IRB Study #08-1725
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Title of Study: NENA - Neuroblastoma Epidemiology in North America
Principal Investigator: Andrew F. Olshan, PhD
UNC-Chapel Hill Department: SPH-Epidemiology
UNC-Chapel Hill Phone number: (919)-966-7424
Email Address: Andy_Olshan@unc.edu
Co-Investigators: Anna Maria Siega-Riz, PhD, Fei Zhou, PhD
Funding Source and/or Sponsor: National Institutes of Health/National Cancer Institute
Study Project Director: Kathryn Carrier, MPH
Study Contact telephone number: 919-966-3000
Study Contact email: kathryn_carrier@unc.edu

What are some general things you should know about research studies?
You are being asked to provide parental consent for a research study to obtain your child’s previously collected and stored biological sample. To join the study is voluntary. You may refuse to give permission, or withdraw your permission for your child’s specimen to be in the study, for any reason.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your family may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about providing parental consent for your child’s specimen for this research study. You will be given a copy of this permission form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

Who is sponsoring this research?
This research is funded by the National Cancer Institute at the U.S. National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What is the purpose of this study?
The purpose of this research study is to understand how genes might affect young children’s chances of developing neuroblastoma. To do this, we will compare the genes of children who were diagnosed with neuroblastoma to the genes of their biological parents. Through the Children’s Oncology Group (COG), tissue samples from children diagnosed with neuroblastoma who are now deceased are collected and stored for future research purposes. This study asks parents to provide permission for our study to obtain part of their child’s sample. By including samples from children with the disease, as well as from their biological parents, our study has the unique opportunity to analyze genetic pathways in the development of neuroblastoma.
We are asking you for parental consent for your child because he/she is registered with the Children’s Oncology Group (COG) and the Childhood Cancer Research Network (CCRN). During that registration process, **you or another guardian indicated willingness to be contacted for non-therapeutic studies.** The NENA study is a non-therapeutic study that is approved by the Children’s Oncology Group. COG provided us with your contact information because your child was diagnosed with neuroblastoma. This study is voluntary.

**Are there any reasons you should not provide parental consent for this study?**
There are no known reasons why your deceased child’s specimen should not be included in this study.

**How many people will take part in this study?**
If you provide parental consent for this study, you will be one of approximately 72 parents of deceased children participating in our research.

**How long will your part in this study last?**
If you agree to provide parental consent for this study, participation is complete once you have read, signed and returned this form to our study office.

**DNA use and storage**
DNA will be extracted from your child’s tissue sample and used for research by Andrew F. Olshan, Ph.D. and his associates for the purposes of learning more about neuroblastoma. We are now aware of some of the genes that we will study, but there may be other genes that we plan to study in the future. Therefore, we would like to keep your child’s DNA sample for a period of time after this study ends. In some cases, your child’s DNA sample could be sent to other research groups for analysis. You would not be notified if this occurs, but any samples we send to another researcher would be identified only with a study ID number that could not be traced back to your child. Your child will not be identified in any publications or reports from this study.

**What is the purpose of this specimen repository or “biobank”?**
Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works, as well as answer other questions by using specimens. Researchers may develop new tests to find diseases or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or “biobank”.

The purpose of this study’s biobank is to obtain samples from children who were diagnosed with neuroblastoma, along with samples from their biological parents as well. By analyzing genes from these samples, our research team and others in the future can investigate genetic pathways related to neuroblastoma.

**Will researchers seek approval from you to do future studies involving the specimen from your child?**
By signing this consent form, you are giving your permission for researchers to use your child’s specimen as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. In some cases, the IRB may require that you be re-contacted and asked for parental consent to use your child’s specimen in a different, specific research study. If you are contacted for that reason, you have the right not to participate for yourself or on behalf of your child in any research study for which your consent is sought.
You can request that the specimen received by the University of North Carolina be destroyed at any time up until 2014 by contacting Dr. Olshan. After 2014, we will remove your child’s name from our files and we will not be able to tell which DNA sample is your child’s.

**What will happen if you provide parental consent for this study?**
If you give parental consent for your deceased child for this study, we ask you to read this consent form carefully, sign and date it on the last page, and send it back to our study office in the prepaid mailer provided. An extra copy of this form is provided for you to keep for your records.

Once we receive your signed consent form, we will seek to obtain your child’s previously collected and stored sample through COG. Sometimes a sample is not available for a deceased child. If a tissue sample is available, we will arrange for part of that sample to be sent to our lab on campus at the University of North Carolina-Chapel Hill (UNC-CH) for analysis.

**What are Genome Wide Association Studies (GWAS)?**
The National Institutes of Health (NIH) has established a national database that will hold information from many individuals across the country, including medical information and genetic information. Your child’s tissue sample contains DNA that is unique to him/her. If coded information about your child is sent to this national database, access will be controlled and limited to other researchers.

DNA is the genetic material in a person’s cells that makes each person unique. There are thousands of genes made up of DNA in each cell. By studying the DNA, scientists can discover the genes that might be involved in the development of neuroblastoma.

