CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
Patient Consent Form-Germline and Tumor Sequencing Arm

H-42376- EVALUATING UTILITY AND IMPROVING IMPLEMENTATION OF GENOMIC SEQUENCING FOR PEDIATRIC CANCER PATIENTS IN THE DIVERSE POPULATION AND HEALTHCARE SETTINGS OF TEXAS: THE KIDSCANSEQ STUDY

Background
Your child is being invited to participate in a research study. Your child’s participation in this study is entirely voluntary. Please note that your child's participation in the study requires that at least one parent also consents to study participation as described in the separate parent consent form. Should you choose to have your child withdraw from this study, your decision will in no way affect the care that your child receives. Please read the consent form carefully and feel free to ask any questions before you agree to take part in the study. If you decide to participate in the study you will receive a copy of this consent form to keep.

Cancer is caused by changes (sometimes called mutations or variants) in the genetic code of a cell. The genetic code is like a set of instructions (referred to as genes) that tells our cells how to function properly. Mutations in these genes can allow cancer cells to grow and spread abnormally. Sometimes these mutations are in every cell of the body (“inherited mutations”) and can be found in a blood sample. Other times they are only in the cancer cells (“tumor mutations”) and can only be found in a tumor sample.

In this study we will use many different genetic tests to look for both inherited mutations and tumor mutations. It is important to understand that these tests are not guaranteed to find all types of mutations that might occur. It is also possible that mutations will be found by some tests but not others. One goal of the study is to decide the best way to perform genetic testing for childhood cancer patients.

These genetic tests are performed in in the same clinical laboratories as other medical tests and the results are part of your child's medical record. However, most children with cancer do not have all of these tests done as part of their regular cancer care, and no one yet knows the best way to use these tests to benefit cancer patients.

This research study is funded by the National Institutes of Health (NIH).

Purpose
The main goal of this study is to learn which genetic tests are most useful for finding inherited mutations and tumor mutations that might be important for the care of childhood cancer patients and their close family members.

There are other goals of this study to help learn how best to use and explain the results of these tests to cancer doctors, patients, and families. We are also hoping to learn more about how cancer doctors and families use these results to help make future medical decisions.

Procedures
The research will be conducted at the following location(s):
Baylor College of Medicine, Children's Hospital of San Antonio, Cook/Fort Worth Children's Hospital, Doctors Hospital at Renaissance, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital, Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center,
WHAT CLINICAL SAMPLES AND INFORMATION WILL BE USED?

We are asking for your permission to use tumor and blood samples from your child. These will be obtained at (or near) the time of your child's tumor surgery and sent to Baylor College of Medicine (BCM) and Texas Children's Hospital (TCH) for the genetic testing.

1. Patient tumor sample. This sample will be tested to find the tumor mutations. Only tumor tissue that has been obtained as part of your child's routine clinical care and is left over after all necessary clinical tests have been completed will be used for this study. No extra surgery will be done.

2. Patient blood sample. This sample will be tested to find the inherited mutations. We plan to obtain about 5 teaspoons of blood for this testing. We will try to do this at the same time as other clinical tests are being ordered and by obtaining the blood sample through your child's central line (a long-term IV line). It is possible that an extra blood draw may need to be done. In the rare case that we cannot obtain the preferred blood sample, a saliva sample will be obtained for this testing.

If leftover genetic material (DNA or RNA) from tumor, blood, or saliva samples is already available in the clinical laboratories, then these samples may possibly be used for testing in this study.

We will also collect information from your child’s medical records, including their age, ethnic background, diagnosis, disease history, medical treatments, and response to treatments. We hope this will help us understand how the genetic test results are related to the clinical features of your child's cancer.

Some of the same clinical genetic tests that are planned as part of this study may have previously been ordered by your child's doctors as part of their routine medical care. If such tests have already been completed, we will review those results as part of this study and not repeat the test(s) unless there is a specific reason to do so (such as if the test was performed a long time ago or the tests have been updated).

HOW WILL I RECEIVE THE RESULTS?

There will be separate reports for the results of the tumor and blood testing.

