# A PARENT'S GUIDE TO
# CLINICAL TRIALS

AMERICAN childhood CANCER ORGANIZATION

In memory of Elyse MacEwen.
Your little footprints led to a safer path for
children today and tomorrow.

# A Parent's Guide to Clinical Trials

Author: Adam Cohen, MS, MD, Howard Colman, MD, PhD. Adapted from Understanding the Journey, A Parent's Guide to DIPG

Edited by Ruth I. Hoffman, MPH



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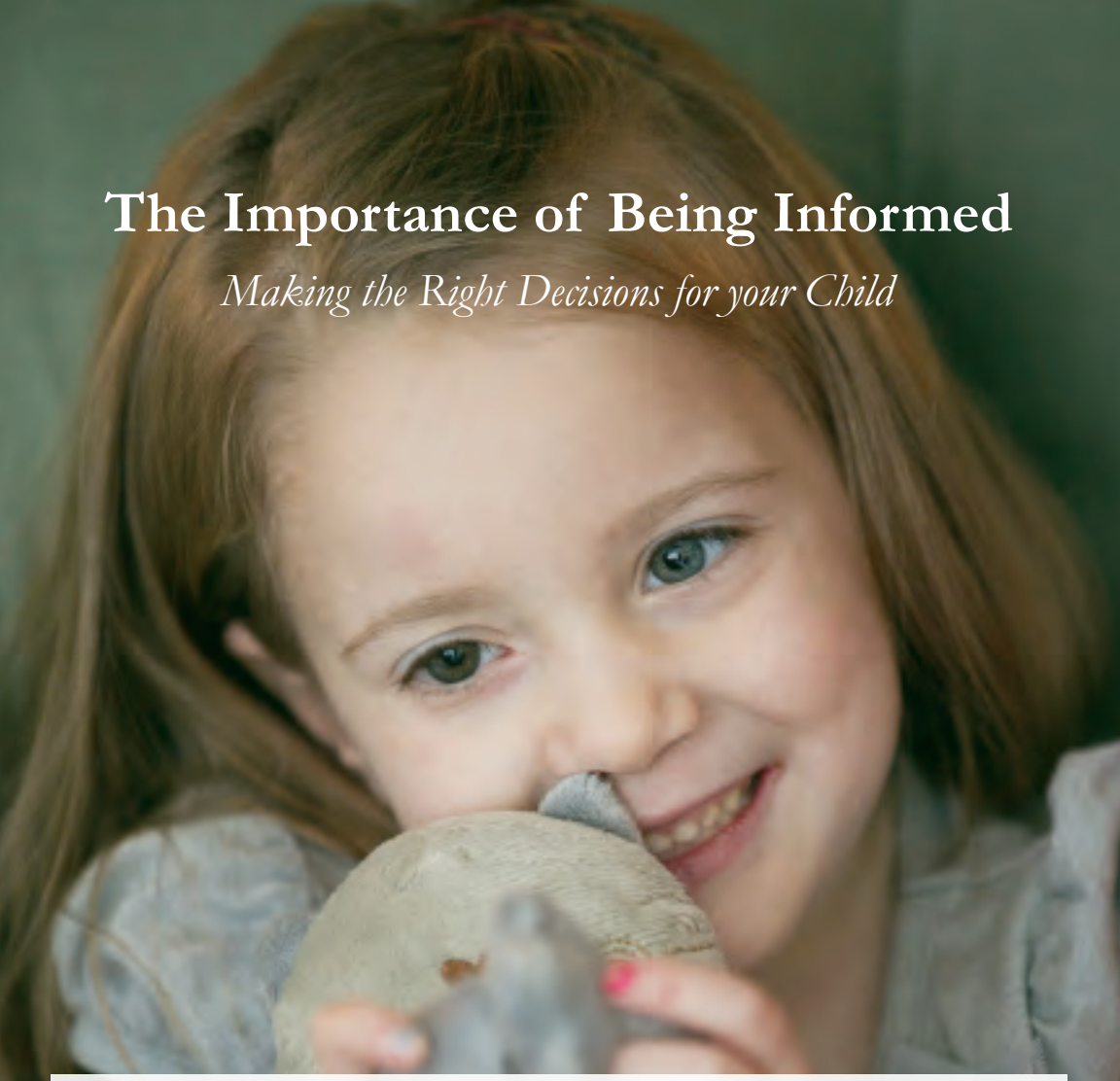
This booklet is written to provide information about childhood cancer and should not be used as an alternative to receiving professional advice. Every effort has been made to ensure that the information in this resource is accurate at the time of printing; however, there is no guarantee that the information will remain current over time. Always seek the advice of a medical professional.



