Informed Consent for Your Child to Participate in Research

Study Title:	Protocol for Collection of Patient Reported Outcomes (PRO) Data
Principal Investigator:	Rachel Cusatis, PhD
Sponsor:	The Center for International Blood & Marrow Transplant Research (CIBMTR)

The ethics of this study have been reviewed and approved by the National Marrow Donor Program Institutional Review Board.

This **Consent Form** includes:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Your child's rights if they join the study

1. Study Overview

We are inviting your child to join this research study. We're doing this study to learn about what patients' lives look like after a blood or marrow transplant (BMT) or other cellular therapy. The study will also help us give better care to future patients.

Your child is being asked to join because:

- They have gotten or will get cellular therapy
- You have agreed that we can contact you or your child about joining research studies

If they join, they will take surveys about their health and well-being. You may assist them with these surveys if necessary. The surveys can be taken wherever your child has access to the internet, can take a telephone call, or can receive and send mail.

Key points:

- Participating in any research study is you and your child's choice.
- Your child may or may not benefit from being in the study. Knowledge we gain from this research may help others.
- There are few risks to being in this study. Some questions on the study surveys may upset you or your child.
- If your child joins the study, we will send them surveys at certain time points in the first year after treatment, and then once a year for the rest of their life. They can quit at any time.
- If they decide to quit the study, it won't affect their care with their medical teams.
- You or your child can contact us at any time if there is anything they don't understand, if they want more information, or if they want to quit the study.
- Take the time to talk about the study with your child, their doctor, study staff, and their family and friends. It's you and your child's choice to be in the study. If you decide to allow them to join, please sign the end of this consent form. You and your child will both get a copy to keep. No one can force you or your child to join this study.

2. Study Purpose

We're doing this study to learn about what patients' lives look like after a blood or marrow transplant (BMT) or other cellular therapy. The study will also help us give better care to future patients.

Side effects are common after cellular therapy and can be serious. Some side effects can last for a long time and can affect the patient's life.

3. Study Activities

If your child joins the study, they will take surveys. You and your child can choose how to take the surveys. It can be:

1. Online. We'll send a link to the survey by email. The link won't have any information that could identify you or your child.
2. On paper. We'll send the survey in the mail, with a stamped and addressed envelope to return the survey.
3. On the phone. We'll call and ask you and your child the questions.

Each survey takes about 15 to 25 minutes. The surveys will ask your child about how they're doing after their cellular therapy. They can skip any questions they want. You or your child can also stop the survey or leave the study at any time.

We may contact your child to complete surveys:

- Before their treatment
- 30 days after treatment
- 100 days after treatment
- 180 days after treatment
- Once a year for the rest of their life

The surveys will ask about their general well-being, and topics that may be sensitive, like:

- Any signs of sadness or depression they may have
- How much they worry or feel nervous
- Your family finances and going back to work or school
- Information about their school and relationships

To participate in this study, your child must also join another study, the *CIBMTR Protocol for a Research Database for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries (Research Database Protocol).* This survey study involves collecting patient reported outcomes data on surveys. The *Research Database Protocol* governs how your child's survey data can be used for research.

Your child may have already joined the *Research Database Protocol*, or they may be asked to join when they receive a transplant or other cellular therapy. If you or your child decide not to join, or decide to leave the *Research Database* protocol, they will stop being in this survey study.

Their answers to the survey questions will be used in research studies. They will not take any medicines for this study or have any tests done.

If we send them a survey, but don't receive it back, we may contact you or your child by phone, email, text, or mail to make sure they got the survey and remind you and your child to complete it. You can tell us how you and your child would like to be contacted.

If their contact information changes (for example emails to you or them bounce back to us), we may ask their treatment center or search online for updated contact information.

Your child can participate in this study for as long as they'd like. There is no limit to how many people can join the study.

4. Risks and Benefits

Possible Benefits

Taking part in this study may or may not help your child. The information from this study may help future patients get better care during and after their cellular therapy.

Possible Risks

There are few risks with taking the surveys.

Some of the questions or topics may upset your child. Your child's doctor won't contact them about their responses, so if they have any concerns about their feelings or thoughts, make sure they tell you or their doctor right away.

There is also a small risk that someone could find out which answers are your child's. We will do everything we can to keep their answers confidential.