The results of the tumor testing will be given to your child's cancer doctor and also placed into your child's electronic medical record. One of these tests will be completed within a few weeks, while the rest will take about 3 months. Your child's cancer doctor will have the opportunity to review the results with the investigators on this study who are experts in tumor tests. Your child's cancer doctor will then explain the results to you, as well as whether the results are important for your child's treatment.
The results of the blood testing will also be given to your child's cancer doctor and placed in your child's electronic medical record. These tests will take about 3 months. Your child's doctor will have the opportunity to review the results with the investigators on this study who are experts in these genetic tests. If there are no important findings in the blood testing, you will receive a letter that describes the results in lay language. For those children with important findings on the inherited report, these results will be provided to you by a study genetic counselor either in person or by telemedicine. Telemedicine utilizes telephone and video to deliver healthcare at a distance.

WHAT TYPES OF RESULTS MAY I RECEIVE?

The results from these clinical genetic tests might reveal tumor or inherited mutations that affect the clinical care of your child and/or family. These tests also often find rare changes that we don't understand yet. Such results are included in the genetic report but no actions are recommended based on these results. Examples of results that might affect your child's care are described below.

1. Tumor mutations that make your child's doctor think your child's tumor will respond better or worse to a particular cancer treatment. The information might help your child's doctor pick a treatment for your child if the tumor has not responded well or has returned after treatment.

2. Tumor mutations that are normally found in a different type of tumor and might mean your child has a different kind of tumor than your child's doctors thought. We think this will be rare, but if it does happen, your child's doctor may talk to you about changing your child's treatment plan.

3. Inherited mutations that mean your child has an increased risk of developing cancer or that explain other medical conditions your child has. Results like this might make your doctor recommend that other family members get tested for an increased risk of developing cancer or other diseases. Additional cancer screening may be recommended for your child or family members depending on the genetic test results.

4. Inherited mutations indicating your child is a carrier of a recessive genetic disorder. This information may not affect your child's health, but it may be helpful to know later on. This test reports on a small number of genes that are recommended for screening in the general population. Your child may be a carrier of mutations in other genes associated with recessive disorders, and may wish to pursue additional carrier testing later in life.

5. Inherited mutations that provide information about an unexpected medical condition in your child for which treatment is available and recommended as standard medical care, for example related to heart disease. Your child's doctor may recommend additional follow-up testing or treatment if this type of mutation is found. These types of mutations are known as secondary findings.

Yes_____ No_____ I consent to receive secondary findings.
If we find any tumor or inherited mutations that affect the care of your child or family, your child's cancer doctor and/or a genetic counselor will explain them to you and work with you to determine the most appropriate screening or treatment (if any) for your child and family members.

STUDY PROCEDURES TO LEARN ABOUT COMMUNICATION OF GENETIC TEST RESULTS

Because we want to learn more about how families and their medical teams discuss and understand genetic test results, we will audiorecord a subset of the clinic or telemedicine visits in which parents learn about the results of their child's blood genetic testing. This will help us learn how to improve communication and understanding about these results between clinicians and families. If your child is at least 15 years old, we will invite him or her to complete a survey about his or her experience with the genetic testing about 6 months after the results are returned. This survey is optional.

ADDITIONAL LABORATORY RESEARCH STUDIES

We may want to do additional research studies on your child’s tumor and/or blood samples left over after the clinical genetic testing. This may include using different or newer genetic tests, studying proteins (material your body makes from genes), or growing tumor or blood cells in the laboratory to test.

Any results of these research tests would be preliminary and would not be reported to you or placed in the medical record unless we identify a genetic change that we think is important to the care of your child. In that case we will share that information with you and your child's cancer doctor and explain how to have the result confirmed by a clinical laboratory.

We would also like to do research to analyze tumor samples from surgeries other than the one at which your child's tumor was obtained for clinical testing, if available. This may help us to learn how tumors change over time and help us to design new tests and treatments. These samples are not required for enrollment on the study. Only tumor tissue that was removed as part of your child's routine clinical care and is left over after all necessary clinical tests have been completed will be used for this study. No extra surgery will be done. This research material will not be available to use for other clinical testing.

Yes_____ No_____ I consent to the use of my child's tumor tissue from other surgeries for these research studies.

Some tumors release their cells and genetic material (DNA and RNA) into the blood. These can potentially be detected by blood draws without having to perform surgery to obtain a piece of the tumor. By analyzing blood samples from different time points, we may be able to learn more about how tumors change over time and respond to treatment. For some patients on the study, we would like to collect additional blood samples for this purpose. These samples would be up to 4 teaspoons each and drawn about every 3 to 6 months during your child's clinical care, including at times of key clinical events or
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We will attempt to collect these samples at times of scheduled clinical blood draws.