# The Importance of Being Informed

*Making the Right Decisions for your Child*

Many of the advances in treatment for childhood cancer can be attributed to the success of clinical trial research. Clinical trials are controlled research studies that test new drugs or devices or a new combination of existing drugs in order to improve available therapies. As new treatments are being developed by academic centers, biotech, pharmaceutical and medical device companies, parents are sometimes given the opportunity to enroll their child in a clinical trial. This booklet is focused on clinical trial design. Parents who are familiar with study design terminology and who have a basic understanding of the purpose of clinical trials are better equipped to make informed treatment decisions. Every child is unique, and treatment decisions are also unique to individual children and their families.

# What is a Clinical Trial?

A clinical trial is a way to test possible new treatments. Clinical trials are done in cancer to find out:

- whether a treatment is safe;
- whether a treatment has the effects on cancer cells that scientists think it will;
- whether it is effective at destroying cancer cells, shrinking tumors, delaying growth of cancer cells /tumors, or making people live longer.

A clinical trial is a scientific study that must follow certain rules to ensure patient safety and that the results are true and not due to chance or bias. A clinical trial may test several different types of experimental treatments including:

- A brand new drug (usually not already FDA approved for other cancers or uses).
- A new combination of drugs (that could include new or existing drugs).
- A new technology.
- An old drug that is being used in a new way or on a new population of patients.

There are many types of clinical trials. When participating in a clinical trial, it is important to know:

- What kind of trial it is.
- What the purpose of the trial is.
- What is new and experimental about the trial.

Clinical trials are an essential part of medical research. Without clinical trials, medical knowledge cannot grow and new treatments that may save or improve the lives of future cancer patients would not be identified.

# What is Not Considered a Clinical Trial?

Clinical trials must have specific characteristics that qualify them as well-designed scientific studies. Not every study is a clinical trial. In this section, we give examples of studies that are not clinical trials and give some of the qualities of a good clinical trial.

Clinical trials must study a predetermined group of people, given a predetermined treatment and use statistics to analyze results. "Case reports" or "case series" are reports by physicians giving the results of a specific treatment observed in just a few patients. While potentially useful to other physicians, case reports of one or two patients are not true clinical trials because not enough patients are treated with a specific therapy to know if the results are due to chance, to the treatment given, or to some unknown factor. Because everyone likes a happy ending, examples of patients who seemed to respond to a treatment are much more likely to be published than examples of patients who did not respond to a treatment.

Retrospective studies are also not true clinical trials, but generally provide more data and reliability than case reports. Retrospective studies look backward in time to study a group of patients with the same disease. Retrospective studies are not clinical trials because the group of people and the treatment were not defined before the treatment was given. Therefore, the results may be biased by the choices both doctors and patients make. For example, healthy people tend to be treated aggressively, and healthy people tend to live longer; but that does not mean that more aggressive treatments make people live longer.

# Qualities of a Good Clinical Trial

A well-designed clinical trial needs to include:

- A clear research question.
- A hypothesis.
- A specifically defined population.
- A description of the treatment so that everyone in the trial gets treated the same way.
- A follow-up plan that describes how often the effects of the treatment will be reassessed.
- A statistical plan that describes how to determine at the end of trial, the answer to the initial question.

A clear research question describes the purpose of the clinical trial. Examples of clear questions are:

- How often do people taking this drug experience severe side effects?
- How often do tumors shrink when people take this drug?
- Which drug makes people with this type of cancer live longer?

A clear question prevents misinterpreting unexpected results that could be due to chance.

The hypothesis is the researcher's educated guess at the answer to the question. The hypothesis spells out how safe or effective a treatment should be for the trial to be considered a success. The hypothesis also makes it clear how to know if the trial does not succeed, so that unsafe or ineffective treatments are not studied again.

Clinical trials are conducted in specific, well-defined populations. The population may be limited by specific diagnoses (cancers), ages, symptom levels, overall health, or other factors. These limitations are called the inclusion and exclusion criteria. For example, a clinical trial of brainstem gliomas may allow adults and children, just children under 18, or just children under 12, etc. Most, but not all, clinical trials require participants to have normal liver and kidney function and will exclude patients with other major medical problems or multiple cancer types. Limiting the population for clinical trials helps to ensure the scientific validity of the trial. However, clinical trial results may not apply to people outside of these limits. For instance, results from a clinical trial allowing adults with brainstem glioma may not apply to children with brainstem glioma if they were excluded from that trial.

A clinical trial must have a treatment plan, follow-up plan, and statistical plan set out before starting the trial. This ensures that everyone in the trial is treated the same way and that the doctors running the trial cannot change things to make the trial results appear better than they actually are. It also may potentially limit the treating doctor because tests or treatments may need to be done at specific times that are less flexible than they would be with treatments outside of a clinical trial.

