

Approved by the Nemours IRB. Valid from		through		IRB #:	
Abbreviated Study Title:					

CHILDREN'S ASSENT FORM FOR CHILDREN AGES 7-11

Your parent has given permission for you to be in a project called a research study. But first, we want to tell you all about it so you can decide if you want to be in it. If you don't understand, please ask questions.

What is the name of the study?

COG ASCT0631/PBMTC SCT051 "A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source In Matched Sibling Recipient Transplantation"

Who is in charge of the study?

The doctor in charge of the study is Dr. Sandler.

What is the study about?

You have a disease that is called leukemia. This means unhealthy cells in your body are growing quickly and crowding your healthy cells, keeping them from doing their job.

You have been treated with cancer fighting drugs called chemotherapy. You will also need to have a bone marrow transplant to help replace the blood cells destroyed during chemotherapy. Bone marrow has stem cells in it. When the stem cells are given to you, they grow into new healthy blood cells. Research doctors want to know if giving your bone marrow donor a drug before they donate bone marrow will increase the number of stem cells in the bone marrow you receive. This drug is called filgrastim, or G-CSF, or Neupogen. Throughout the rest of the form, we will call it G-CSF.

What will happen to me in the study?

If you choose to be in the study, you will receive the standard treatment for your disease. In this study your bone marrow donor might receive a medicine called filgrastim, or G-CSF, or Neupogen. Throughout the rest of the form, we will call it G-CSF. The doctors want to find out if G-CSF will help you recover better compared to patients whose donors did not get the medicine.

There might be some things about being in this study that you won't like. The treatment in the study may make you feel sick. The doctors and their staff will watch you closely for any side effects you experience while on this study.

After the transplant, you will have normal examinations to see if the medicine helped you. The doctors will check on you for about 10 years to see how you are doing.

Do I have to be in the study?

You don't have to do the study if you don't want to. If you are in the study, you can stop being in it at any time. Nobody will be upset with you. No matter what you decide, the doctors and their helpers will take care of you just like they did before. If you have any questions or don't like what is happening, please tell your parent, the doctor or helper.

You have had the study explained to you. You have been given a chance to ask questions. By writing your name below, you are saying that you want to be in the study.

Child's Signature

Date

Name of Person Obtaining Assent

Signature of Person Obtaining
Assent

Date

- The assent information was read to the child by the person obtaining assent
- The child read the assent him/herself.