We know little about the factors we are studying, so the results will not provide information that is useful to your family. This information is for research purposes only, and you will not be informed of any analysis results pertaining directly to your child’s specimen. However, you have the option to receive or not to receive information about the overall findings from the study once the study has been completed.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge. Your family may not benefit personally from being in this research study.

**Will you receive results from research involving your child’s specimen?**
Research with your child’s specimen is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other participants with individualized results.

**What are the possible risks or discomforts involved from being in this study?**
There is a risk that providing parental consent for your deceased child may be emotionally upsetting. Our research staff is available to assist you in answering questions about the study and understanding this parental consent form so that you can make an informed decision about participation.

There may be uncommon or previously unknown risks. You should report any problems to the researcher and/or study’s Project Director.
**What are the possible risks involved with the use of your child’s specimen?**
There is a risk of breach of confidentiality. Because this research involves genetics, there is also a potential risk for some of your child’s relatives and other members of your child’s ethnic group, since they share some of your child’s genetic makeup.

**Who owns the specimens?**
The tissue sample that we obtain for your child becomes the exclusive property of the University of North Carolina at Chapel Hill (UNC-CH). This organization may retain, preserve or dispose of your child’s specimen and may use this specimen for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of your child’s specimen.

**How will your child’s privacy be protected?**
The tissue samples obtained through COG are labeled with COG-specific identification numbers only, no names or other easily identifiable information appears on the sample. At our UNC-CH lab, an additional ID number is added. Only the NENA Study Project Director and a small core staff are able to link participants with specimens. Once DNA are analyzed at the lab, results only appear with study IDs.

All linking information will be kept in locked and/or password protected files accessible only to the core study team. All members of the core research team have completed human subjects training through the IRB and signed an additional study-specific confidentiality pledge.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child’s information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

**Certificate of Confidentiality**
The Children’s Oncology Group has received a Certificate of Confidentiality. Information about the certificate is described below.

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.
Efforts will be made to keep your and your child’s personal information confidential. We cannot guarantee absolute confidentiality. Your child’s personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your child’s 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
- Pediatric Central Institutional Review Board (CIRB) of the National Cancer Institute

Your child’s specimen may be shared with researchers at this or other institutions. Research studies may be done at many places at the same time. Your child’s personal identifying information will not be sent to other researchers.

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 a person based on his/her genetic information. GINA does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect against discrimination based on an already-diagnosed genetic condition or disease.

Your child’s sample obtained for this study will be stored long-term, unless you request that it be destroyed before then. Your child’s privacy will be protected through 2014 by the protections explained above in this consent form, and furthermore by coverage from the COG Certificate of Confidentiality. After 2014, all identifying linkages will be destroyed and our study will not know which sample is from your child.

Privacy protections for Spanish-speaking participants
Interpreters are available for this study for Spanish-speaking parents. The interpreters have completed human subjects training at UNC and signed an additional study confidentiality form to help protect your and your child’s privacy. The same steps this study takes to protect privacy for English-speaking participants are put into place for Spanish-speaking participants, including the way IDs are used and the limited number of staff available to link participants to their data.

What if you want to stop participation?
You can withdraw participation at any time, without penalty. The investigators also have the right to decide not to obtain or use your child’s tissue sample. This could be because your child no longer meets eligibility criteria or because the entire study has been stopped. If this occurs and we have already obtained a tissue sample for your child, you can either allow it to remain with the study for analysis or ask that it be destroyed.

Can you withdraw the specimens from the research repository?
If you decide that you no longer wish for your child’s specimen to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing. Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your child’s remaining specimen components will be destroyed. If you do not make such a request, your child’s specimen may be stored forever. The researchers may
choose to destroy the specimen at any time.

**Will you receive anything for providing parental consent for your child’s specimen to be obtained?**
The study will send an incentive check in the amount of $10. to you, the parent signing this form, upon receipt of the signed form.

**Will it cost you anything to be in this study?**
There are no costs for you associated with being in this study.

**Will it cost you anything for storage of your child’s specimen?**
There will be no cost to you for the storage and use of your child’s specimen.

**What if you are a UNC student?**
You may choose not to give parental consent for your child’s specimen to be in the study or to withdraw your child’s specimen before the study is over. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you agree for your child’s specimen to be part of this research.

**What if you are a UNC employee?**
Consenting for your child’s specimen to be in this research is not a part of your University duties, and refusing to give permission will not affect your job. You will not be offered or receive any special job-related consideration if you agree to have your child’s specimen in this research study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights or rights on behalf of your deceased child as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your child’s rights and welfare. If you have questions or concerns about your child’s rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.
Title of Study: NENA - Neuroblastoma Epidemiology in North America
Principal Investigator: Andrew F. Olshan, PhD

Parent’s Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

Printed Name of Research Participant (Child)

Signature of Parent/Guardian ___________________________ Date __________________

Printed Name of Parent/Guardian_________________________