# Clinical Trial Phases

Clinical trial phases correspond to the different stages of testing that a drug goes through before approval. For patients with cancer, the clinical trial phases are phase 0, phase 1, phase 2, or phase 3. The phases are sometimes referred to using the Roman numerals 0, I, II, III.

| |
|---|
| **PHASE 0**<br>*Tests whether a drug gets into the cancer cell and "hits" the expected target.* |
| **PHASE 1**<br>*Tests what dose of a drug is safe to give.* |
| **PHASE 2**<br>*Tests to see whether a drug is effective against a certain type of cancer.* |
| **PHASE 3**<br>*Tests to definitely prove whether or not the treatment really works.* |

*"Our doctors at the Children's Hospital provided us with an option: a Phase II clinical drug study at NIH which was testing the effectiveness of a proposed treatment. Side effects were minimal if any. We opted to participate in this study for two reasons: first, it would provide information to researchers; and second, we did feel like we were doing something to help our son."*

*"We wanted opinions of studies and clinical trials that might have benefited our son. We were told very forthrightly that generally children live six months following the progression of my child's type of cancer and that oftentimes had little to do with what new treatments were tried. We made the very personal decision not to pursue a clinical trial at that time. We decided to do a combination of two standard chemo drugs in the hopes that they would keep things relatively 'quiet' for as long as possible."*

# PHASE 0
*studies*

Phase 0 clinical trials are usually done very early in the testing of a new drug. Phase 0 clinical trials test whether a drug gets into the tumor cells and whether it "hits" the expected target. For example, if a new drug is developed to inhibit the growth protein EGFR, a phase 0 study can look at the activity of the EGFR protein in the tumor before and after treatment with the new drug. Phase 0 studies usually require surgery to obtain a sample of the tumor after treatment with the drug; however, depending on the specific drug and the expected target, testing of drug effects can sometimes be done on blood samples or other tissues.

A common way of doing phase 0 studies is to have someone take a drug for a week before a planned surgery and then use some of the tumor removed during surgery to determine the effects of the drug on the tissue. One important aspect for parents to understand about phase 0 studies is that they generally are not expected to benefit the individual entering the study. These studies are often done very early in the development of a drug before the optimal dose is determined, with treatment often continued for a short period of time. These studies do, however, potentially allow for a better understanding of how a drug works; this, in turn, aids in the planning of further trials in an effort to speed up the drug discovery process. Phase 0 studies are not widely used, are generally not applicable for patients with inoperable tumors, and are seldom done in children.

# PHASE 1
*studies*

Phase 1 clinical trials are done early in the testing of a new drug or new treatment combination to find what doses of a drug are safe to give. Phase 1 clinical trials often also test how long the drug stays in the body and how the body processes and gets rid of the drug. There are sometimes a number of extra clinical tests required in phase 1 studies, such as blood tests, urine tests, EKGs of the heart, etc., that test for toxicity to different organs and to see how long the drug is staying in the body and how it is getting out of the body.

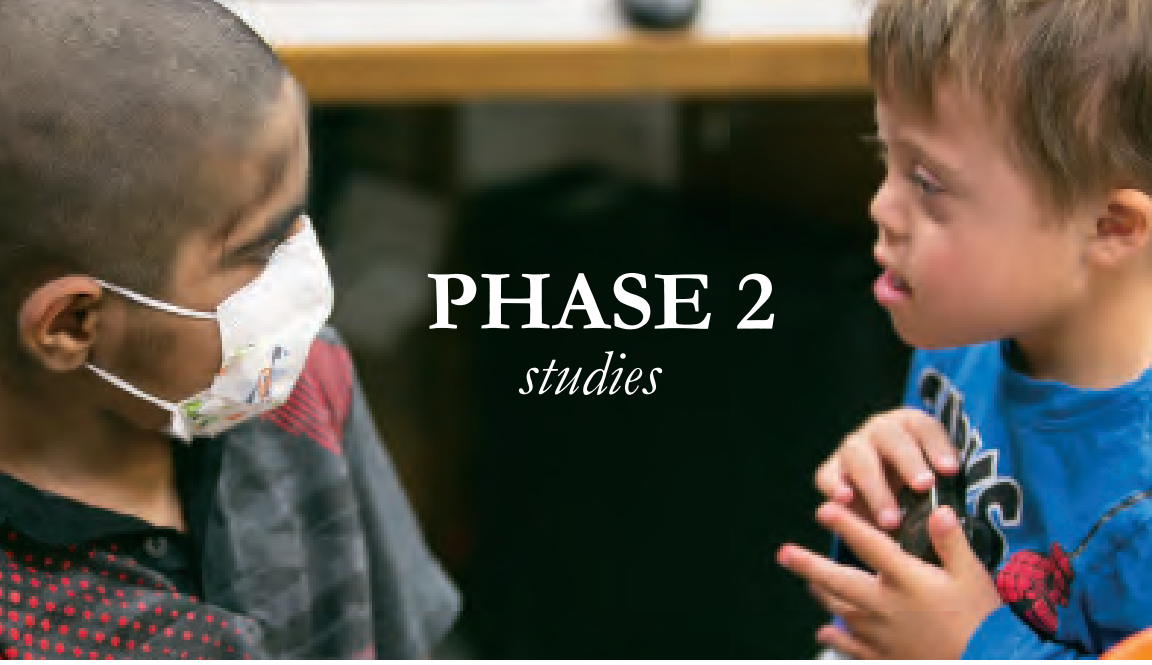
For traditional chemotherapy drugs, phase 1 studies often have the goal of defining what is called the Maximum Tolerated Dose, or MTD. The maximum tolerated dose is the dose just below where a high proportion of people have unacceptable side effects from a drug. The maximum tolerated dose is the highest dose that should be used for that drug because higher doses are generally too toxic. Sometimes, particularly for modern drugs that target specific molecules in cancer cells, phase 1 studies do not go all the way to the maximum tolerated dose, but stop at a dose where the drug is expected to completely inhibit the molecule it is targeting. This is called the Biologically Effective Dose.

