's own blood cells. A genetic material, called DNA, is inserted into the blood cells to produce a hemoglobin that doesn't cause the red blood cells to sickle. Doctors think that the gene therapy will help the biological father's red blood cells not sickle and improve symptoms of SCD.

Gene Therapy has not been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities. This study is registered with the FDA, and they will monitor it for safety.

The purpose of this consent is to learn if exposure to gene therapy cells affects an unborn baby. The biological father has received gene therapy. At this time, it is not known whether gene therapy has an effect on an unborn baby or sperm.

3. Study Treatment and Tests

The biological father's study doctor will **not** do any examinations, tests, or procedures on you.

You or your health care provider will answer questions about you and your pregnancy and we will collect information from your medical records.

We will collect information about:

- Your age, sex, and race/ethnicity
- Your physical or mental health
- Any medicines that you take during your pregnancy
- Any previous pregnancies, including any complications
- Your current pregnancy
- Your delivery
- Your baby's health

If you have an abortion or a miscarriage, we'll ask for health information from you or your doctor so we can learn if the study treatment affects pregnancy.

4. Risks and Benefits

Possible Benefits

You will receive no benefits or payment for joining this study. The information we learn may help us care for people in the future who become pregnant after they or their partner has received gene therapy.

Possible Risks

There are very few risks with sharing your medical information and answering questions about your pregnancy. The main risk is that your confidentiality could be lost. The study team will do everything it can to keep your answers confidential.

5. Your Rights to Withdraw, Ask Questions, and Seek Other Treatment

Agreeing to provide information about your pregnancy and newborn is your choice. You can choose **not** to provide medical information. If you initially agree to provide information you can change your mind at any time. If you choose to not participate, it won't affect your regular medical care in any way. If at any time you are considering no longer providing medical information, talk to the biological father's study doctor or your doctor about your health and safety.

If you do **not** want to share information about your pregnancy, you may still contact the study doctor at any time to get updated information about the safety of the gene therapy.

You have the right to ask questions about the study at any time. If you have questions about the study, please contact:

[Insert contact details of Principal Investigator or Study Team]

If you want to talk with someone not directly involved in the study, or have any complaints or questions about your rights or about potential risks and injuries, you may contact the NMDP IRB Administrator at:

1-800-526-7809

You must tell [insert name of Principal Investigator] if you decide to leave the study.

6. New Information Available During the Study

During the study the biological father is/was a part of, the study doctors may learn new information about gene therapy and the risks to pregnancy or babies. If they learn new information, they'll tell you or the biological father as soon as it's available.

7. Privacy, Confidentiality, and Use of Information

Your privacy is very important to us. The study doctors, study sponsor, and other groups with access to your pregnancy-related medical information will do everything they can to protect it. The study doctors can protect your records if there is a court case. However, some of your medical information may be shared if required by law. If this happens, the study doctors will do their best to make sure that any information that goes out to others will **not** identify you or your newborn.

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept confidential (private). However, we cannot promise total privacy.

To make sure the study is running ethically, some government agencies or other groups may need to access part of your medical records. For this study, those groups include:

- [Institution]
- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN DCC), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP)/Be The Match registry and The Emmes Company, who are coordinating the studies of the BMT CTN

- The Food and Drug Administration (FDA) and National Institutes of Health (NIH), which includes the National Heart, Lung and Blood Institute (NHLBI) and the National Cancer Institute (NCI) – including the Recombinant DNA Advisory Committee (RAC)

- Office of Human Research Protection (OHRP)
- The Data and Safety Monitoring Board (DSMB), not part of [Institution]
- Institutional Review Boards (IRBs) responsible for this study
- Connell & O'Reilly Families Cell Manipulation Core Facility, Dana-Farber Cancer Institute
- California Institute for Regenerative Medicine (CIRM)
- Study investigators

If information regarding pregnancy from the biological father's study is published or presented at scientific meetings, your name and other personal information will not be used. Study information may also be used for research in the future.

A description of the biological father's clinical study is available on http://www.clinicaltrials.gov. This website does not include information that can identify the biological father or you. You can search this website at any time.

8. Leaving the Study

You may choose to no longer provide pregnancy or newborn information at any time.

If you leave, the information already collected from you will still be included in the biological father's study. If you don't want your information to be used, you **must** let his study doctor know.

9. Cost and Reimbursement

You will receive **no** benefits or payment for providing information to the biological father's study. This research will not cover any costs related to your pregnancy, delivery, newborn care, abortion or miscarriage.

10. Health Insurance Portability and Accountability Act 1 (HIPAA) Authorization to use health information for research

Your local study site will give you a separate form with information about the Health Insurance Portability and Accountability Act 1 (HIPAA).

TITLE: **BMT CTN 2001:** A Multi-Center, Phase 2 Gene Transfer Study Inducing Fetal Hemoglobin in Sickle Cell Disease

- I have read and understood this Consent Form. The purpose and description of the information requested has been explained to me.
- I have had the chance to ask questions and understand the answers I have been given. I understand that I may ask questions at any time.
- I freely agree to provide pregnancy information to my partner's study.
- I have had the chance to discuss my participation with a family member or friend if I choose.
- I understand that…
    - I may not directly benefit from providing pregnancy or newborn medical information.
    - My name and personal information will not be identified even if information gained is published.
    - I can stop providing medical information at any time and doing so will not affect my current care or prevent me from receiving future treatment.
    - I will be given a copy of this signed consent form.
    - I do not give up any legal rights by signing this form.

_____ _____

Participant Name (or Parent/Guardian) Date (MM/DD/YYYY)

_____ _____

Participant Signature (or Parent/Guardian) Date (MM/DD/YYYY)

Physician certification

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

Counseling Physician Name	Date (MM/DD/YYYY)
Counseling Physician Signature	Date (MM/DD/YYYY)

Interpreter certification (if needed)

I certify that I have provided an accurate interpretation of this consent form. I believe the participant has understood the information provided.

Interpreter Name	Date (MM/DD/YYYY)
Interpreter Signature	Date (MM/DD/YYYY)