

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 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.

Why are you asking me to be in this study?

You are being asked to be in the study because you have agreed to help your brother or sister by donating your bone marrow cells for their transplant.

What will happen to me in the study?

There is more than one treatment plan given on this study and the doctors want to know if one works better than the other. A goal of this study is to find out if one of the treatment plans is better. Normally, we don't give people G-CSF before they donate their bone marrow. The two treatment plans are:

- Treatment plan #1: G-CSF is given to you before you donate your bone marrow
- Treatment plan #2: No drugs are given to you before you donate your bone marrow

The treatment plan assigned to you will be chosen by a computer and not by your doctor, your parents or you. You have an equal chance of being assigned either one of the treatment plans.

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.

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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.

What will happen after bone marrow donation?

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. If you agree to let the research doctors call you by phone to check on you, they will call you at one month, 6 months and every year for 5 to 10 years, after you leave the hospital.

Can being in this study hurt me?

If you are on treatment plan #1 and receive the drug G-CSF, some pain or achiness happens often, and you may need some pain medicine for this, which the doctor will give you. There may be a rash at the place where the drug is given. You may also have some cramping or feel weak. There are also some reactions to the medicine that are rare or very rare, such as bruising, allergic reactions, trouble breathing for a period of time, and shoulder pain. You should definitely tell your doctor if you have a lot of pain in the left shoulder, because a very small number of adults who have gotten G-CSF have had bleeding from an organ on the left side of your body called the spleen. This has not been seen in kids, but it could happen.

As a bone marrow donor, you will have some soreness and pain will be felt afterwards around your hip area for several days. You may also have some cramping or feel weak. Your doctor will give you some medicine to make you feel more comfortable and take away any pain.

When blood is drawn from your arm, a needle will be used. This will only hurt for about a minute. Your arm might be sore for one day, but it should not bother you too much.

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?

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 if you don't want to be in the study or if you want to stop being in the study. The doctors and nurses will take care of you as they have in the past. If you have any questions or don't like what is happening, please tell the doctor or nurse.

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.

Adolescent's Signature

Date

Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date