People are enrolled in phase 1 studies as part of a small group, which typically is called a cohort. Cohorts usually consist of three to six people but can vary in size from one person to many people. Each cohort is given a different dose of the drug being tested.

If the side effects of the first cohort are tolerable, the next cohort gets a higher dose. This continues until too many people in a cohort get intolerable side effects. These intolerable side effects are called Dose Limiting Toxicities (DLT).In pediatric cancer studies the first cohort receives a dose that usually begins at 70% to 80% of a previous adult cohort's Maximum Tolerated Dose (MTD). Unlike adult studies, all doses in pediatric cancer studies are in the biologically relevant range.

Phase 1 trials are a very important step in developing new cancer drugs. Pediatric phase 1 studies always include an aim to determine the preliminary efficacy or anti-tumor activity of the drug. In most phase 1 studies, once the patient is in a cohort, the dose of the drug will stay the same. Other patients who are in other cohorts may get a higher dose of the drug. Therefore, patients in the earlier cohorts of a phase 1 study may not receive the dose of the drug that is ultimately recommended for treatment. For this reason, as well as the fact that most drugs tested in phase 1 will not go on to demonstrate significant efficacy in future studies, the expectation is that most patients in a phase 1 trial are not likely to personally benefit from the treatment being tested. Therefore, phase 1 trials are often most appropriate after patients have failed standard treatments with proven benefit or when there are no proven treatment options available.

As drug companies have become more focused on drugs targeting specific molecular pathways in cancer cells, the role of phase 1 testing has started to change. If the specific targets are known before the study, it is possible that patients whose cancer cells have that specific molecular target may be more likely to respond to that specific drug. So, in addition to defining the MTD, some more recent phase 1 studies also include initial measurements of tumor response or drug effects on cancer cells. This approach has been used to demonstrate potential efficacy of promising drugs early in their development, which has accelerated the subsequent phase 2 and 3 studies and FDA approval. It is possible that in the future, patients participating in phase I trials of targeted drugs may have a higher chance of benefiting from the treatment in the situation in which the patient's cancer cell has that molecular target.



# PHASE 2
*studies*

Once the safe dose of a drug is known, phase 2 clinical trials are used to see if the drug is effective against a certain type of cancer. Phase 2 trials may have many different designs. In some phase 2 studies, called single arm studies, everyone gets the same drug and dose. In multi-arm or randomized studies, there are several different treatments being tested or compared. Patients may get a specific treatment based on particular criteria of the study, or patients may be randomly assigned to treatment arms. Randomly assigned, also called randomization, means that neither you nor your doctor can choose what treatment your child receives. Such randomization is necessary because otherwise conscious or subconscious biases can influence the results of the trial. For example, if doctors gave everyone with small tumors the new drug and everyone with big tumors the old drug, then the new drug might look better even though it might not be better than the old drug.

The goal of a phase 2 study is to see if a new drug or combination of drugs has some beneficial effect on the tumor or other preferred patient outcomes. However, even though some phase 2 trials include more than 100 patients, they are generally not large enough to conclusively prove whether people live longer when they take the new drug or to prove absolutely that a new drug helps. Instead, phase 2 trials often look at alternate endpoints - metrics other than how long people live - that can indicate whether a drug is helpful.

## Alternate Endpoints can include:

Response rate: the percent of tumors/cancer cells that shrink a certain amount (usually 25%) with a treatment.

Disease control rate: the percent of tumors/cancer cells that shrink or stay the same size with a treatment. Note that because of random variation between scans, solid tumors must grow by at least 20% to 25% to not be considered the same size. Thus, if a solid tumor grows 10% or shrinks 10% it is generally considered stable, i.e., the same size.

Progression Free Survival (PFS): the amount of time from the start of treatment until someone either dies or the tumor progresses, which means it grows more than a set amount. PFS is often described as a median, the amount of time until half of people die or have tumor progression. For example, if the median PFS is 6 months, then by 6 months after the start of treatment, half of the patients have either died or had their tumor grow and half of the patients are alive with tumors that are either the same size or smaller.

PFS3 or PFS6: the progression-free survival at 3 months or 6 months respectively, after the start of treatment. This is the percent of people who are alive with tumors that are the same size or smaller at the specified time point.

