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## Overview

The **Pediatric Cancer Clinical Trials Learn Guide** is designed to help support patients and their families as they face the challenges of their cancer journey.

This guide is interactive and serves as a creatively driven resource developed to support, educate and empower both patients, and their caregivers.

Here are a few ways that this guide can be used as an ongoing resource:

• **Parts 1-2** include an overview of clinical trials to introduce you to what they are and help you to understand whether participating in a clinical trial might be right for your child. These sections feature Dr. Leonard Sender and Sharon Bergeron, RN.

• **Parts 3-6** explain how clinical trials are created, and outlines in detail the clinical trials at CHOC, introducing the members of the clinical trial team and going over the steps of the clinical trial process. These sections feature Dr. Leonard Sender, Dr. Ivan Kirov, and Kathy Duvall, RN.

• **Part 7** explores the future of clinical trials and the latest advances in cancer treatment and research. This section features Dr. Leonard Sender.

**We suggest that you bring your ebook of this guide to meetings with Healthcare Professionals**. You can get the ebook from the "**Request this EBook**" button above and will then be able to use it on your phone, tablet, computer, or print it out on paper.

## Introducing Dr. Sender

**Leonard Sender, M.D.**

A nationally-recognized expert, Dr. Sender serves as the director of the Adolescent and Young Adult (AYA) Cancer Programs at CHOC Children's, leading one of the nation's largest programs focused on the unique needs of cancer patients ages 15-39 years old.

As a pioneer in oncology treatment for more than 20 years, Dr. Sender specializes in treating adolescents and young adults (AYAs), a largely unknown and underrepresented group in the war on cancer. His team offers a comprehensive approach toward AYA patient cancer care and survivorship that considers their unique challenges, including preservation of fertility, management of acute and chronic effects of treatment, and the psychosocial impact.

As an innovative leader in research, Dr. Sender is conducting extensive studies to improve outcomes and quality of life for AYAs. A passionate advocate for AYA's with cancer, Dr. Sender serves as chairman of the organization Stupid Cancer. He is a founding member and chairman of SeventyK.org.

*"I'm Leonard Sender, the medical director of the Hyundai Cancer Institute and CHOC Children's Hospital. I've been taking care of children with cancer since 1989. As a pediatric oncologist, I'm involved in clinical trials by bringing together the clinical team and the research team to affect the outcome for children who have cancer. We do this at all levels – we're involved in designing trials, carrying out the trials, making sure the data is collected, and making sure the data is shared both locally and nationally. We work on all these levels so we can have the greatest possible impact on the outcome for kids with cancer."*

**To Learn More**:
- Dr. Sender's Full Bio (http://www.choc.org/providers/oncology/leonard-sender-md/)
- The Hyundai Cancer Institute at CHOC Children's (http://www.choc.org/cancer/)
- Society for Adolescent and Young Adult Oncology (http://www.sayao.org/)
- SeventyK (http://www.seventyk.org/)

## Introducing Sharon Bergeron, RN, BSN, CPON

**Sharon Bergeron, RN, BSN, CPON**

As a research educator, **Sharon Bergeron, RN, BSN, CPON**, is dedicated to providing the Cancer Institute at CHOC nurses with the latest news and information available on pediatric cancer treatment, including cutting-edge clinical trials.

*"My name is **Sharon Bergeron**. I'm a Nursing Research Educator for the Hyundai Cancer Institute at CHOC Children's Hospital. I'm a certified pediatric oncology nurse, and have cared for children with cancer for over 30 years. I'm involved in clinical trials in a very unique manner. Being a nursing research educator allows me to share my best knowledge of clinical trials to nursing and physician staff, as well as to patients and their families so they know what to expect when they are receiving treatment on a clinical trial."*

*"Over a span of almost 30 years, I have been deeply touched by the many patients and families I have helped cared for through the ups and downs of the cancer treatment journey," Sharon said. "It is with this knowledge and experience that I teach other pediatric hematology/oncology nurses what I know about caring for these children so that I can create an environment that allows nurses to provide the highest level of nursing care and flourish in their role. In addition, I work hard to provide an educational environment that encourages nurses to demonstrate independent and critical thinking skills so that they can deliver care yielding excellent patient outcomes and a high level of job satisfaction."*

**To Learn More**:

- Spotlight on Sharon Bergeron (https://blog.chocchildrens.org/hyundai-cancer-institute-associate-spotlight-sharon-bergeron-research-educator/)

