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| 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 Donor Transplantation"

Who is in charge of the study?

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

What is the study about?

Your brother or sister has a disease that is called leukemia. This means unhealthy cells in their body are growing quickly and crowding their healthy cells, keeping them from doing their job.

They have been treated with cancer fighting drugs called chemotherapy. They will need to have a bone marrow transplant to help replace the blood cells destroyed during chemotherapy. You have agreed to help your brother or sister by donating your bone marrow cells for their transplant. Bone marrow has stem cells in it. When the stem cells are given to your brother or sister, they grow into new healthy blood cells. Research doctors want to know if giving you a drug before donating bone marrow will increase the number of stem cells in your bone marrow. 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, a very small amount of blood (about 2 teaspoons) will be drawn from your vein in your arm in order to test for any disease. For girls who already have had their period, you will be tested to see if you are pregnant.

If you are on treatment plan #1 and your lab tests are normal, the drug G-CSF will be given to you before you donate your bone marrow. It will be injected under the skin once a day for five days in a row. If you are on treatment plan #2, you will not be given G-CSF before donating your bone marrow.

All siblings who donate bone marrow have this done in the operating room. You will be given medicine so you are asleep when the bone marrow is collected. The doctor will draw the bone marrow with a needle, going through the skin, (without cuts) near your hipbones. Within a short time, your bone marrow will re-grow back to normal. You may need to be hospitalized on this day when you donate the bone marrow, but you should be able to leave the hospital one to two days later.

After you have donated your bone marrow, the research doctors will ask you questions to see how you are feeling. The research doctors also want to continue to check on you by calling you to ask how you are feeling.

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.

