

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Physician Consent Form

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

You are invited to take part in the KidsCanSeq research study. With your participation in the study, your patients will be eligible to be enrolled on this KidsCanSeq. Please read this information and feel free to ask any questions before you agree to take part in the study.

Cancer is a disease caused by changes (mutations) in the genetic code of a cell that allow it to divide and spread in an uncontrolled way. Some of these mutations are present in every cell of the body ("inherited mutations") and can be identified from a blood sample, while others are acquired over time in the specific cells that form the cancer ("tumor mutations"). Both types of mutations can be detected by a variety of genomic sequencing technologies such as targeted gene mutation panels, copy number arrays, whole exome sequencing (WES), and transcriptome sequencing (RNA-seq). These tests are increasingly available for clinical use but 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.

In the KidsCanSeq study we plan to utilize a combination of clinical sequencing tests to identify inherited mutations and tumor mutations in children with central nervous system (CNS) and non-CNS solid tumors and lymphomas. These tests will be performed in CLIA and CAP-certified clinical laboratories at Texas Children's Hospital (TCH) and Baylor College of Medicine (BCM), with results returned to each patient's treating oncologist and entered into their electronic medical record (EMR). This study will evaluate how often these sequencing tests identify mutations of potential clinical relevance and impact patient care decisions and will also evaluate potential clinical utility from the perspective of the treating oncologist. In addition, we aim to study psychosocial and ethical aspects of incorporating genomic sequencing data into the care of diverse childhood cancer patients and families in varied clinical settings.

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.

There are a number of secondary goals of this study that involve learning how best to use and explain the results of these tests to oncologists, patients, and families. We are hoping to learn more about how oncologists and families use these results to help make future medical decisions. Because you are a pediatric oncologist who will be caring for children and families enrolled on the study, we are inviting you to participate in surveys and interviews about the impact of these genetic tests on patient care.

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,

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Clinic, TCH: Texas Childrens Hospital Clinical Research Center, UT: MD Anderson Cancer Center, University Health System - San Antonio, and Vannie Cook Cancer Center.

We plan to enroll up to 1200 patients and their parents over the 4 years of the study, as well as approximately 80 pediatric oncologists.

You are being asked to participate as a pediatric oncologist who will potentially care for KidsCanSeq study patients. We will provide you a copy of the full study protocol which outlines the procedures in which study patients and parents will be participating. For oncologists who enroll in the study, the following study procedures will occur:

A. Study education session. At the time of enrollment, study physicians will participate in an educational session in which study investigators will review study procedures and the content of tumor and inherited mutation reports. These sessions will occur in person or via teleconference/videoconference and will last approximately 30-60 minutes.

B. Return of tumor and germline test reports. Blood and tumor samples (if applicable) from study patients will be sent for clinical genomic sequencing tests as described in the study protocol. All study patients will have sequencing of a blood sample performed to identify inherited mutations. A subset of patients (those with relapsed/refractory tumors or newly-diagnosed high-risk tumors) will also have sequencing of a tumor sample to identify tumor mutations. Newly-diagnosed patients with high-risk tumors qualifying for tumor sequencing will be identified by study investigators in consultation with their primary oncologist. You will have the opportunity to discuss results of all study testing with the study investigators by e-mail and/or phone consultation.

Germline reports (for all patients). These reports will be returned to you (once both tests are complete) and incorporated into the EMR. The reports will include (i) any diagnostic findings related to cancer or other diseases, (ii) recessive carrier information, and (iii) secondary findings related to unexpected medical conditions for which treatment is available and recommended as standard medical care (with parental consent), For patients with negative germline reports, the site project coordinator will provide parents with a packet that includes the reports and a genetic counseling letter. For patients with a positive germline finding, the parents will receive these results from a genetic counselor either in person or via telemedicine and will be mailed copies of the reports and a genetic counseling letter.

The germline tests are:

- Targeted DNA mutation panel testing (turnaround time ~ 3 months)
- WES report (turnaround time ~ 3 months)

Tumor reports (for qualifying patients only). These reports will be returned to you and incorporated into the EMR. The results will be provided to patient families by you at a time that is convenient to you and the patient's family.

The tumor tests are:

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Targeted DNA/RNA mutation panel testing (turnaround time ~ 2 weeks)

Integrated tumor report combining results of WES, RNA-seq, and copy number array (turnaround time ~3 months)

Some of the same clinical genetic tests that are planned as part of this study may have previously been ordered by you or any of your patient’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).

C. Oncologist surveys. We plan to explore oncologists’ self-reported expectations and perceived utility of genomic sequencing. If you participate in the study, you will be asked to complete electronic surveys about these topics twice over the course of the study: (1) after study orientation and before any return of study results, and (2) one year prior to the end of study if you have enrolled at least one patient. These surveys will collect information on your age, gender, race/ethnicity, years of practice, and experience with genetics, and assess your perceived utility of genomic sequencing.

You will also be asked to complete brief electronic surveys if positive results (either tumor or germline) are identified in any of your patients enrolled on the study as well as for a select number of negative results. It is anticipated that these surveys will take 5 minutes or less to complete. They will focus on your impression of the clinical relevance of the results and any resulting clinical action(s) that have been. If further clarification is needed, you may be contacted by study investigators.

As this study develops, there is a possibility in the future that we may ask you to complete additional surveys and/or interviews. Completion of any additional surveys and/or interviews will not be required for continued study participation.

Who will have access to study data?

Each physician will be assigned a numeric identifier. Only the KidsCanSeq project leaders will have access to the master list of names and identifiers. Coded survey responses will be shared within the CSER Consortium. Names of physicians will be erased from audio-recordings and excluded from the transcripts. Thus, coders analyzing the transcripts and recordings will have no exposure to identifying information. Publications will identify respondents only in generic terms, e.g., "pediatric oncologist" or "parent of child with brain tumor." The master list of names and identifiers will be destroyed when data analysis is complete.

Can I change my mind after I consent to participate in the study?

You can withdraw from this study for any reason at any time. If you decide to withdraw from the study we will ask you to complete the initial provision of the reports to any families already consented to the study but will not include you in additional subjects. If your survey data have already been shared within the

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CSER Consortium, it may not be possible to remove that 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.

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

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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, TCH: Texas Children's Hospital, Clinic, TCH: Texas Children's 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 Children's Hospital Clinical Research Center, UT: MD Anderson Cancer

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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

There are no physical risks of the study for the oncologists.

Other risks:

1. Loss of privacy (interview/survey data)
2. Stress and anxiety related to discuss of study clinical sequencing results with patients/families.

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: The benefits of participating in this study may include: learning more about genomic testing, its clinical applications, and how to discuss this data with patients.

It is not known how frequently this study will reveal findings that are of potential clinical benefit to your patients and their families. Your patients may have no direct benefit from your participation in this study.

The study will allow the investigators to better understand how cancers develop and how cancer might respond to various treatments and how to use this new type of genetic testing in caring for children with cancer and thus may benefit your other patients in the future. We expect that analysis of physician - patient communication will provide better understanding of how to convey complex genomic information to parents and to incorporate this information when caring for patients with cancer.

. However, you may receive no benefit from participating.

Alternatives

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You may choose to not participate in this study.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

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.

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,

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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.

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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

Investigator or Designee Obtaining Consent

Date

Witness (if applicable)

Date

Translator (if applicable)

Date

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