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Abbreviated Study Title:					

**NEMOURS  
PARENTAL PERMISSION / INFORMED CONSENT FOR PARTICIPATION IN AN ONCOLOGY  
RESEARCH STUDY**

This form may be used as a PARENTAL PERMISSION form for participants less than 18 years of age, or as an INFORMED CONSENT form for participants 18 years of age and older. If you are an adult participant in this research study, please note that any time the term “*your child*” appears in this document, it should be read and understood to mean “you”.

You have been asked to permit your child to be in a research study. This form explains the research, your child’s rights as a study participant, and any responsibilities that you may have as a result of your child’s participation. You should understand the research study before you agree to permit your child to be in it. You will get a copy of this form. Read it carefully. You will be given a copy of the protocol (full study plan) if you ask. You may also talk with your family or friends about it. The research team will answer any questions you have before you make a decision. Your child’s oncologist is the study doctor and will explain the research and other options in detail. Do not sign until all your questions are answered.

**1. WHAT IS THE TITLE 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” **Donor Informed Consent Form**

**2. WHO IS SPONSORING OR PAYING FOR THIS STUDY?**

This study is a National Cancer Institute (NCI)-approved study conducted through the Children’s Oncology Group (COG). COG develops and coordinates cancer studies conducted in over 200 member institutions throughout the U.S. and Canada, as well as sites in Europe and Australia. As a member institution, Nemours Children’s Clinic receives funding from COG to conduct pediatric oncology studies. Funding from COG supports research and educational programs at Nemours.

**3. WHO IS IN CHARGE OF THE STUDY AT NEMOURS?**

	<b>Nemours – Jacksonville</b>
<b>Principal Investigator</b>	Eric Sandler, MD
<b>Co-Investigators</b>	Paul A. Pitel, MD Michael J. Joyce, MD, PhD Cynthia Gauger, MD Scott Bradfield, MD Manisha Bansal, MD
<b>Address</b>	Division of Hematology/Oncology 807 Children’s Way Jacksonville, Florida 32207
<b>Daytime Phone</b>	[REDACTED]
<b>After Hours Phone</b>	[REDACTED]
<b>Long Distance</b>	[REDACTED]

**4. WHO SHOULD RESEARCH PARTICIPANTS CONTACT ABOUT THEIR RIGHTS?**

Tim Wysocki, Ph.D., Chairperson, Nemours-Florida Institutional Review Board at [REDACTED]  
 Paul Garfinkel, MSH., Director, Nemours Office for Human Subjects Protection, at [REDACTED]  
 (Nemours Long Distance Operator) [REDACTED]  
 Website: <http://www.nemours.org/research/nohsp.html> . Email: [NOHSP@nemours.org](mailto:NOHSP@nemours.org).

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### 5. WHO CAN BE IN THE STUDY?

Your child is being asked to participate in this study because he/she has agreed to donate bone marrow cells to his/her sibling who has been treated for leukemia and will be getting a transplant. If you choose to allow your child to be part of this study, he/she may be given a drug called filgrastim, or Neupogen, or G-CSF. Throughout the rest of the consent form, we will call it G-CSF. The purpose of this study is to find out if G-CSF will increase the number of stem cells in the bone marrow. We also want to find out if patients who get bone marrow transplants from donors who had G-CSF do better.

There will be about 425 patients participating in this study at Children’s Oncology Group member institutions across the country.

### 6. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to find out if G-CSF will increase the number of stem cells in the bone marrow. We also want to find out if patients who get bone marrow transplants from donors who had G-CSF do better.

The goal of this study is:

- **To evaluate the effects, good and/or bad, on the person having a bone marrow transplant when G-CSF is given to a donor before the bone marrow donation (experimental treatment) compared to a standard bone marrow donation (standard treatment).**

In addition to the treatment goal, we would like to do a companion study (RDSafe Study) that involves follow-up by phone survey. The goal of this follow up portion of the study is:

- **To evaluate and compare the short and long-term risks for the donor, whether they have received G-CSF given before bone marrow donation (experimental treatment) or donated bone marrow without G-CSF (standard treatment).**

The follow up information on this study may help us answer some research questions that might benefit future donors. You can choose to allow your child to be in this clinical trial without taking part in the companion study.