*While it seems intuitive that treatments that shrink tumors or that delay cancer progression will make people live longer, there are occasional cases where this has turned out not to be true. For example, sometimes tumors can grow back faster after a drug stops working or a tumor may appear to shrink on an MRI but the cells are continuing to grow and invade new parts of the body. Because the study is testing how effective a drug is, patients participating in a phase 2 trial have a higher chance of personally benefiting from taking the drug than in earlier phase studies. However, trial participants may not benefit if the treatment turns out to be ineffective or if the treatment only works at certain doses or in certain people. Often as part of a phase 2 trial, tests are done on tumor specimens or on blood samples to try to identify which people are more likely to benefit from the drug. A test that can distinguish people who might benefit from a drug and those who will not benefit from a drug is called a biomarker.*

# PHASE 3
## *studies*

Phase 3 clinical trials are large trials designed to definitively prove whether or not the new treatment is better than the prior treatment. Phase 3 clinical trials are done to compare a new treatment to something else— often the treatment that is considered "standard of care" for that disease and situation. Phase 3 trials must be randomized; meaning the treatment the patient receives is decided randomly by a method determined by the study designers, not by the patient or the doctors. Random means no one can control what treatment the patient gets, as if it is determined by a system that is similar to the flip of a coin or the roll of a die. The group the patient is randomized into is called an arm of the trial. Randomized phase 3 trials are needed because the results of non-randomized trials, such as many phase 2 studies, can be misleading. Non-randomized trials compare their results to what one would expect to happen to the usual patient in that situation.

However, non-randomized studies can give a falsely optimistic view of a new drug because:

- People who volunteer for clinical trials are usually healthier and physically stronger than those who do not volunteer. The inclusion criteria for clinical trials, as discussed above, weed out people who have other health problems or are expected to be very sick soon.
- People who can travel to big hospitals for clinical trials tend to have slower growing cancers than people who cannot travel.
- Over time doctors have gotten better at preventing and managing symptoms and side effects, so people may live longer.
- People in clinical trials may see their doctor or be contacted by nurses more often than people not in clinical trials. Therefore, problems can be dealt with early before they become untreatable.
- When doctors and patients think a treatment is working, they are more likely not to see evidence that it is not working.

*"The Children's Oncology Group (COG) is the world's largest organization devoted exclusively to child and adolescent cancer research. COG (www.childrensoncologygroup.org) unites more than 8,000 experts in childhood cancer at more than 200 children's hospitals, universities, and cancer centers in the fight against childhood cancer. Research performed by the COG over the past fifty years has helped transform childhood cancer from a virtually incurable disease to one with a combined 5-year survival rate of 80%.*

*This remarkable progress has come through a partnership with families whose children with cancer participate in clinical research. An important first step for any family considering entering into this partnership is an understanding of clinical trials. The language of clinical trials—phase 1, 2, or 3, randomization etc. can often appear as an alphabet soup. To help sort through this, the "Parent's Guide to Clinical Trials" will be a most welcome source of information.*

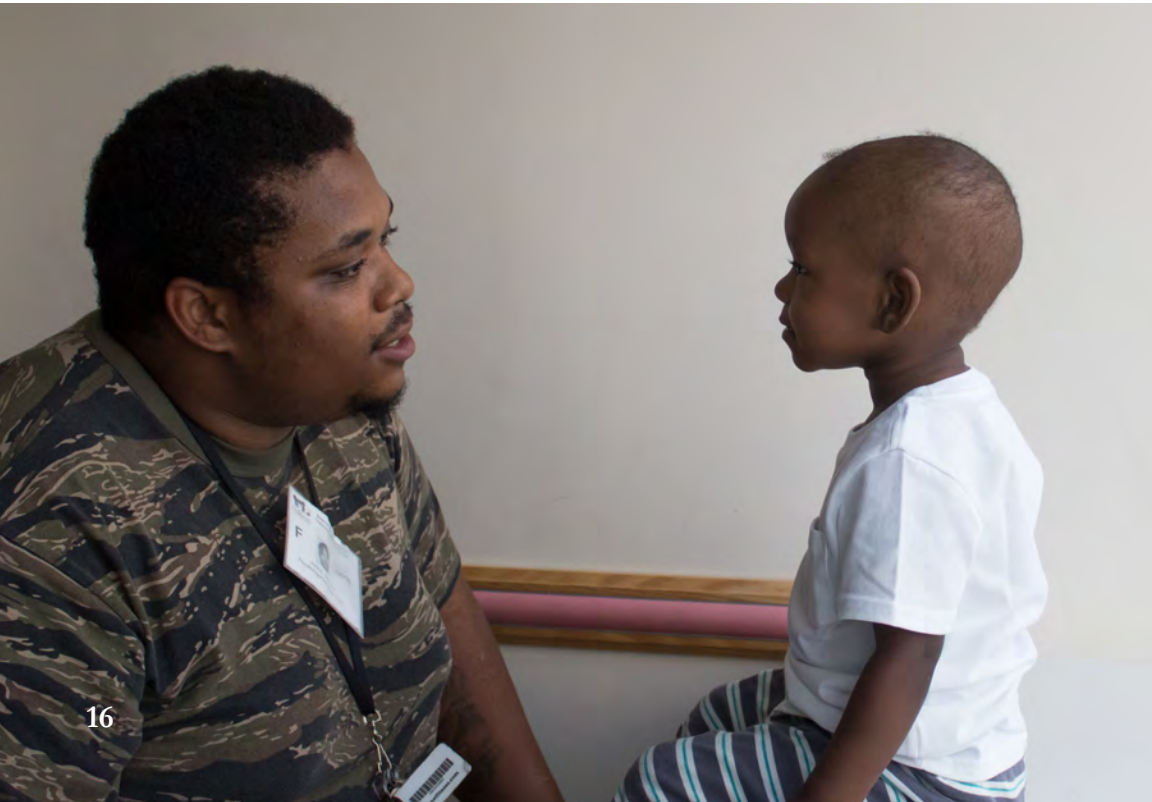
*Clinical research for childhood cancer is still very much needed to improve cure rates and decrease the side effects children experience both during and after treatment. This booklet will help families understand clinical research, and move us closer to achieving the shared vision of finding better cures."*