## Introducing Dr. Kirov


**Ivan Kirov, M.D.**

*"My name is **Ivan Kirov**, and I'm a pediatric oncologist at CHOC Children's Hospital, Hyundai Cancer Institute, where I'm a director of the Recurrent Cancer Program and the principal investigator for Phase 1 clinical trials. I've been caring for children with cancer for almost 30 years in both the United States and Europe."*

*"As a Primary Investigator (PI) for Children's Oncology Group Phase 1 studies at CHOC Children's Hospital, I'm coordinating and supervising all the aspects of Phase 1 clinical trials in our institution. I'm also a PI on multiple pharmaceutical industry driven clinical trials, and coinvestigator on all Phase 2 and Phase 3 clinical trials at CHOC."*

**Dr. Kirov**, *"The primary focus on my job at CHOC is to diagnose and treat children with different kinds of cancer, leukemia, and lymphomas. Together with my team, we are offering our patients the best treatment options available, as well as all the necessary support and care throughout their treatment and for many years after their therapy is completed.*

*Personally, I'm very interested in the treatment of children, adolescents and young adults whose cancer has returned or doesn't respond to the current standard therapies.*

**To Learn More:**

- Dr. Kirov's Full Bio (http://www.choc.org/providers/oncology/ivan-kirov-md/)
- The Hyundai Cancer Institute at CHOC Children's (http://www.choc.org/cancer/)
- Leukemia Treatment Program at CHOC (http://www.choc.org/cancer/leukemia-treatment-program/)
- Recurrent & Refractory Cancer Treatment Program (http://www.choc.org/cancer/recurrent-refractory-cancer-treatment-program/)

## Introducing Kathy Duvall, R.N.

**Kathy Duvall, R.N.**

*"I'm Kathy Duvall, I'm a Registered Nurse and a manager of clinical research. I've been caring for children with cancer for over 20 years. As a clinical research manager, I oversee the daily operations of our clinical research program. "*

*"I make sure that studies are maintained according to federal regulations, and I supervise our group of clinical research coordinators and follow up on their studies."*

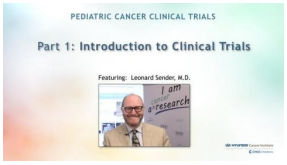
## Introduction

Part 1: Introduction to Clinical Trials

# The Role of a Clinical Trial in Improving Cancer Outcomes

**Dr. Sender**, *"Cancer outcomes have improved dramatically for children with cancer since 1948 when Dr. Sidney Farber treated the first child diagnosed with acute leukemia. The pediatric cancer community has been absolutely committed to making sure all children are offered clinical trials. The greatest result of that is that more kids are being cured of cancer today.*

*Clinical trials have played a very important role in improving the survival of children with cancer. We know this because our outcomes have dramatically improved over the last 50 years. If we do not do clinical trials, then we cannot improve the outcome."*



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**To Learn More**:
- CHOC Children's Research and Clinical Trials (http://www.choc.org/cancer/research-clinical-trials/)
- More Information on Children's Cancer Research (https://childrensoncologygroup.org/index.php/research)

### What is a Clinical Trial?

A clinical trial is a set of instructions on how to treat a patient. It may be testing a particular drug. In this example, we'll call that "Drug A". The trial tests how Drug A works when delivered in a particular fashion to a patient, whether that be oral or intravenous, whether it's given on a certain day of treatment, etc. The clinical trial has a certain set of instructions, and those instructions become known as a protocol. The protocol has every aspect that the treating physician and the hospital need to know.

Think of a clinical trial as a way of asking a particular question and then providing the institution, the researchers, and the physician with a set of detailed instructions on how to carry out the trial, so that every institution that is doing the clinical trial does it the same way and we can therefore measure the impact of the treatment of Drug A and see if that created an improvement in the outcome.

**To Learn More:**
- Information on Clinical Trials from the National Cancer Institute (http://www.cancer.gov/about-cancer/treatment/clinical-trials)
- Clinical Trials at the Children's Oncology Group (https://www.childrensoncologygroup.org/index.php/what-is-a-clinical-trial)

### What is the Purpose of a Clinical Trial?


A clinical trial is trying to find out whether Treatment A is better than Treatment B. Do more patients survive if they receive Treatment A or Treatment B? We believe that clinical trials should be considered in the phase that we call the curative phase. We're always trying to cure our patients of the disease, with the outcome being that more of our patients are alive for longer.

