Pregnancy Partner Informed Consent to Participate in Research v1.0

BMT CTN 1705

A Randomized, Double-Blind, Placebo-Controlled Multicenter Phase III Trial of Alpha 1 – Antitrypsin (AAT) Combined with Corticosteroids vs. Corticosteroids Alone for the Treatment of High Risk Acute Graft-versus-Host Disease (GVHD) Following Allogeneic Hematopoietic Stem Cell Transplant

Your Name: _____

Principal Investigator:

Insert local PI information

Sponsor: This study is sponsored by CSL Behring and 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 the National Marrow Donor Program Institutional Review Board (NMDP IRB).

Your 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

We invite you to join this clinical trial, also known as a research study. We're doing this study to see if exposure to Alpha-1 antitrypsin (AAT) affects an unborn baby.

You're being asked to join because you became pregnant while you or your partner was in a study of AAT. Researchers are studying AAT to see if it will help treat graft-versus-host disease (GVHD). GVHD is a common and serious side effect of an allogeneic blood or marrow transplant (BMT).

If you join:

- You'll 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:

- Being in any research study is your choice.
- Knowledge gained from this study may help others.
- If you join the study, you can quit at any time. If you decide to quit the study, it will not affect your care at [name of facility or institution].
- 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 the study with your doctor, study staff, and your family and friends. It is **your** choice to be in the study. If you decide to join, please sign the end of this Consent Form. You'll get a copy to keep. No one can force you to join this study.

2. Study Purpose

We're doing this study to learn if exposure to AAT affects an unborn baby. You or your partner may have received either AAT or placebo. A placebo is a treatment with no medicine in it. At this time it is not known whether AAT has an effect on an unborn baby, sperm or egg, and it is not known if AAT is passed through sperm.

AAT has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with AAT deficiency and evidence of emphysema, with a recommended dose of 60 mg per kg of body weight. The known side effects/risks are listed in the table in Section 4 below. AAT has NOT been approved by the FDA for the treatment of acute GVHD. This research study is registered with the FDA, and they will monitor it.

3. Study Tests

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

You 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 your doctor so we can learn if AAT 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 while they or their partner is taking AAT.

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

Being in this study is your choice. You can choose **not** to be in this study or leave this study at any time. If you choose to share information about your pregnancy, it won't affect your or your partner's regular medical care in any way.

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 AAT.

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 as a research participant 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 this study, the study doctors may learn new information about AAT or the risks and benefits of taking part in the study. If they learn new information, they'll tell you 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 study-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.

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]
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protection (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state, and local health departments
- The Data and Safety Monitoring Board (DSMB), not part of [Institution]
- The National Marrow Donor Program (NMDP) Institutional Review Board (IRB) responsible for this study
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Data and Coordinating Center (DCC), including:
    - The Center for International Blood and Marrow Transplant Research (CIBMTR)
    - The NMDP
    - Emmes, a company that coordinates the BMT CTN studies
- CSL Behring, its collaborators, or designees. This may include people within or outside of the United States (U.S.). **Privacy laws outside of the U.S. may be less strict.**
- Study investigators

If information from this 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.

You will **not** be able to access your study results before the study is done. This helps keep the study results accurate and trustworthy.

When the study is complete, you can ask your study doctor for information from the study. **By signing this Consent Form, you agree to ask for results only after the study is done.** You will still have access to your regular medical records.

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

8. Leaving the Study

You may choose to leave the study at any time.

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

9. Cost and Reimbursement

You will receive **no** benefits or payment for taking part in this research. 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 hospital will give you a separate form with information about the Health Insurance Portability and Accountability Act 1 (HIPAA).

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- I have read and understood this Consent Form. The purpose and description of the research study 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 during the study.
- I freely agree to be a participant in the study.
- I have had the chance to discuss my participation in this research study with a family member or friend if I choose.
- I understand that…
    - I may not directly benefit from taking part in the study.
    - My name and personal information will not be identified even if information gained during the study is published.
    - I can leave this study 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	Date (MM/DD/YYYY)
Participant Signature	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)