5. Your Rights to Ask Questions and Leave

Being in this study is you and your child's choice. You and your child can choose **not** to be in the study or leave this study at any time. If you or your child choose not to join or leave this study, it won't affect your child's regular medical care in any way.

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

CIBMTR survey research group
Call: 1-888-298-6714
Email: surveys@cibmtr.org

If you or your child want to talk to someone outside this study about general problems, concerns, or questions, please contact:

NMDP Patient Support Center
Call: 1-888-999-6743
Email: PatientInfo@nmdp.org

If you or your child want to leave the study, please contact:

CIBMTR survey research group
Call: 1-888-298-6714
Email: surveys@cibmtr.org

If you or your child have questions about their rights as a research participant, please contact:

NMDP Institutional Review Board (IRB) Administrator at 1-800-526-7809

You and your child will receive a copy of this consent form for your records. Your child doesn't lose any of their legal rights by signing this consent form.

6. Confidentiality and Use of Information

We will do our best to make sure that your child's survey answers are not seen by anyone else. However, there is a small risk that someone could find out which survey answers belong to your child.

We will label your child's survey answers with a code. The code does not include any information about them. If information from this study is published or presented at scientific meetings, your child's name and other personal information will not be used.

We will not tell anyone that your child is in this study. However, some of your child's information may be shared if required by law. If this happens, we will do our best to make sure that it will **not** identify your child.

To make sure the study is running ethically, some government agencies or other groups may need access to some of the information in your child's study records. Your child's survey responses in the research database may also be shared with these organizations.

Some of these organizations are:

- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- Institutional Review Board (IRB) or ethics committee
- Health Resources and Services Administration (HRSA)
- The Food and Drug Administration (FDA)
- U.S. government agency sponsor
- The National Marrow Donor Program (NMDP)

If your child leaves the study after giving us survey answers, you or your child can decide if we can use them.

At the time of your child's cellular therapy, they may have agreed to have data about their cellular therapy added to the CIBMTR Research Database. Your child's treatment center gave you and your child the consent form for the CIBMTR Research Database. Your child's survey results will be added to their data that is already in the CIBMTR Research Database. Your child's name and other information that could identify them will not be placed in the CIBMTR Research Database.

Your child's survey results may also be used in studies they specifically consent to, or for process improvement and evaluation within the CIBMTR. Your child's survey results may be used this way, even if you or your child have not agreed to the CIBMTR Research Database.

What is a research database?

It is a place where researchers share information from studies, like survey answers. They put the information into a system, where it is stored with information from other studies. Other researchers can look at the information to learn more about health and treatment.

7. Leaving the Study

You or your child can choose to leave the study at any time.

You or your child may also be told to leave the study for reasons such as:

- Your child doesn't meet the study requirements
- It would be harmful to your child to stay in the study
- The study is stopped for any reason

8. Cost and Reimbursement

It will not cost you or your child anything to join this study. Your child will not be paid for taking part in this study.

Permission to Share Survey Answers with Your Doctor

We will not share your child's survey answers with their cellular therapy/transplant doctor without their permission. Your child may still participate in the study even if they do not agree to share their results with their cellular therapy/transplant doctor.

☐ I **AGREE** to have my child's individual survey results shared with their cellular therapy/transplant doctor.

☐ I do **NOT** agree to have my child's individual survey results shared with their cellular therapy/transplant doctor.

TITLE: *Protocol for Collection of Patient Reported Outcomes (PRO) Data*

- I've read and understand this consent form. The type of study and the reason for the study has been explained to me.
- I've had the chance to ask questions, and I understand the answers I've been given. I understand that I may ask questions at any time during the study.
- I freely agree to allow my child to take part in the study.
- I've had the chance to talk to my child about taking part in the research and also have had the chance to talk with a family member or friend, if I want.
- I understand that…
    - My child may not directly benefit from taking part in the study.
    - My child's name and personal information will not be identified even if information gained during the study is published.
    - My child's survey results will be stored in the CIBMTR Research Database and can be seen by researchers for future studies.
    - My child can leave this study at any time, and doing so won't affect their current care or future treatment.
    - I will be given a copy of this consent form.
    - My child does not give up any legal rights by me signing this form.

Please write your name: ______________________________________	Please write your child's name: ______________________
Please sign your name: ______________________________________	Please write today's date: ______________________