### 7. HOW LONG WILL PARTICIPATION IN THE STUDY LAST?

Participants in this clinical trial are expected to receive treatment on this study through the day their bone marrow will be collected (Day 0).

Follow-up: After your child’s bone marrow has been collected, he/she will be given a follow up questionnaire on the same day and will continue to receive standard clinical care for any bone marrow donation related complications.

### 8. WHAT ARE THE RESEARCH PROCEDURES?

#### **Random Assignment**

Participants will go on 1 of 2 different arms of the treatment plan. The arm your child is assigned to is decided by a process called randomization. Randomization means that the treatment is assigned based on chance. It is a lot like flipping a coin, except that it is done by computer to make sure that there are about the same number of people on each treatment arm of the study. Some participants will be randomized to receive the standard treatment arm. Others will get the experimental treatment arm. If you consent to your child taking part in the study, randomization will be done after study entry. The randomization process is described in your child’s COG Family Handbook for Children with Cancer.

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**Treatment Plan**

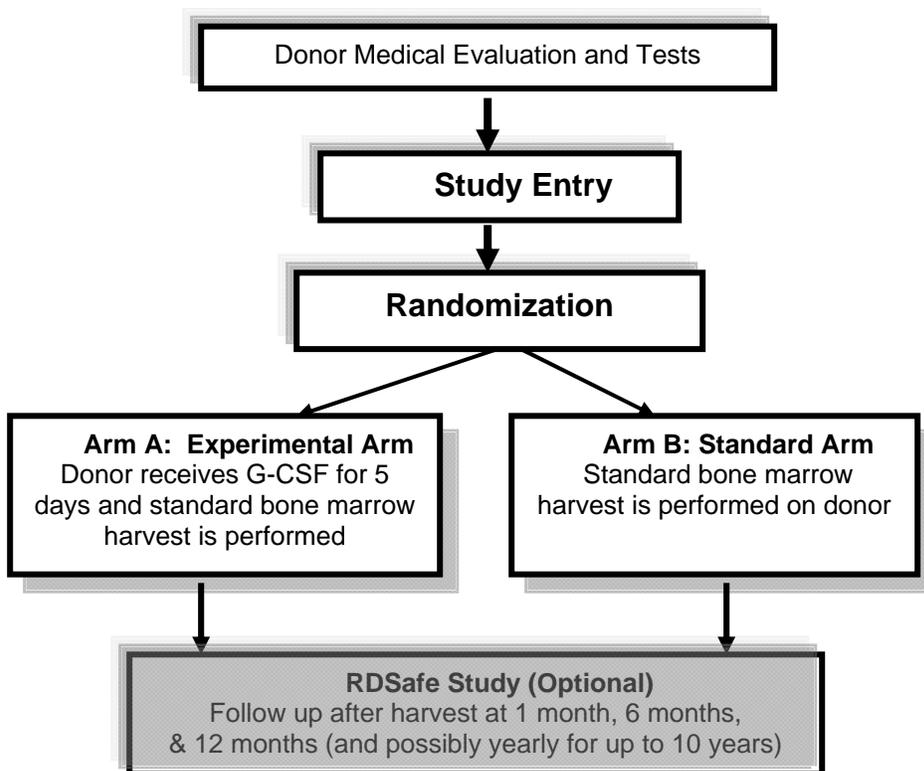
The two treatment arms of the study are called A and B as follows:

- **Arm A:** Experimental Treatment Arm (G-CSF given to your child before bone marrow donation)
- **Arm B:** Standard Treatment Arm (standard bone marrow donation)

A diagram and table of the treatment plan for both arms of the study can be seen below.