Yes_____ No_____ I consent to having additional blood samples collected for these research studies.

If research from this project is presented at research conferences or published in professional journals, we will not use any information such as name, address, telephone number, or social security number to identify you or your child.

WHO WILL HAVE ACCESS TO YOUR STUDY INFORMATION?

The clinical tumor and inherited genetic reports will be handled like any other clinical tests and placed into your child's electronic medical record. These reports plus all other study data (surveys, audiotapes and all research genetic and clinical information) will also be stored in a confidential computer database along with all data about your child's biological samples and labeled with a code. Only the study investigators and selected research staff will be able to match the code to a particular person. Only the investigators and selected research staff will be able to access the database.

It is also helpful for other researchers to use your child's excess tumor and blood samples and genetic information paired with clinical information for their research. Coded leftover blood and tumor samples, as well as coded parts of your child's genetic information, and in some instances, clinical information, may be shared with other researchers who are conducting approved research studies. Study data, including your child's genetic and clinical information, as well as your survey responses, may also be shared with other researchers within the NIH Clinical Sequencing Consortium for approved research studies.

Your child's genetic and clinical information will be shared by releasing it into scientific databases including those maintained by Baylor College of Medicine and some maintained by the National Institutes of Health. These databases are restricted and can only be accessed by approved researchers. Sharing this information helps advance medicine and medical research by allowing other researchers to use this information to help solve questions of what causes cancers and other diseases. This is part of participating in a genetics study supported by the National Institutes of Health.

We will follow each child in the study for 2 years to determine if their cancer doctor has found the genetic test information useful in their care or for family members. In the future, it may be helpful to our research or those of other research groups to be able to re-contact you to obtain additional clinical information or to ask your permission to collect another research sample. Any first re-contact would come from a member of our KidsCanSeq research team.

CAN I CHANGE MY MIND AFTER I AGREE TO LET OUR SAMPLES BE USED?

You can withdraw your child from this study for any reason at any time. If you decide to withdraw from the study, we will destroy all personally identifiable information and destroy any coded information or data that identifies you or your child as soon as possible.

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Last Amendment: 7/13/2020 Approved from November 09, 2020 to November 03, 2021 Chair Initials: G. H.
study, your child's samples will be discarded.

If you decide to withdraw your child from this study before your child's genetic results have been reported and placed in the medical record, these results will be discarded and will not be used for any research purposes. However, it will not be possible to remove any reports that have already been submitted into the medical record. In addition, if your child's genetic and clinical information, your survey responses and other study data have been shared with other investigators or released into scientific databases, it may not be possible to remove this data from those databases.

This consent form is for a multi-site research study that requires one single IRB (institutional review board) of record for all of the participating sites. An IRB is a committee established to review and approve research involving human participants. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines. For this study, Baylor College of Medicine is the IRB of record and all of the participating sites are listed below.

Research related health information
Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, Children's Hospital of San Antonio, Cook/Fort Worth Children's Hospital, Doctors Hospital at Renaissance, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital, Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center, University Health System - San Antonio, and Vannie Cook Cancer Center to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning sickle cell anemia
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Children's Hospital of San Antonio, Cook/Fort Worth Children's Hospital, Doctors Hospital at Renaissance, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital, Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center, University Health System - San Antonio, Vannie Cook Cancer Center, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

The data coordinating center will have access to the research records including your health information.
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Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

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Please note that the research does not involve treatment. Baylor College of Medicine, Children's Hospital of San Antonio, Cook/Fort Worth Children's Hospital, Doctors Hospital at Renaissance, TCH: Texas Children's Hospital, Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center, University Health System - San Antonio, and Vannie Cook Cancer Center may not condition (withhold or refuse) treating you on whether you sign this Authorization.
Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, data coordinating center, Children’s Hospital of San Antonio, Cook/Fort Worth Children's Hospital, Doctors Hospital at Renaissance, TCH: Texas Children's Hospital, TCH: Texas Children’s Hospital, Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center, University Health System - San Antonio, and Vannie Cook Cancer Center may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Sharon Plon
1102 Bates St., FT 1200
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**
The only physical risk of this study is related to obtaining the blood sample. We will do our best to get these samples when your child is already having blood drawn for regular medical care. We will try to use an IV or central line your child already has. The risk of drawing blood includes a small risk of bleeding or infection at the site, and some pain or discomfort with the needle stick. There may also be some bruising at the site of the needle stick after the blood draw. Because the tumor tissue was collected during a tumor surgery for regular cancer care, there is no extra physical risk from getting a tumor sample.

