

Assent Form 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)

1. What is this study?

We would like to ask you if you are willing to take part in a research study. Research is a way to test new ideas or medicines, and it helps us learn new things.

You and your parents or legal guardians can decide if you want to take part in the study. Being in this study is your choice, even if your parents/guardians want you to be in the study. If you do not want to take part in the study or if you want to leave, you will not get in trouble. If your parents or legal guardians do not want you to take part in the study or if they want you to leave the study later, you will not get in trouble.

You do not have to choose right now. The information included in this document should help you to make your choice, so it is important that you understand everything. We will give your parents/guardians a consent document as well. When you have read everything, they will talk with you about it.

2. Why is this study being done?

The study will help us learn how blood or marrow transplants or other cell and gene therapies affect the lives of children and adolescents. It will also help us give better care to future children and adolescent patients.

You are being asked to join this study because you have gotten or will get cell or gene therapy for your health condition. The study doctors hope that your answers and health information will help young people get better, but they don't know if it will for sure. That is why they are doing the study.

3. What will happen if you decide you want to be in this research study and how long will it take?

If you agree to be in this study, you will answer questions about your health and feelings on a survey. You can take the surveys on the computer, on a phone call, or by writing with paper and pen. Each survey can take 15 to 25 minutes if it is 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 ask you to answer a survey:

- Before your treatment
- 30 days after your treatment
- 100 days after your treatment
- 180 days after your treatment
- Once a year

What questions will we ask you?

The surveys will ask you about your health and feelings, and the topics may or may not be upsetting, like:

- How you are doing
- Signs you are feeling unhappy or depressed
- How much you worry or feel nervous
- How you feel going back to school
- Information about your relationships with friends and family

4. What are the possible benefits or risks of this study?

Benefits:

Being in this study may or may not help you. Your answers from this study may help future children and adolescents get better care during and after their cell or gene therapy.

Risks:

There are a few risks with taking surveys. Some of the questions or topics may upset you. Your doctor won't contact you about your answers, so if you have any worries about your feelings or thoughts, tell your doctor or guardian 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 private.

5. What are your choices?

It is your choice whether you will take part in this study or not. You can say 'Yes' or 'No'. Whatever you decide is okay.

If you say “**No**”; the doctors will still take care of you.

Your parents or legal guardian may have said that it is okay with them if you want to be in the research study. Even though they have said it is okay with them, you can still say 'No'. No one will be upset with you if you do not want to do this.

If you say “**Yes**”; You will be asked to confirm that you agree to take part in this study. You will be given a copy of this form. Your parent or legal guardian will also be asked to confirm that they agree that you can take part in this study. Please know that you can change your mind and decide to stop being in the study at any time without giving a reason.

What happens to you when the study is finished?

There is no end to this study unless you want to stop.

Who can you ask if you have more questions?

If you have any questions about this study, you or your parents/guardians can call the study's survey group at 1-888-298-6714, or email at surveys@cibmtr.org.

What happens with the information that is collected about you?

At the time of your cell or gene therapy and during the study, information about you and your disease will be recorded and electronically stored in the CIBMTR research database. Your survey answers will also be added to the database. Your name will not be mentioned in this database, and you will only be identified in the study under a specific code.

Certain people, like the people in charge of the study, the doctors and staff at the hospital, and maybe the national health authorities involved in the study, may have access to your original medical records. This is to make sure that the study is performed correctly. They are allowed to know your name and to inspect the documents.

If you would like to stop participating in the study, you are allowed to. Please know that the data about you and your disease that have already been collected will remain stored even after you are no longer in the study. Your parents/guardians have received further information about this.

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.

Permission to Share Survey Answers with Your Doctor

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

- ☐ I **AGREE** to have my survey answers shared with my cell or gene therapy doctor.
- ☐ I do **NOT** agree to have my survey answers shared with my cell or gene therapy doctor.

By signing this form, you agree to the following:

- I have read the information about this study and/or had someone explain it to me.
- I understand what this study is about.
- I have asked all the questions I want and understand the answers I've been given. I understand I can ask questions whenever I want during the study.
- I have talked to my parents or guardian about being in this study if I want.
- I understand that...
 - I may or may not benefit from this study.
 - My name and personal information will not be told to anyone outside of the study.
 - My answers will be stored in the research database for future scientists to use.
 - I will get a copy of this form.
 - I do not give up any legal right by signing this form.

Your Name: _____

Your Signature: _____

Today's Date: _____