**Diagram of treatment**

A diagram of treatment can be seen below.



**Treatment Plan Tables**

The following tables show the difference in how treatment will be given to participants on Arm A and Arm B of this study.

**Treatment for participants who get the experimental arm (Arm A)**

Drug/Procedure	How the drug/procedure will be given	Days
Filgrastim (G-CSF)	SQ Injection for 5 days	Daily before your child's sibling's transplant, for 5 days
Standard bone marrow harvest	Bone Marrow Collection for 1-2 hours	Day of sibling's transplant (Day 0)

\*SQ –Drug is given by injecting a needle into the tissue just under the skin (SQ shot)

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**Treatment for participants who get the standard arm (Arm B)**

Drug/Procedure	How drug/procedure will be given	Days
Standard bone marrow harvest	Bone Marrow Collection for 1-2 hours	Day of sibling's transplant (Day 0)

If your child is on Arm A, he/she will be given 5 mcg/kg/day of G-CSF daily for five days and his/her bone marrow will be harvested on the day of your child's sibling's transplant.

If your child is on Arm B, he/she will undergo a standard bone marrow harvest.

**Standard procedure for bone marrow donation** -The procedure to collect the donated stem cells is called the harvest. Prior to the harvest, a medical evaluation is done and blood is drawn to test for diseases such as hepatitis and AIDS. If your child is a female who is able to become pregnant, a pregnancy test will be required from her. If your child's medical examination and the lab tests show any abnormalities, you will be informed.

If your child's medical evaluation and blood tests are normal, he/she will have the harvest in the operating room. Donated stem cells in children are usually collected from the bone marrow, but they can be collected from the blood as well (peripheral blood stem cells).

The largest amount of bone marrow that contains stem cells is found in the hip bone. The stem cells are collected from the hip bone by insertion of needles and aspiration (*removing by suction of a syringe*) of the marrow. The bone marrow cells are collected over a time period of one to two hours. This is almost always done in the operating room. The donor is given medicine so that they are asleep and don't feel the procedure. Hospitalization may be required on the day of the marrow harvest and your child can expect to be discharged from the hospital one to two days later.

A follow up questionnaire will be administered after harvest on the same day.

**Optional Biology/Research Studies**

Your child is also being asked to participate in some additional studies that are optional. You can choose to allow your child to take part in this clinical trial without taking part in these optional studies. The results will not be used to make any treatment decisions on this study and will not be given to you or your child's doctor. The results may help us answer some research questions that might benefit future donors. No matter what you decide, your child's care will not be affected.

Researchers would like to evaluate and compare the cells of regular bone marrow against bone marrow treated with G-CSF. If you agree to allow your child to participate in the Bone Marrow Cells Evaluation Study, about 2 teaspoons of bone marrow will be taken from the bone marrow collected at harvest. This will be tested for the immune (body system that helps fight infections) response of the cells and will also be stored for future testing.

These research tests will not affect the treatment your child receives on this study and therefore the results of these tests will not become part of your child's health records, and will not be available to your child or your child's doctor.

If you give permission to use your child's samples and later decide that you no longer want your child's samples used for these studies, you can let your child's doctor know and the specimens will be destroyed.

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Please see the signature section at the end of this consent form for details about how the COG will use your child's blood for research purposes. You can decide if your child would like to participate in these optional studies at the end of this consent form. Please read the information sheet at the end of this consent form called "How is Tissue Used for Research?" to learn more about using specimens for research.

**RDSafe Study (Optional Companion Study)**

If you agree to allow your child to participate in the RDSafe Study someone from the National Marrow Donor Program (NMDP) will call you after your child's harvest at 1 month, 6 months, and 12 months (and possibly yearly for up to 10 more years). The person will ask you questions related to your child's health and changes to your child's health. If you choose to allow your child to take part in this study, we would like to share data, collected on your child, with the NMDP.

Follow-up: A follow up questionnaire will be administered after harvest on the same day.

