Informed Consent 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 NMDP Institutional Review Board.

This **Consent Form** includes:

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

1. Study Overview

We invite you 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.

You're being asked to join because you:

- Have gotten or will get cellular therapy
- Agreed that we can contact you about joining research studies

If you join, you'll take surveys about your health and well-being. You can take the surveys wherever you have access to the internet, can take a telephone call, or can receive and send mail.

Key points:

- Participating in any research study is your choice.
- You 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.
- If you join the study, we will send you surveys, or call you for surveys, at certain time points in the first year after treatment, and then once a year for the rest of your life. You can quit at any time.
- If you decide to quit the study, it won't affect your care with your medical teams.
- You can contact us at any time if there is anything you don't understand, if you want more information, or if you want to quit the study.
- Take the time to talk about the study with your doctor, study staff, and your family and friends. It's 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 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 your life.

3. Study Activities

If you join the study, you will take surveys. You can choose how to take the surveys. It can be:

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

Each survey takes about 15 to 25 minutes if done online or on paper, or up to an hour if done over the phone. The surveys will ask you about how you're doing after your cellular therapy. You can skip any questions you want. You can also stop the survey or leave the study at any time.

We may contact you to complete surveys:

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

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

- Any signs of depression you may have
- How much you worry or feel nervous
- Sexual health and your ability to have children
- Your finances and going back to work or school
- Information about your job and relationships

To participate in this study, you 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 survey data can be used for research.

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

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

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

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

You can participate in this study for as long as you'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 you. 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 you. Your doctor won't contact you about your responses, so if you have any concerns about your feelings or thoughts, tell your doctor right away.

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

5. Your Rights to Ask Questions and Leave

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

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

CIBMTR survey research group
Call: 1-888-298-6714
Email: PRO-Surveys@nmdp.org

If you 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 want to leave the study, please contact:

CIBMTR survey research group
Call: 1-888-298-6714
Email: PRO-Surveys@nmdp.org

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

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

You will receive a copy of this consent form for your records. You don't lose any of your legal rights by signing this consent form.

6. Confidentiality and Use of Information

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

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

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

To make sure the study is running ethically, some government agencies or other groups may need access to some of the information in your study records. Your 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
- NMDP
- Office of Naval Research (ONR), a partial funding source for this study.

If you leave the study after giving us survey answers, you can decide if we can use them.

At the time of your cellular therapy, you may agree to have data about your cellular therapy added to the CIBMTR Research Database. Your treatment center has given or will give you the consent form for the CIBMTR Research Database. Your survey results will be added to your data that is already in the CIBMTR Research Database. Your name and other information that could identify you will not be placed in the CIBMTR Research Database.

Your survey results may also be used in studies you specifically consent to, or for process improvement and evaluation within the CIBMTR. Your survey results may be used this way, even if you 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 can choose to leave the study at any time.

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

- You don't meet the study requirements
- It would be harmful to you to stay in the study
- The study is stopped for any reason

8. Cost and Reimbursement

It will not cost you anything to join this study. You will not be paid for taking part in this study.

Permission to Share Survey Answers with Your Doctor

We will not share your survey answers with your cellular therapy/transplant doctor without your permission. You may still participate in the study even if you do not agree to share your results with your cellular therapy/transplant doctor.

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

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- 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 take part in the study.
- I've had the chance to talk about taking part in the research with a family member or friend, if I want.
- 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.
    - My survey results will be stored in the CIBMTR Research Database and can be seen by researchers for future studies.
    - I can leave this study at any time, and doing so won't affect my current care or future treatment.
    - I will be given a copy of this consent form.
    - I do not give up any legal rights by signing this form.

Please write your name: Please write today's date:

_____ _____

Please sign your name.

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