Title of Research Study: Molecular Epidemiology of Pediatric Germ Cell Tumors STUDY00002538

Researcher Team Contact Information: Jenny N. Poynter, Ph.D.
For questions about the research study, research results, or other concerns, call the study team at:

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Why am I being asked to take part in this research study?
We are asking you and your child to take part in this research study because you enrolled in our original study of pediatric germ cell tumors. As a part of the original study you agreed to be contacted for new portions of the study.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you and your child take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
This new portion of the research study is being conducted for two reasons:

1) We are interested in learning more about how the treatment your child received for his/her germ cell tumor has affected his/her health and quality of life. We know that the treatments that are used to treat cancer can sometimes have side effects that may affect his/her health and other daily life. We would like to learn more about the side effects that are important for children and adolescents who have had a germ cell tumor.

2) As part of the original study, your child and possibly other family members provided a saliva sample that was used to collect DNA. We have used these samples to look at selected parts of the DNA. Our ability to study DNA is improving rapidly and it is now possible for us to look at all of the DNA. We are contacting you to see if you would be willing to let us evaluate all of your DNA. As part of this new research, we may also place some of your genetic materials and health information in scientific databases, along with that from many other people. Information that could directly identify you would never be included. We hope this will help us to identify new genes that are important in germ cell tumors that we might not think to study right now.
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How long will the research last?
We expect that your child will be in this research study until the samples are used up or until you decide that you no longer want to participate. When your child turns eighteen we will ask him/her whether or not he/she would like to continue participation.

How many people will be studied?
In the initial part of the study, 867 children and adolescents with a germ cell tumor and more than 1,500 family members agreed to participate and provided a DNA sample. Most of these families (95%) agreed to be contacted for future studies. We hope to enroll 700 people with a germ cell tumor in this new part of the study.

What happens if I say “Yes, I want to be in this research”?

Summary
If you and your child participate in this new portion of the study, we will ask the following:

1) For you to complete a questionnaire about your child’s health and quality of life since his/her treatment
2) For you to allow us to access your child’s medical records
3) For your permission to evaluate all of your child’s DNA
4) For your permission to place your child’s and your genetic and health information in scientific databanks.

Each of these are described below.

- Questionnaire about health and quality of life
  We will ask you to complete a questionnaire either online through the secure study website or we can mail a paper questionnaire if you prefer. We will ask you questions about your child’s current health status, any medications he/she uses, physical measurements like height and weight, health behaviors, and school/employment history. It will take you about 30 minutes to complete the questionnaire.

- Medical records
  We will ask for your permission to obtain your child’s medical records related to his/her treatment for GCT and any resulting health issues. If you agree to provide your child’s medical information, we will ask you to sign a separate authorization form. We will also ask you to list the places where your child has received medical care.

- Permission to evaluate all of the DNA
  With your permission, we would like to use a technique called sequencing to look at all the genes to understand if changes are related to germ cell tumors. In order to sequence DNA, laboratory procedures will be used so that parts of the genetic code can be read into a computer. These parts will then be compared in the computer to parts of the genetic code of other people.

- Scientific databanks
  In order to speed up research, other researchers would like to have access to your child’s genetic information so that they can compare it to the genetic information of people from other research studies and use it to answer future research questions. This information is most valuable when it is
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linked to general information about medical history (clinical information.)

With your permission we would like to place your child’s genetic and health information in scientific databanks, along with that from many other people. Information that could directly identify your child will never be included. Qualified researchers who want to study the information must apply to the databank and have appropriate security measures in place.

No names or any other personally identifying information will ever be released. Nobody will be able to know just from looking at a database who the information belongs to. However, because genetic information is unique, there is a small chance that someone using a publicly accessible database could trace the information back. The risk of this happening is very small, but may grow in the future. As technology advances, the information in these databases will become more valuable to scientists, but there may also be new ways of tracing the information back, increasing the risk over time that privacy would be breached.

Sample use and storage
If you choose for your child to be in this portion of the study, we will give the samples and data a code (instead of a name) while they are stored and when they are used in research. This code allows data to be used without anyone knowing whose sample it is just by looking at the label.

Results of genetic testing
Our laboratory is a research laboratory. This means our studies are being performed to learn about genes that cause germ cell tumors. Because this is a research study, we will not give you results of your child’s genetic testing. Participation in this research study does not replace any genetic tests that your child’s healthcare provider may have recommended.

While we are not planning to give out any results of genetic testing, there may be rare situations where we find genetic changes that could significantly impact medical care. If our laboratory should identify a genetic variant that impacts medical care, called “medically actionable findings,” we will work with the physician or the healthcare team associated with the Children’s Oncology Group to have the result verified in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. We will provide information to the laboratory to allow them to complete the testing. This additional testing in a clinical CLIA laboratory will usually require a new sample and be charged to insurance as a clinical laboratory test. At the end of this consent form, you may choose whether or not you want to be contacted with any “medically actionable findings.”