**9. WHAT ARE POSSIBLE RISKS OF BEING IN THIS STUDY?**

Any research has some risks (things that could make your child sick, make your child feel uncomfortable, or hurt your child). The risks with the most chance of happening to someone in this study are listed below. There is a chance of other risks that almost never happen. Other presently unknown side effects may occur. Your child will be watched closely and the drug doses will be decreased or discontinued if serious side effects develop.

**Study Risks Associated with G-CSF (filgrastim):**

**The most common side effects of G-CSF injection include pain, swelling and redness at the injection site. Other common side effects include bone pain and muscle cramps that may be severe and can last for several days after the last injection. Most pain should be relieved with acetaminophen (Tylenol) or ibuprofen (Advil). Aspirin or aspirin containing drugs must not be taken during G-CSF administration.**

**There is a small (estimated 1 in 10,000) risk of pain and bleeding from the spleen. Symptoms of this side effect are pain in the upper left side just below the rib cage. If your child feels pain in this area you should contact your child's doctor immediately as this is a potentially serious side effect.**

The drug risk table for G-CSF is listed on the next page.

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Risks and side effects related to filgrastim (G-CSF) include those which are:

- | Likely  | Less Likely   | Rare But Serious  |
|---|---|---|
| <ul style="list-style-type: none"> <li>• Aching or pain in the bones</li> </ul> | <ul style="list-style-type: none"> <li>• Local irritation at the site of the injection</li> <li>• Headache</li> <li>• Higher than normal levels of liver enzymes which may indicate liver irritation or damage and uric acid in the blood</li> <li>• A low number of platelets in the blood which may cause your child to bruise and bleed more easily</li> <li>• Low fever</li> <li>• Enlargement of the spleen which may cause pain in the abdomen or left shoulder</li> <li>• Worsening of skin rashes</li> <li>• Inflammation of a blood vessel in the skin leading to a raised purple rash and bruising</li> <li>• Higher than normal white blood count</li> </ul> | <ul style="list-style-type: none"> <li>• Allergic reactions which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, hives and facial swelling. This reaction is very rare and has been associated mainly with intravenous administration.</li> <li>• If your child is known to have sickle cell disease, filgrastim may cause a sickle cell crisis.</li> <li>• Severe damage to the spleen (an organ in the abdomen/belly which stores blood cells) which could lead to pain and loss of blood into the abdomen (belly) and maybe life threatening</li> <li>• Difficulty breathing and lung damage that may be due to the white blood cells that are stimulated by filgrastim traveling to the lungs when they are inflamed or infected.</li> <li>• A blood disorder or leukemia that has only been seen in patients with certain immune disorders who are treated for a very long time.</li> </ul> |

There has not been a lot of study so far of the long-term effects of G-CSF (filgrastim) use in healthy people. But in the studies done so far, no serious long-term effects of G-CSF use have been seen. Healthy people are at risk for getting cancer, including leukemia, lymphoma, or other blood diseases during their lifetime. Researchers do not know if G-CSF increases or decreases a person's risk for getting cancer. In some rare cases, patients with white blood cells and bone marrow that are not normal have gotten leukemia after using G-CSF for years. Researchers do not know if using G-CSF had anything to do with these patients getting leukemia. Also, when high doses of this drug are given to normal cells in test tubes it can cause some changes in the genes of those cells. We think that it is very unlikely that the short use of G-CSF in Arm A of this study has any risk for causing cancer.

The data being collected during follow up with the RDSafe study will help find out if there are any positive or negative long-term effects from receiving a short treatment of G-CSF.

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## REPRODUCTIVE RISKS

The current standard procedure for donating stem cells require that if your child is a female who is able to become pregnant, a pregnancy test will be performed.

### 10. WHAT ARE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

Your child will not receive any direct benefit from participating in this study. The potential benefit could include helping us find a better chance of prolonging your child's survival and getting rid of his/her cancer for a long time.