**Dr. Sender**, *"The one thing that I want parents to know about clinical trials is that if we want to change the 80% statistic that 80% of our kids are cured, and if we want to get the extra 20% to make that a 100% rate of success, the only way is going to be through clinical trials."*

**To Learn More:**
- The Impact of COG's Research (https://childrensoncologygroup.org/index.php/home/62-about-us/about-us)

## Participation

Part 2: Participating in a Clinical Trial

# Selecting the Appropriate Trial for a Child

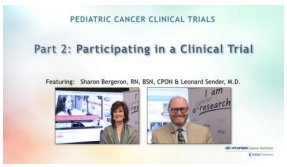
The following will be considered when determining eligibility for participation on a clinical trial...

- The diagnosis of the disease.

- How it has spread throughout other organs.

- Organ function and current health of your child.

- Willingness to participate in a clinical trial.



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### Is Participation Voluntary?

Participation in clinical trials is voluntary. Patients who decide not to participate will receive the best standard of care, there will be no negative reaction towards your child.

### The Benefits of Participating

The benefits to your child of going into a clinical trial are that it allows us to give them the most up-to-date and advanced treatment plan that we can give them. In a standardized way, it allows us to evaluate whether the new treatment, the new drug, the new combination, the new timing in how the drugs are given actually amounts to any improvement in outcome.

We know that we would never have achieved the standard that we have today without previous children having gone into clinical trials. Therefore, it is a short-term gain for a particular child that provides a long-term gain for all children. Today, we are living on the backs of the children who came before us, and we are appreciative of what's happened to them, but we have also shown them that each time we finish a clinical trial the outcomes improve. That's our goal – to do what we can to give the best treatment to your child.

**To Learn More:**
- Impacts of COG's Clinical Trials Research (https://childrensoncologygroup.org/index.php/home/62-about-us/about-us)
- Possible Benefits and Risks In Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/taking-part)

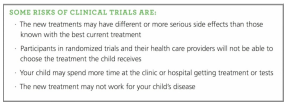
Parents sometimes ask, "What can I do to give my child the best opportunity for a cure?" We absolutely believe that going on a clinical trial gives the child the best chance, because then we are doing treatment in a way that is standardized, is rigorous, and has been overseen by a larger collective.

## Facts About Clinical Trials

The findings from clinical trials add to knowledge and progress in the treatment of cancer. Since childhood cancer is rare, by trying different treatments and looking at the results we can find out which treatments are the best much more quickly. By treating children on clinical trials at COF-affiliated hospitals, overall survival rates have improved from less than 10% in the 1950's to over 80% at the present time. Organized clinical trials have made the difference.

### Risks in Participating

The risk to your child if they participate is that there may be unknown, unanticipated side effects that may affect their quality of life and may put them at risk. However, in the design of the trial, these potential side effects have been thought out to great effect, and we optimize the



trial mechanism to make sure that the child is safe.

We also have what is called a data safety monitoring committee, which is an independent group who looks to make sure that any clinical trial where toxicities start occurring is immediately shut down at our institution.

**To Learn More:**

- Information on International Review Boards and Data & Safety Monitoring Boards (http://www.cancer.gov/about-cancer/treatment/clinical-trials/patient-safety/scientific-review)

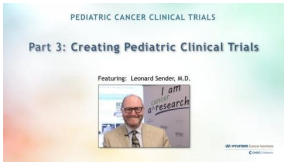
## Risks in Not Participating

Often we're asked by parents "what are the risks to my child if they do not participate?" Sometimes they just cannot use certain drugs, because there are drugs that we are testing that the FDA (Food & Drug Administration) will not release to children who are not on clinical trials. We also cannot in good faith put a child on a treatment plan that is experimental in nature, meaning that we don't know what the long-term outcome or toxicities will be. Whenever someone chooses not to go on a clinical trial, we give them the best practices that we know today.

## COG

**Part 3: Creating Pediatric Trials**

In the United States, the largest and most effective group treating kids with cancer using clinical trials is called the Children's Oncology Group, also known as COG. COG is funded by the National Cancer Institute and is the largest clinical trials group for children in the world. It has the greatest results and has brought together the most pre-eminent oncologists from around the country and the world to focus on a particular disease type and to bring their discoveries to the many hospitals that are its members.