What happens if I say “Yes”, but I change my mind later?
You and your child can leave the research at any time. Leaving will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can discard your child’s samples. If you decide to withdraw from this study after DNA has been analyzed, the genetic information will be discarded and will not be used in this portion of the study. However, research already done and data that has been shared about those samples cannot be undone.

Choosing not to be in this study or to stop being in this study will not result in any penalty or loss of benefit entitled to you or your child. Meaning, your choice not to be in this study will not negatively affect your child’s right to any present or future medical treatment or current or future relations with the University of
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Minnesota.

What are the risks of being in this study? Is there any way being in this study could be bad for me?

Personal Information
There is a risk that personal information could accidentally be released to someone other than study staff. We would keep all personal information in locked file cabinets or in computer databases protected by passwords. Only study staff would have access to these documents and files.

Genetic information
- The testing in some cases may reveal information not anticipated. For some DNA testing, this includes information about paternity or blood relationships between the people being tested. We will not tell you this type of information if we find it unless it affects your medical care.
- DNA sequence is like a fingerprint: it is unique. All precautions will be taken to protect privacy and confidentiality. All genetic information will be stored in a secure database that is labeled only with an identification number. Only Dr. Poynter and qualified researchers will have access to these data.
- If you decide that you want to receive “medically actionable findings,” it is possible that we will tell you that your child is at high risk for a serious medical condition. In most cases, we do not expect to identify medically actionable results.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against based on genetic information. This law generally will protect you in the following ways:
- Health insurance companies and group health plans may not request genetic information that we get from this research.
- Health insurance companies and group health plans may not use genetic information when making decisions regarding eligibility or premiums.
- Employers with 15 or more employees may not use genetic information that we get from this research when making a decision to hire, promote, or fire when setting the terms of employment.

Be aware that this federal law does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What do I need to know about reproductive health and/or sexual activity if I am in this study?
Participation in this study will not affect your child’s reproductive health and/or sexual activity.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you or your child.

Will being in this study help me in any way?
There will be no direct benefit to you or your family. This research may help us understand why young people get germ cell tumors.
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What happens to the information collected for the research?
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you or your child as a subject. Your participation in this study will not be noted in your child’s or your medical record. Your record for the study may, however, be reviewed by departments at the University that make sure research is done right. To these extents, confidentiality is not absolute.

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 subjects. Information about the certificate is included in Attachment #1.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- Children’s Oncology Group
- 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 Institutional Review Board of this hospital

Research that uses your child’s samples might be done a long time after the sample has been collected. The samples will be used for research by Dr. Jenny Poynter and qualified researchers for the purposes of learning more about germ cell tumors and similar conditions. If you agree to let us use the sample for this additional portion of the study, it will be labeled with a number, not a name, and kept indefinitely. Your child’s identity would always remain private and would not be provided with the samples.

A description of this research study will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify anyone. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who do I contact if I have question, concerns or feedback about my experience?
This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants’ Advocate Line at 612.624.4490 or go to www.irb.umn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.
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If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the “Investigator Contact Information” of this form for study team contact information and “Whom do I contact if I have questions, concerns or feedback about my experience?” of this form for HRPP contact information.

What else do I need to know?
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that your child has suffered a research related injury, let the study physicians know right away.

When your child turns eighteen we will ask him/her whether or not he/she would like to continue participation and whether or not he/she would like to receive potentially medically actionable results.

Will I be compensated for my participation?
After you complete the study questionnaire, we will provide a $25 gift card to your family in appreciation of your time and effort.

Use of Identifiable Health Information
We are committed to respect your privacy and to keep your child’s personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child’s personal health information that includes health information in your child’s medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.
Parental Consent Form

Your signature documents your permission to take part in this research. You will be provided a copy.

_______________________________________________      __________________
Signature of Parent                                                           Date

_______________________________________________
Printed Name of Parent

_______________________________________________
Printed Name of Child Participant

____________________________________________            __________________
Signature of Person Obtaining Consent                                     Date

______________________________________________________
Printed Name of Person Obtaining Consent
Parental Consent Form

- **Medically actionable information**
  Rarely, the researchers may find that a participant a genetic change that places him/her at high risk for a serious medical condition. If we find this type of genetic change in your child’s sample *and* there are steps that can be taken to prevent this condition from happening, we can tell you about this genetic change. You have the choice of whether or not you want us to tell you about this type of information if it is found in the sample.

If our lab identifies a medically actionable finding in your child’s sample and you want to receive these findings, the healthcare team associated with the Children’s Oncology Group will be contacted by a genetic counselor. The genetic counselor will explain the following:

1. What type of medically actionable information was found in your child’s sample.
2. If the genetic results we obtain are not found in a clinically certified laboratory, the results cannot be used for healthcare. The genetic counselor will help the healthcare team find a clinical laboratory.

The cost of confirming medically actionable findings in a clinical laboratory will not be covered by this study. Any medical care that arises from this finding is part of your child’s regular medical care and will not be paid for by this study.

Would you like to receive your potentially medically actionable information?

☐ Yes  ☐ No  Initials_____  

*Please check one box and initial on line above*
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 subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers 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.