We expect that the information learned from this study will benefit other transplant patients and donors in the future.

### 11. WHAT HAPPENS IF A PROBLEM OR INJURY RESULTS FROM THE RESEARCH PROCEDURES?

If you think that your child has been injured while in this study or has a problem related to the study, you should tell one of the study doctors. The study doctor or research staff will tell you what you should do. The investigators' names and phone numbers are on the first page of this form. If your child needs treatment for a problem related to the study, you might be asked to bring him/her to the clinic or you may be told to take your child to the closest emergency room. Nemours will assure that your child receives treatment, if needed, for study related injuries. However, there are no funds set aside by Nemours the study doctors, or COG, to pay for medical care provided to treat problems or injuries resulting from participating in this study. If your child has health insurance, it may, or may not pay for the cost of treatment resulting from a study-related injury. If insurance does not pay, you understand that you will be responsible for paying for the cost of treatment.

If you have a question or problem related to the study, you can call the staff anytime. The study staff is available Monday-Friday from 8:00am to 5:00pm. During these hours, call the daytime number for your clinic (one page 1 of this form) for medical advice.

During evenings, weekends, and holidays, call the after hours number for your clinic (on page 1 of this form). You will reach the Nemours operator. Ask to page the Oncologist on call.

### 12. IS BEING IN THE STUDY VOLUNTARY?

Being in this study is totally voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your child's usual medical care if your child decides not to be in the study or decides to stop being in the study. No one will be angry with your child, or treat your child any differently than before your child was asked to be in the study.

If you withdraw your child from this study, your child may continue treatment at Nemours, or you may seek treatment for your child from another doctor of your choice. If you withdraw your child from the study treatment, the study doctor will ask your permission to continue study follow-up. All health information related to the study may continue to be collected from your child's medical records.

### 13. WHAT OPTIONS ARE AVAILABLE OTHER THAN BEING IN THIS STUDY?

You can refuse to permit your child to participate in this study. There may be other research or treatment choices that could be considered for your child. Your child can still be treated at Nemours according to standard medical care, even if he or she does not take part in this study. Instead of being in this study your child has these options:

- **Standard donation of bone marrow in the clinical setting.**
- **Use of G-CSF bone marrow is not standard therapy. However, your doctor could choose to use it in the clinical setting.**
- **Donating peripheral stem cells in the clinical setting.**
- **Not donating any stem cells.**

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The study doctors will provide detailed information about the benefits and risks of the various treatment options available to your child. Please discuss these options with your regular doctor as well as other trusted personal and family advisors.

**14. CAN THE RESEARCHERS REMOVE SOMEONE FROM THE STUDY?**

The study doctors may take your child off study treatment if they feel it is in your child’s best interest, or if new information becomes available that might affect your child’s participation. If the disease becomes worse, if side effects become very severe, or if the study doctor feels that study treatment is no longer the best treatment for your child, the treatment would be stopped and other treatment options would be discussed. If study treatment is stopped, your child will continue in the follow-up phase of this study. There is no reason that we know of for your child to be removed from the study altogether.

**15. WHAT ARE THE COSTS OF BEING IN THIS STUDY?**

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your child’s cancer in this study. **These include the cost of the G-CSF if your child gets it.** Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

There is no charge for procedures that are done for research purposes only, like the samples that are sent to the COG research laboratories.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. You can also call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

**16. WILL PEOPLE BE PAID FOR BEING IN THIS STUDY?**

No arrangement exists that would allow participants to share in any profit generated from this study or future research, or any new products that may be developed from research on biologic specimens.

**17. WILL I BE TOLD OF ANY NEW INFORMATION THAT MIGHT AFFECT MY WILLINGNESS TO PERMIT MY CHILD TO STAY IN THE STUDY?**

Any new information that may change your mind about allowing your child to be in this study will be given to you. A committee called the Institutional Review Board (IRB) will review this study at least once per year. If the IRB finds that there is new information that you should know about while your child is taking part in this study, it will ask the study doctor to tell you about it. You may be asked to sign a new version of this form after discussing the new information with a member of the research team.