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**To Learn More:**
- About the Children's Oncology Group
(https://www.childrensoncolo
/index.php/aboutus)

**COG's Role in Creating Pediatric Clinical Trials**


COG's role in pediatric clinical trials is to be the comprehensive organization that brings together many types of trial opportunities to patients. Whether it be a registration trial, a biology section, or therapeutics, treatment or long-term and survivorship trials, COG makes sure it's available to as many patients as possible.

**To Learn More:**
- Information On Different Types of Clinical Trials
(http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/types)

**Creating a Network for Effective Clinical Trials**

### Why is Collaborative Research Important?

While nearly 12,500 children and adolescents are diagnosed with cancer each year, there are many different kinds of children's cancer. When divided into the specific cancer types, the number of children with each is relatively small. In research, large numbers of patients are critical to ensuring that study results are meaningful. By enrolling patients from many hospitals in the same trial, the results become statistically significant. The approach is called collaborative research and is how the Children's Oncology Group functions.

We all realize that although we can do single hospital trials, we don't have enough patients in a single hospital to provide sufficient results to effect change throughout the country and the world. Another very important reason for having a network is that when we get a cooperative group together, we bring together the best minds from around the country, all thinking on the same problem. Through that process, we're able to create a clinical trial and a network that allows the best care for kids, regardless of where they're being treated.

**To Learn More:**
- Info on COGs Collaborative Research Model
(https://childrensoncologygroup.org/index.php/childrens-oncology-group)
- COG Research Collaborations
(https://childrensoncologygroup.org/index.php/research-collaborations)

**COG's Role in Creating Access to Clinical Trials**

COG democratizes the approach to making trials available to all centers. The majority of clinical trials available on the COG website are available to every center, except for the few trials that are either Phase 1, which means that they're limited to certain institutions, or sometimes limited Phase 2 trial opportunities.


**To Learn More:**
- Find a COG Location Near You
(https://childrensoncologygroup.org/index.php/locations/)

## CHOC's Involvement With COG

CHOC Children's Hospital and the Hyundai Cancer Institute is involved in all 3 aspects of the COG experience. We are one of the 22 institutions that are part of the consortium that offer Phase 1 clinical trials. We offer Phase 2, Phase 3, as well as transplant related clinical trials through the Children's Oncology Group.

**To Learn More:**

- The Hyundai Cancer Institute (http://www.choc.org/cancer/)
- Research & Clinical Trials at CHOC Children's (http://www.choc.org/cancer/research-clinical-trials/)

## CHOC Trials

**Part 4: Clinical Trials at CHOC**

The types of trials that we have available to our patients at CHOC Children's and the Hyundai Cancer Institute can be divided into three main categories.

There's a trial mechanism that has a very fancy name: **HDII (Hypothesis Driven Investigator Initiated Trial)**. This means that an investigator has an idea of what could work for your trial, writes the clinical trial protocol, gets it through an institutional review board, and then makes it available. That's an HDII trial.

- NCI's Info on Types of Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/types)

The second type of trial is a **Cooperative Group Trial**. That is the type of trial that comes through the Children's Oncology Group and has the collective wisdom, if you will, of over 200 institutions coming together and designing a treatment plan for a particular patient and making that a clinical trial.

- Types and Phases of Clinical Trials (http://www.choc.org/cancer/research-clinical-trials/)

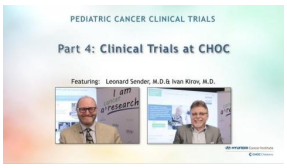
The third type of trial is a trial that is **Pharmaceutically Driven**. This means that the pharmaceutical industry was testing a particular drug, designed the trial, and made that drug available to our institution. In this case, we have very little input into changing the trial, but sometimes the only way to get access to that drug for our patients is to participate in that trial.

**Trials Available Other Than Theraputic**

**Non-therapeutic trials** do not provide a treatment to patients, but they study factors which help advance the understanding of cancer and its impact. Such trials include…

**Registration:** These trials track the number of patients who have been affected by a particular type of cancer per year. This information is then added to the national database.

**Supportive Care:** These studies evaluate ways of helping reduce the side effects of cancer treatments.



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**Biology:** These studies collect tissue and other samples from patients, such as blood, tumor tissue, hair, urine or stool. These specimens enable researchers to analyze the biology of the disease and the behavior of cancer cells.