Peter C. Adamson, MD, Former Chair, Children's Oncology Group

# Consent and Assent

One basic principal of medical ethics is that no person should be included in any sort of experiment without his or her agreement. This agreement is called consent. In the past, heinous examples of medical experiments occurred where people were given injections of experimental drugs or even diseases without knowing it. However, since the Nuremburg trials in the 1940s and particularly since the 1970s, conducting research on people without their agreement and consent has been considered unacceptable in the U.S. and the rest of the civilized world.

Informed consent refers to the idea that not only should people know they are in a clinical trial, but that they also must understand what will happen to them during the trial. Informed consent is a process that involves both talking to someone involved in running the trial to learn about the trial and signing a paper, called the consent form, that explains the trial.



## Informed consent should include the following information:

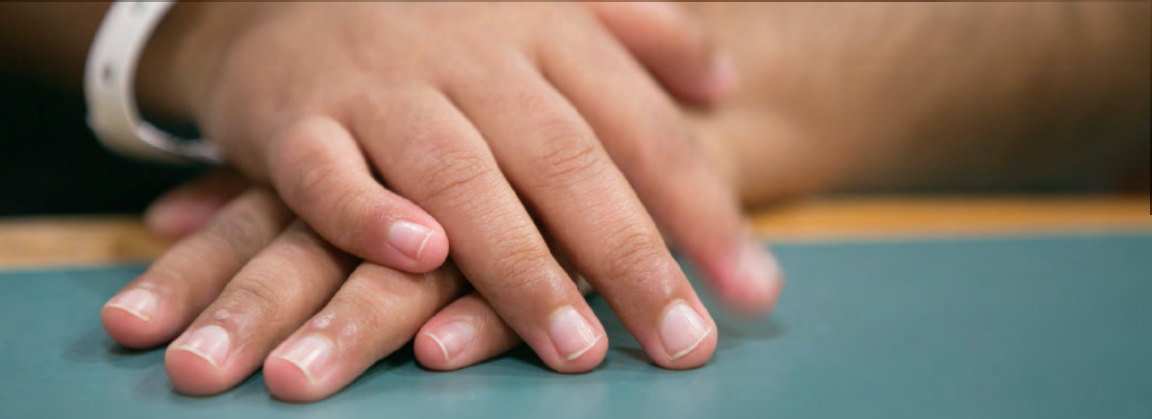
- What is known about the experimental treatment.
- What will happen during the clinical trial, including the duration of the study, what drugs will be taken, when and how they will be taken, nad what and when tests or procedures will be done.
- What parts of the trial are considered standard, meaning they would happen even if the patient is not involved in the trial, and what parts of the trial are considered research. Research parts of the trial can include treatments, additional office visits, tests, etc.
- What the alternative is to being in the trial and what the treatment and testing would be like if the patient does not participate in the study.
- Whether there will be any financial costs, whether personal or through health insurance coverage.
- Whether the trial is expected to benefit the participants personally or whether it is to benefit patients in the future.
- Whether there are any known or possible risks of participation.
- Whom to contact with questions complaints about the trial.
- What the procedure is to stop participating in the trial.

All clinical trials are overseen by an Institutional Review Board (IRB), which is a group of scientists and lay people from the community that ensure that clinical trials are done in an ethical manner. Each university or cancer center has its own institutional review board. Additionally, clinical trials conducted in the United States by the Children's Oncology Group (COG) utilize the National Cancer Institute's Central IRB (CIRB). The CIRB was created to ensure a high level of protection for study participants while reducing the administrative burden on local IRBs. The CIRB approves all aspects of clinical trials, including what is included in a consent form. The consent form should have contact information for the local institutional review board in case you as a parent ever feel uncomfortable with what is happening in your child's clinical trial.