For more information, you may call the National Cancer Institute's (NCI) Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI’s clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI’s general information about cancer, go to <http://cancer.gov/cancerinfo/>

The **COG Family Handbook for Children with Cancer** has information about specific cancers, tests, treatment side effects and their management, adjusting to cancer, and resources. Your doctor can get you this Handbook, or you can get it at [www.curesearch.org/](http://www.curesearch.org/) <<<http://www.curesearch.org/> .

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**18. WHAT INFORMATION ABOUT MY CHILD WILL BE USED OR DISCLOSED?**

Your child’s health information will be used and/or disclosed to conduct this study. It will also be used for follow up of possible adverse events, monitoring and audit purposes. By signing this parental permission form, you give permission for the use and/or disclosure of your child’s health information for the study described in this form. This authorization to use or disclose your child’s protected health information does not have an expiration date.

Nemours study doctors and staff will use information from your medical record as well as information gathered during your child’s treatment on this study. The following protected health information will be collected during your child’s involvement with this study:

- Personal medical history
- Current and past medications, therapies, surgeries, procedures
- Current and past hospitalizations
- Information from current and past physical examinations
- Results of tests noted in the “Procedure” section of the informed consent

Your child’s identifiable health information will be disclosed to organizations other than Nemours to conduct the study. It is possible that information identifying your child may not be removed from these documents, but the agencies reviewing this information will be required to maintain confidentiality. The health information listed above may be used by and/or disclosed to:

- Children’s Oncology Group and The Pediatric Blood and Marrow Transplant Consortium
- Representatives of the National Cancer Institute (NCI), Food and Drug Administration (FDA), and other U.S. and international governmental regulatory agencies involved in keeping research safe for people
- The Nemours Institutional Review Board (IRB) (The IRB is a group of people that reviews research activities. The IRB is responsible for the safety and rights of study participants.); and
- Nemours internal audit staff
- The Pediatric Central Institutional Review Board (CIRB) of the National Cancer Institute
- The National Marrow Donor Program (NMDP)

Research information about your child will be kept in your child’s medical record at Nemours and the Hospital. This will give the doctors and nurses more information about the study so they can take better care of your child. The same information might also be seen by anyone who can look at your child’s medical records, such as your insurance company.

Nemours will protect your child’s health information by allowing only authorized Nemours, Hospital and Study staff to have access to paper and electronic copies. Study records are kept in secure offices and in password protected computer files. The research results may be presented at meetings or in print. Participants’ identities will not be disclosed in those presentations.

To be sure information about your child is kept private, the COG will assign your child a unique identification (ID) number. This unique ID number will be used instead of your child’s name or other identifying information. Test results, physical examination reports and therapy summaries will be sent to the COG with your child’s unique ID number. COG will take careful steps to prevent misuse of records, and agencies reviewing this information will be required to maintain confidentiality.

Specimens, including blood, bone marrow, and stem cells will be labeled with your child’s name, the date, institution and type of specimen. Once the laboratory receives these samples, the information will be recorded and stored in a password-protected database. This database may only be accessed by the COG laboratory staff with proper authority. Once the information has been transferred to the database, the samples will be stored with a random lab number, which can only be identified in the password-protected database. It is crucial that the samples are originally shipped to these laboratories with your child’s name in order to avoid errors.

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Your child's identity will be protected as much as the law permits. The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research participants. A copy of the certificate is in Attachment #2 of this consent. The Certificate protects against the involuntary release of information about participants collected during the course of our covered studies. The study doctors involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, you may choose to voluntarily disclose the protected information. For example, if you request the release of information in writing, the Certificate does not prevent that voluntary disclosure. Information about the certificate is attached at end of this consent.