**Psychology:** Studies that focus on the emotional and social aspects of cancer and improving the outcome for patients.

**Epidemiology:** These studies look to understand the reasons why children develop cancer.

### TRIALS FOR FIRST-LINE THERAPY OR FOR RECURRENT DISEASE

The trials for up-front therapy, also known as first-line therapy, are always designed to be absolutely curative in nature. This means that the intent is to safely cure as many children as possible. When a child relapses, we don't always understand what the best treatment is, and those trials are trying to ask much more complex questions about how we can change the outcome once a patient has relapsed.

**To Learn More:**
- Recurrent & Refractory Cancer Treatment Program at CHOC (http://www.choc.org/cancer/recurrent-refractory-cancer-treatment-program/)

### CLINICAL TRIALS FOR AYA PATIENTS

The adolescent and young adult (AYA) cancer patient, as compared to the pediatric patient, can sometimes be caught in between. They sometimes need to be on adult clinical trials that are not part of the Children's Oncology Group, or they're part of the Children's Oncology Group as a subset of a larger pediatric opportunity. There is no one trial group for AYA patients, and it's unlikely that one will be created under the new NCI guidelines. Therefore, it's very important that any hospital taking care of AYA patients has access to both pediatric and adult trials to make sure that they bring the best clinical trials to the patient.

**To Learn More:**
- AYA Treatment Program at CHOC (http://www.choc.org/cancer/adolescent-young-adult-treatment-program/)

**The Three Types of Phases of Clinical Trials**

### What is a Phase 1 Clinical Trial?

Phase 1 clinical trials usually involve a small number of patients with very advanced cancer that cannot be effectively treated with current standard therapies. The primary goals of Phase 1 studies are: to evaluate the safety of the new medication; to define the maximum tolerated dose that could be given to the patients without harmful side effects. A secondary goal of Phase 1 studies is to preliminarily define the potential anti-tumor effects of new medications.

### What is a Phase 2 Clinical Trial?

Phase 2 trials usually follow Phase 1 trials. They test the effectiveness of the new drug on patients with a particular type of cancer, and also continue to monitor the safety of the new treatment.

### What is a Phase 3 Clinical Trial?

Phase 3 trials compare the new treatment to the current standard treatment for the specific type of cancer. If the new treatment turns out to be more effective, it usually becomes the standard for this particular type of cancer.

**To Learn More:**

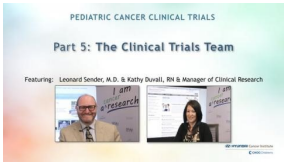
- The 3 Phases of Clinical Trials (http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/phases)

## Our Team

**Part 5: The Clinical Trials Team**

**Dr. Sender**, *"PI stands for Principle Investigator. On a clinical trial, the PI is responsible for all aspects of the delivery of the trial, from its first inception through the regulatory bodies within the hospital, to how it is carried out by the team, how the date is collected and fed back to the organization, whether that be the Children's Oncology Group or any other organization.*

*The PI makes sure that the trial is carried in a way that meets all the requirements of the FDA and the National Cancer Institute."*



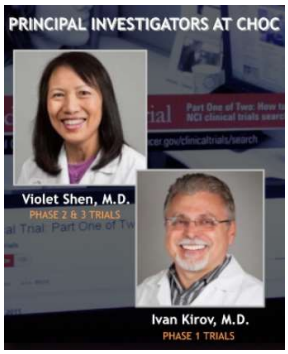
(https://vimeo.com/149282769)

### THE ROLE OF THE PI IN DESIGNING THE STUDY

The principal investigator may be the person who designs the trial, and then the trial is called a Hypothesis Driven Investigator Initiated Trial. That makes up a small percentage of the trials open at children's hospitals. The majority of clinical trials come through the Children's Oncology Group, which has a head principle investigator for the entire country. However, every institution chooses a principle investigator for their hospital who makes sure that their trial at that hospital is carried out correctly.

**To Learn More:**

- COG Disease Committee Leadership (https://childrensoncologygroup.org/index.php/cog-disease-committee-leadership)




### THE PI AT CHOC

The principle investigator at CHOC Children's Hospital is Dr. Violet Shen. She has run our Phase 2 and Phase 3 trials. We also have Phase 1 trials through the Children's Oncology Group, and our principle investigator on those trials is Dr. Ivan Kirov. We also have clinical trials through pharmaceutical companies and HDII trials, and sometimes those have their own particular principle investigators.

