

Assent to Participate in Research (7 to 11 years of age)



Study Title: Clinical Transplant-Related Long-term Outcomes of Alternative Donor Allogeneic Transplantation (CTRL-ALT-D)

Protocol: BMT CTN 1702

A. Why am I here?

We'd like you to join our study because you have a blood disease and you need a transplant.

B. Why are you doing this study?

We want to know:

- How well kids and grown-ups do after transplant depending their chance of finding a matched unrelated donor.
- How well some people with diseases called AML, ALL, and MDS do after their transplant.
- Problems people have when trying to get a transplant.
- How many of the people in this study get a transplant.
- How well people do after having a transplant, depending on the type of donor used.

C. What will happen to me?

If you join the study, we will ask you to let us search for a donor for you.

We will divide patients into groups based on the chances of finding a matched unrelated donor for them. For patients with a good chance, we will search to try to identify a matched unrelated donor. For those with a low chance, we will quickly consider other types of transplant rather

than waiting to try to find a matched unrelated donor. At the end of the study, we will compare the results in patients in the two groups to see if they are similar or different.

D. Will it hurt?

If you agree to the extra studies, we may collect a little blood from you. If we take your blood, it will hurt for a few seconds and the place where the needle went in might be a little red and sore. You might get a little bruise, but it goes away in a few days.

E. Will the study help me?

This study might help you get a transplant sooner but may not directly help you feel better.

F. What if I have questions?

Your doctors and nurses will answer your questions. It's important that you get all of your questions answered.

If you forget to ask a question but think of it later, you can call your doctor at [insert office number]. You can also ask your question the next time you see your doctor.

You can call the study office at [insert office number].

Be sure to get all of your questions answered.

G. Do I have to join this study?

You don't have to join this study. Tell your doctor and your parents or guardians if you don't want to be in the study. Your doctor won't be angry with you.

It's okay if you say yes now, and change your mind and say no later.

You'll still need treatment for your sickness if you don't join this study.

Talk to your parents or guardians before you decide if you want to join this study. We'll also ask your parents if it's okay for you to join.

Extra studies: Blood Draws and Surveys

If you have one the diseases called AML, ALL, or MDS, we want to ask you a few more questions, if you and your parents or guardians say it's ok.

If you are at least 8 years old, we'll ask you how you're feeling. We'll also ask you how well you're able to do the things you normally do during the day.

We also may collect a little blood from you. We'll take up to 6 teaspoons, depending on how much you weigh.

These are extra studies. You can join the main study and say no to these extra studies. Your doctor won't be angry with you if you don't want to join the extra studies.

Check the boxes below to let us know if you want to join the extra studies and answer some questions and have your blood drawn:

☐ N/A, I do not have AML, ALL, or MDS.

Blood Samples

☐ Yes, you may take my blood samples.

☐ No, you may not take my blood samples.

Surveys

☐ Yes, you may ask me questions about how I'm feeling.

☐ No, you may not ask me questions about how I'm feeling.

Writing your name on this page means that you agree to be in the study. If you decide to quit the study, all you have to do is tell the person in charge.

You and your parent or guardian will get a copy of this form after you sign it.

Signature of Participant

Date

Printed Name of Participant

Signature of Researcher

Date

Printed Name of Researcher