It is very unlikely that the research testing might uncover important information about your child or your child's current or future health. If this unlikely event occurs, the study doctors at other COG centers may contact your child's Nemours doctor through Children's Oncology Group about what the test results might mean. Only your child's doctor will be notified and the information will remain confidential. Your child's doctor may discuss this unexpected finding with you, and may recommend consultation with a genetic counselor and/or repeat testing in a clinical (not research) laboratory if necessary.

Only health care organizations have to follow laws and rules about protecting the privacy of your child's health information. Other kinds of organizations such as drug companies, private foundations or data management firms can disclose your child's health information without your permission once they have received it.

It may be necessary to contact you at a future date regarding new information about the treatment your child has received. For this reason, we ask that you notify Nemours Children's Clinic of any changes in address. If you move, please provide your child's new address to your local tumor registrar. The contact information for Nemours is provided in the table below.

Nemours – Jacksonville
Cancer Registrar Nemours Children's Clinic 807 Children's Way Jacksonville, FL 32207 [REDACTED]

The remainder of this page is intentionally left blank

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**19. SIGNATURES:**

I am making a decision whether or not to permit my child to participate in this research study. I understand that my child may also have to agree to participate in the study before he/she will be allowed to be in this study. I have read, or had read to me in a language that I understand, all of the above. I have been given enough time to make this decision. I have asked questions and received answers about things I did not understand. I willingly give permission for my child to participate in this study. By signing this form, I am not giving up any rights to which I am entitled under law.

I understand that:

- I must sign this permission form in order for my child to be in this study
- I can withdraw this permission by writing to the person in charge of the study listed on the first page of this form. The use and/or disclosure of my child's protected health information will stop after Nemours receives the withdrawal notice. Information that is used or disclosed before the withdrawal may still be used.
- My child's protected health information may be disclosed again by the person or entity (other than Nemours) that receives it. If this happens, Federal or state law may not protect the information.
- I have the right to refuse to sign this form.
- I have the right to ask Nemours to tell me who has received my child's protected health information.
- I have the right to revoke my authorization for the use and disclosure of my child's health information at any time, which would end my child's participation in this study.
- I will receive a signed and dated copy of this completed document in its entirety.

My signature indicates that:

- I give the study doctors and Nemours permission to use and/or disclose my child's individually identifiable health information, for this study, as described in Section 18.
- As his or her parent or legal representative, I give my permission for the minor child named below to participate in the study described in this Parental Permission Form.

\_\_\_\_\_  
Name of Participant (Print)

\_\_\_\_\_  
Participant Date of Birth:

\_\_\_\_\_  
Signature of Parent/Legal Representative

\_\_\_\_\_  
Printed Name of Parent Legal/Representative

\_\_\_\_\_  
Date

Relation to Participant:     Parent     Legal Guardian

I the undersigned, certify that to the best of my knowledge the parent/legal representative signing this permission had the study fully and carefully explained and that he/she understands the nature, risks and benefits of participation in this study.

\_\_\_\_\_  
Name of Person Obtaining permission (Investigator or Designee)

\_\_\_\_\_  
Signature of Person Obtaining permission

\_\_\_\_\_  
Date

[ ] Copy provided to Parent/Legal Representative and participant on \_\_\_\_\_Date



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## How is Tissue Used for Research?

### Where does tissue come from?

Whenever a biopsy (or surgery) is performed, the tissue that is removed is examined under the microscope by a trained doctor to determine the nature of the disease and assist with the diagnosis. Your child's tissue will always be used first to help make healthcare decisions. After all tests have been done, there is usually some left over tissue. Sometimes, this tissue is not kept because it is not needed for the patient's care. Instead, a patient can choose to have the tissue kept for future research. People who are trained to handle tissue and protect the donor's rights make sure that the highest standards are followed by the Children's Oncology Group (COG). Your child's doctor does not work for COG, but has agreed to help collect tissue from many patients. Many doctors across the country are helping in the same way. If you agree, only left over tissue will be saved for research. Your child's doctor will only take the tissue needed for his or her care during surgery.