**To Learn More**:

- Dr. Violet Shen's Provider Profile (http://www.choc.org/providers/oncology/wei-ping-violet-shen-md/)
- Dr. Ivan Kirov's Provider Profile (http://www.choc.org/providers/oncology/ivan-kirov-md/)
- CHOC Children's Specialists (https://specialists.chocchildrens.org/)

**Responsibilities of the Clinical Research Coordinator**

- Carrying out the protocol requirements, under the direction of the PI.
- Monitor patient safety.
- Inform oncology team when lab tests are done.
- Make sure Treatment Plan has been updated.
- Gather information of any side effects that may be occurring.
- Inform the PI of any adverse event.
- Update the PI of patient's status.
- Extract medical record information and enter into appropriate data collection tool.
- Communicate schedule of events to parent.
- Inform parents of possible side effects to look out for.

**The Role of the Institutional Review Board**

The IRB is the Institutional Review Board, and they are charged with ensuring patient safety on all clinical trials. A child cannot be started without their approval. The Institutional Review Board reviews every single protocol before it is ever opened at an institution, and it must be approved before the institution can start enrolling patients. The trial is also reviewed on an annual basis, where the IRB reviews all serious adverse events.

**To Learn More**:

- The Institutional Review Board's Role at CHOC (https://blog.chocchildrens.org/institutional-review-boards-role-research/)

## Process

Part 6: Steps in the Clinical Trials Process

# The Protocol

The protocol is the document that describes the study in its entirety. It includes the background information, the purpose of the study, the treatment plan, and the possible risks or benefits. Each protocol targets a certain patient population. This is called the Eligibility Criteria, which may include age, diagnosis, disease status, or organ function.

**Kathy Duvall**, *"We understand that you're making a decision at a difficult time in your child's life. Because of research from families like yours that have gone before, we've been able to improve treatments and outcomes for children with cancer."*

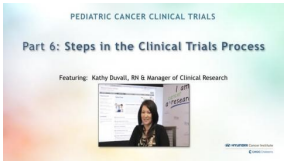
The Protocol is the document that describes the study in its entirety, including...

- Background information
- The purpose of the study
- The Treatment Plan
- The possible risks and benefits

The Comprehensive Treatment Plan

The Comprehensive Treatment Plan, or the "Roadmap," is usually a one-page document for a particular phase or cycle of treatment. It includes the patient's dosing schedule, their actual schedule, and any required observation that may need to be done by the entire team.

If the patient experiences any side effects, we will document that on the Roadmap and adjust the doses accordingly if the protocol allows for that. This way the entire team knows of any changes that were made.



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The Occurence of an Adverse Event

An adverse event is a research term for a side effect. Each adverse event is monitored by our Clinical Research Coordinators while you're on a clinical trial. Each adverse event is graded, and may or may not be recorded based on the protocol requirements. Depending on the severity of the adverse event, we may do nothing and continue on with the protocol, or we may decrease the patient's dosage or hold the patient's dosage. Either way, your child will still receive care.

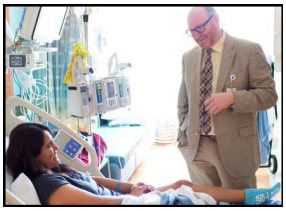
The research coordinator is responsible for communicating regularly to the oncology team regarding the patient's status and any changes in the protocol or protocol requirements.

The Consent Conference

The consent conference is the meeting you have with the physician to discuss the treatment plan. It's the time when you may or may not be offered participation in the clinical trial. In addition to the physician, the case coordinator, the social worker, or the research coordinator may also be in attendance. The consent conference can take anywhere from an hour to an hour and a half. Questions are encouraged during the consent conference. We want to make sure that you're informed about any clinical trial or treatment plan.

**To Learn More**:
- More Info on Informed Consent
(https://childrensoncologygroup.org/index.php/informed-consent-311)

The Informed Consent Form



The Informed Consent Form is a document that explains the protocol in very simplified terms. It includes:

- The purpose of the study
- The Treatment Plan
- The possible risks or side effects

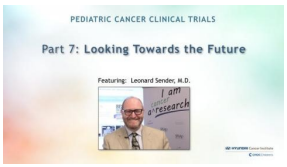
Should you decide to participate, you will need to sign the

consent form, and you will receive a copy at the end of the conference.