Giving informed consent requires that someone has the mental capacity to understand his or her options and to make a rational and consistent choice. Some patients, such as children or people with mental impairments, are thought to need special protection because they may not understand enough to give informed consent. In that case, two things are needed. First, the person's guardian, such as the parent of a child, must give informed consent. Second, if possible, the child or impaired person needs to agree to the trial, which is called giving assent. Sometimes this is impossible, for example for young infants or people who cannot communicate. The age at which assent is required will vary from trial to trial. National groups such as the American Academy of Pediatrics, and the Children's Oncology Group recommend that assent is not required of younger children (e.g., under the age of 7 years); is required for older children (e.g., 14 years and older); and is variably required for children between the ages of 7 and 14 depending upon the type of clinical trial.

Regardless of whether assent is required, children should be provided with developmentally appropriate information about their diagnosis, treatment, and proposed research participation. Requiring assent allows a child to say no and to have some control over what happens to his or her body. Not only are uncooperative children difficult to get useful scientific results from, but some children may tire of participating in medical research before parents, who naturally hope for a miracle.

*"Our son was always doing some sort of treatment or clinical trial. His quality of life was very good aside from the expected side effects of the treatment he endured. He wanted to fight, so he participated in two clinical trials. We took our cues from him. As long as he wanted to fight and live, we found treatment options for him."*



# Side Effects in Clinical Trials

There is a special vocabulary for talking about side effects in clinical trials. The side effect of a treatment during clinical trials is called an Adverse Event (AE). The National Cancer Institute (NCI) has established a standardized way to measure the seriousness of an adverse event. This is called the Common Toxicity Criteria for Adverse Events (CTCAE). Over the years these criteria have changed, and in 2013 the most current version is version 4. The complete CTCAE can be found at the NCI website:

*http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm.*

Adverse events are graded on a scale from 0 to 5. (Grade 0 refers to not having a symptom or problem, so someone with grade 0 pain has no pain at all.) Grade 1 adverse events are mild and generally not bothersome. Grade 2 events are bothersome and may interfere with doing some activities but are not dangerous. Grade 3 events are serious and interfere with a person's ability to do basic things like eat or get dressed. Grade 3 events may also require medical intervention. Grade 4 events are usually severe enough to require hospitalization. Grade 5 events are fatal.

Most clinical trials and doctors focus on grade 3 or higher events, because those are the most dangerous. Grade 2 events however, can significantly impact the patient's quality of life, even if they are not medically dangerous. For example, a grade 1 headache is mild. A grade 2 headache keeps the patient from doing things like shopping or cooking. A grade 3 headache keeps the patient from getting out of bed even to go to the bathroom.

## Rights of Trial Participants

- Joining a research study is voluntary. The patient or his/her parent(s) should never feel pressured or forced to participate in a trial.
- Patients and their parent(s) have the right to ask questions about the study before, during, and after it takes place.
- Study participants have the right to privacy and to know how personal information will be shared and protected. The majority of participant records are identified by a unqiue number rather than the patient's name.
- Study participants have the right to know about any new findings or information discovered as a result of participating in the trial.
- Study participants have the right to leave a research study at any time. The patient or his/her parent(s) should never feel pressured to stay in a clinical trial. Patients cannot lose access to standard treatment if they leave a research study.