### Why do people do research with tissue?

Research with tissue can help to find out more about what causes cancer, how to prevent it, and how to treat it. Research using tissue can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

### What type of research will be done with my tissue?

Many different kinds of studies use tissue. Some study doctors at other COG centers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs.

Some research looks at diseases that are passed on in families (called genetic research). Research done with your child's tissue may look for genetic causes and signs of disease.

### How do study doctors get the tissue?

Scientists from universities, hospitals, and other health organizations conduct research using tissue. They contact COG and request samples for their studies. COG reviews the way that these studies will be done, and decides if any of the samples can be used. COG gets the tissue and information about your child from your child's study doctor, and sends the tissue samples and some information about your child to the researcher. COG will not send your child's name, address, phone number, social security number, or any other identifying information to the researcher.

### Will I find out the results of the research using my child's tissue?

No, you will not receive the results of research done with your child's tissue. This is because research can take a long time and must use tissue samples from many people before results are known. Results from research using your child's tissue may not be ready for many years and will not affect your child's care right now, but they may be helpful to other people in the future.

Though research involves the test results of many different people, your child's biopsy result involves only your child. Your child's doctor will give you the results of the biopsy when results are known. These test results are ready in a short time and will be used to make decisions about your child's care.

### Will I benefit from the research using my child's tissue?

There will be no direct benefit to your child because your child's tissue may not be used for some time after it is donated and because research can take a long time. However, it is hoped that the results of research on your child's tissue and tissues from other patients will provide information that will help other patients in the future. Your child's tissue will be helpful whether your child has cancer or not.

### Why do you need information from my child's health records?

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In order to do research with your child's tissue, the study doctors at other COG centers may need to know some things about your child. (For example: Is your child male or female? What is your child's race or ethnic group? How old is your child? Has your child ever smoked?) This helps them answer questions about diseases. The information that will be given to the researcher includes your child's age, sex, race, diagnosis, treatments, and possibly some family history. This information is collected by your child's Nemours study doctor from your child's health record and sent to COG without a name or other identifying information. If more information is needed, COG may send it to the researcher.

**Will my child's name be attached to the records that are given to the researcher?**

No. Your child's name, address, phone number and anything else that could identify him or her will be removed before they go to the researcher.

**How could the records be used in ways that might be harmful to my child?**

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to your child, but to family members. For diseases caused by gene changes, the information in one person's health record could be used against family members.

**How is my child protected?**

COG is in charge of making sure that information about your child is kept private. COG will take careful steps to prevent misuse of records. Your child's name, address, phone number and other identifying information will be taken off anything associated with the tissue before it is given to the researcher. This would make it very difficult for any research results to be linked to your child or your family. Also, people outside the research process will not have access to results about any one person, which will help to protect your child's privacy.

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**Attachment #1**  
**Standard Risks of Bone Marrow Donation**

- 1) **General anesthesia may produce acute heart, lung, or allergic reactions, which may prove to be fatal. The occurrence of these reactions is extremely rare (less than 1 in 10,000) and will be minimized by careful preoperative evaluation by your doctors.**
- 2) **Regional or spinal anesthesia may result in pain, numbness or weakness (caused by nerve damage) to the leg(s) or low blood pressure during surgery.**
- 3) **Marrow collection will be associated with pain and swelling at the sites of hip bones for several days.**
- 4) **Bleeding or infection at the aspirations are also possible but are minimized by careful surgical techniques in the operating room.**
- 5) **It may be necessary to transfuse red blood cells during or after marrow donation. This is more likely in cases where the donor is small and the recipient (your child's sibling) is large. Although these risks are extremely small, the transfusion of blood from someone other than your child carries a risk of transfusion reaction and infection such as hepatitis or AIDS.**

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**Attachment #2**  
**Certificate of Confidentiality**

*The Children's Oncology Group has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research participants. The Certificate protects against the involuntary release of information about participants collected during the course of our covered studies. The study doctors involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.*