## Future

**Part 7: Looking Towards the Future**

### Genomic Research: Unlocking the building blocks to tomorrow's cures today.



(https://vimeo.com/149282752)

**Dr. Sender**, *"The CHOC Genomics Program, also called the Hyundai Genomics Project, is a very well-funded project that is going to take a deep dive into the coding of tumors. The goal of the genomics project is to personalize our treatment approach for a particular patient with cancer. We use genomics, which means that we sequence or decode the tumor to find what's causing the cancer. We then look to see whether we can find a treatment that can be personalized, based on their genomics, and therefore targeted to treat that particular patient's tumor."*

**To Learn More**:
- Clinical Trials and Genomic Research at CHOC (http://www.choc.org/cancer/research-clinical-trials/)

**Participating in the Genomics Project**

Being involved in the genomics project means giving us permission, through a consent form, to take the tumor and pathology that's already been collected and allow us to do sequencing. It also means giving us one additional blood sample or a buccal swab from the side of the mouth so that we can take that sample and analyze it for the normal. We compare the tumor to the normal. Some of you have played "Where's Waldo?" – this is like that. We're looking for "Waldo" in the tumor, because the sequencing in the tumor is different than it is in the normal part of your body.

Your child can participate in the Genomics Project in two stages. We are collecting samples at diagnosis from every single child at CHOC Children's Hospital and the Hyundai Cancer Institute. We want to collect a sample of your tumor and your normal. The second opportunity is for the percentage whose tumor comes back, so when their tumors are recurrent or refractory (meaning they haven't responded to therapy), then we may get another tissue sample at that time.

**To Learn More**:
- Research at CHOC (http://www.choc.org/research/)
- Dr. Sender Discusses Genomic Cancer Research (https://docs.chocchildrens.org/dr-leonard-sender-discusses-genomic-cancer-research/)

**Genomic Research and Cancer Treatment**

The goal in the Hyundai Cancer Institute is to collect tumor and non-tumor specimens from each and every child that is diagnosed with cancer at CHOC Children's. At this time, specimens are not sequenced unless the child's cancer is refractory (meaning the cancer is not responding to treatment) or recurrent (meaning the cancer came back after treatment). The DNA and RNA is extracted from the tissues in the Molecular Laboratory at CHOC Children's and sent to an off-site facility where the whole genome and transcriptome sequencing procedures are performed.

**Why CHOC Collects and Stores Tumor Tissue**

One of the big advances in the last few year is the development of unbelievable tools to analyze tumors. For the first time, we really have the capacity to see what's causing these tumors to kill our patients. We believe that the only way that you can have the starting material to do the necessary science is to collect the tissue of the tumor itself. Without having the tumor tissue safely banked and stored away, we won't be able to do the science when a new test or machine is created in the future. These future advances in cancer treatment are why we need to bank the tissue now, and why we need to annotate it, which means to link it to everything about that particular patient's cancer and treatment. That way, when we do the analysis, we're able to make conclusions.

By sharing biospecimens and research data, the

**To Learn More**:
- Project:Everychild (http://projecteverychild.org/index.php)
- Hyundai Hope On Wheels™ Biorepository (https://www.childrensoncologygroup.org/index.php/hyundai-hope-on-wheels-biorepository)

Children's Oncology Group's Project:EveryChild will help lead scientists around the world to find cures for every child with cancer. Visit our Hyundai Hope On Wheels™ Biorepository to learn more.

## The CISCO Tumor Board at CHOC

The CISCO Tumor Board at CHOC is part of a grant-funded opportunity to create a Virtual Pediatric Network. We have five institutions that are already linked together using tele-presence systems to allow us to bring the best experts to the table. This system allows us to bring the best knowledge to the patient, especially in complex cases. Using the Virtual Pediatric Network means that we're not only accessing our own experts here at CHOC Children's, but we're also involving the experts at the five other institutions.

**To Learn More**:

- The Virtual Pediatric Network at CHOC (https://blog.chocchildrens.org/bringing-together-best-minds-pediatric-cancer-care/)

We believe that the CISCO Tumor Board will make better patient care because we're bringing experts to very complex cases, allowing them to interact in a way that's never been done before, in real-time, which allows us to make real-time decisions for the patient, not retroactive decisions. This allows us to clearly see the best science that we can bring to a particular child today.

## A Final Word About Clinical Trials

*"The one thing I want every parent to know about clinical trials is that if we want to change the 80% rate of success in curing our children's cancer to a 100% success rate, the only way is going to be through clinical trials."*

**- Leonard Sender, M.D.**

**To Learn More**:

Research Clinical Trials at CHOC (http://www.choc.org/cancer/research-clinical-trials/)