If these genetic tests show a risk of developing a second cancer, or a risk of cancer in family members, or a risk of developing other types of diseases unrelated to cancer, you might feel anxious or upset by the results. Your cancer doctor can discuss these results with you and determine any medical follow-up that is indicated. There is also a potential risk in this type of genetic analysis for uncovering and conveying unwanted information regarding the biological relationship of parents and their children.

There is also the risk of a loss of privacy of your child's genetic information. The genetic reports will be placed in the electronic medical record and may be seen by your other doctors and health care workers. Health insurance companies may also have access to this information. There are laws to protect against the use of this information in making decisions about health insurance and employment. However, you may be asked to provide medical record information when you apply for life insurance or...
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disability insurance.

Since your child's coded genetic and clinical information will be shared by releasing it into scientific databases, there is a risk that others will be able to trace this information back to your child or your family. This may impact the ability of your child or other family members to obtain life insurance (as mentioned above), health insurance, or other products that may take into account the result of these genetic studies. Nobody will be able to know just from looking at a database that the information belongs to your child. However, because your child's genetic information is unique, there is a small chance that someone could trace the information back to your child or close biological relatives. The current risk of this happening is very small, but may grow in the future as new ways of tracing genetic information are developed. Thus, the risk that your privacy would be breached may increase over time. Researchers who access your child's genetic and clinical information will have a professional obligation to protect your privacy and maintain your confidentiality.

In performing these genetic tests as part of the study, it is possible that all of the available tumor sample will be used, and therefore no longer be available for future clinical testing or clinical trial enrollment. While we believe that the risks to you child and your family from participating in this study are low, we are unable to tell you exactly what all of the risks are. We believe that the benefits of learning more about cancer outweigh these potential risks.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits
The benefits of participating in this study may be: It is possible that tumor and/or inherited mutations may be discovered in this study that have implications for the treatment of your child and/or family and would not have been found by other standard tests. These may be used by your doctors as part of the clinical care of your child and/or family. However, we do not expect these types of clinically-relevant results to be found in most patients. However, you may receive no benefit from participating.

Alternatives
The following alternative procedures or treatments are available if you choose not to participate in this study: If you choose not to participate in this study, your child’s doctor may order some similar types of genetic testing outside the study, although the tests are expensive and not all of them are currently routinely available. Your child's physician would need to order the test and the hospital would need to determine insurance coverage. This decision will not affect the care that your child receives for their cancer.

Subject Costs and Payments
You will not be asked to pay any costs related to this research.
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If eligible to participate, your child will be given $25 after completion of the 6 month follow-up survey in the form of cash, gift card, or debit card.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury
If you are injured as part of your participation in this study, there are no plans to compensate you.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, SHARON PLON, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: For Texas Children’s Hospital, Vannie Cook Cancer Center, or Children’s Hospital of San Antonio, please contact SHARON E PLON at 832-824-4251 during the day. After hours, call (832) 824-2099 and ask to page Dr. Plon or Dr. Parsons.

For Cook Children’s of Fort Worth, please contact Dr. Kelly Vallance at 682-885-4007 during the day and at 682-885-4000 after hours.

For University Health System-San Antonio, please contact: Gail Tomlinson, M.D., Ph.D. can be reached at (210) 567-9116 or (210) 275-6507 cell after hours: Shawn Gessay, M.S., C.G.C. at (210) 562-9148; Christine Aguilar, M.P.H. at (210) 562-9123 or (210) 262-2472 cell after hours.

For MD Anderson, please contact Dr. Jonathan Gill at (713) 792-6620 during the day and (713) 792-5173 after hours.

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Approved from November 09, 2020 to November 03, 2021  Chair Initials: G. H.
Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

National Institutes of Health and the National Cancer Institute may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient Zip code, Patient country code and Patient Birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here __________________________
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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

__________________________  ____________________________
Subject                                         Date

__________________________  ____________________________
Legally Authorized Representative          Date
Parent or Guardian

__________________________  ____________________________
Investigator or Designee Obtaining Consent  Date

__________________________  ____________________________
Witness (if applicable)                Date

__________________________  ____________________________
Translator (if applicable)            Date

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