

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

## ADOLESCENT ASSENT FORM FOR YOUTH AGES 12-17

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. You can choose to be in the study, not be in the study or take more time to decide.

### 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.

### Why are you asking me to be in this study?

You are being asked to be in the study to test if G-CSF bone marrow transplantation will keep more patients in remission. You have been treated for a cancer of the blood cells called leukemia and have received chemotherapy treatment for your cancer and now have no visible signs of leukemia. This is called remission. Your doctor has recommended that you have a stem cell transplant. Stem cell transplant (SCT) is a method of replacing blood-forming cells that were destroyed by cancer treatment. The stem cells are given after treatment to help the bone marrow recover and continue producing healthy blood cells.

### 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.

### Will I be paid to be in this study?

You will not be paid for being in this study.

### Do I have to be in the study?