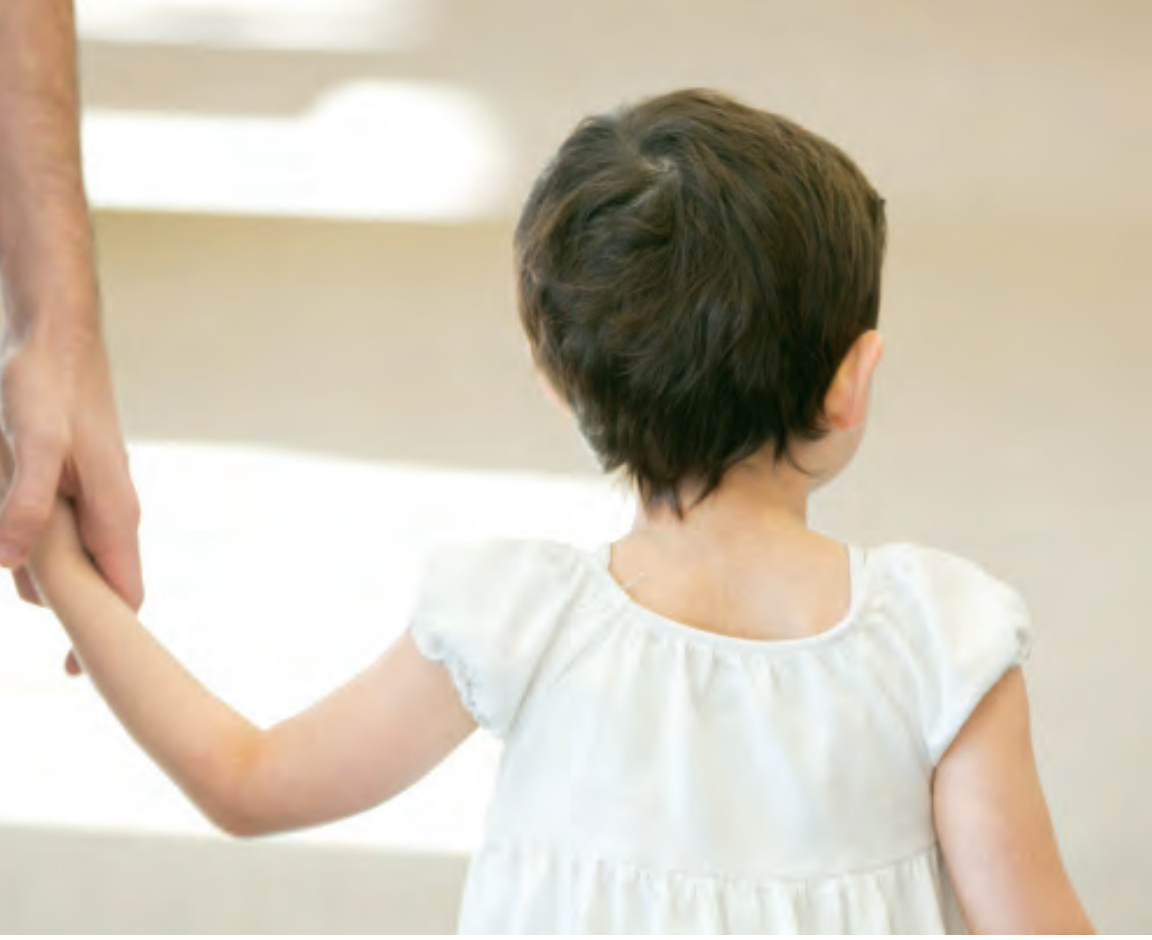
## Who is Part of the Clinical Trial Team

- Principal Investigator (PI)- The person responsible for overseeing the trial at a participating hospital. This will often be a medical doctor, and it may even be your child's pediatric oncologist.
- Research Nurse(s)- This is often a Nurse Practitioner, and he/she is responsible for communicating with participants as well as collecting data.
- Study Coordinator- The person responsible for ensuring that the staff has everything they need to conduct the study.
- Data Safety Monitoring Board (DSMB)- Trials sponsored by the National Cancer Institute or by certain drug companies may have a DSMB in place. This is a group of people, in addition to the Institutional Review Board (IRB), that reviews potential risks of the trial.

# Questions to Ask Your Child's Doctor

If you are considering having your child participate in a clinical trial, here are some questions you may want to ask:

- What phase is this trial?
- What do we know right now about the treatment being tested and what is unknown?
- What is the purpose of the trial?
- What is the chance that this trial will benefit my child?
- What would my child's treatment be if he/she does not participate in the trial?
- Are there extra tests my child would have to undergo if he/she participates in the trial?
- What will I or my insurance be charged for and what will the trial pay for during the trial?
- If my child gets sick or is hospitalized during the trial, who will pay for that?
- Who do I contact if we have medical questions or concerns?
- Who is our contact for emergencies?
- Is the trial randomized? Will I know what drug my child is taking?
- Who is paying for the clinical trial research? Is it the company producing the drug?
- Does my child receive any type of financial reimbursement for participating in this trial?
- Will we be able to find out the results of the trial? How long will it take for the results to be published?
- _____
- _____
- _____



## Conclusion

All of the advances that have developed to successfully treat many types of cancers have come from clinical trials. Millions of people are alive today because of people who participated in clinical trials. However, while clinical trials have the potential to benefit the individual patient and future cancer patients, clinical trials are scientific studies and there are important considerations that need to be understood before patients agree to participate. There are pros and cons to participating in clinical trials. A clinical trial may or may not benefit the patients in the trial. Clinical trials limit the flexibility of doctors and patients because it is necessary to get scientifically valid results. Asking questions of your doctor is the best way to get information about any clinical trial you are considering for your child.

# Helpful Clinical Trial Resources

## National Cancer Institute: Cancer Trials Search

***www.cancer.gov/about-cancer/treatment/clinical-trials/search***

The National Cancer Institute's website provides a search function for NIC-supported cancer clinical trials which are sponsored or financially supported by the National Cancer Institute. Clinical trial searches can be narrowed by age, cancer type as well as zip code.

## National Institutes of Health: Clinical Trial Search

***www.clinicaltrials.gov***

The U.S. National Institutes of Health, through its National Library of Medicine, developed ClinicalTrials.gov to provide patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The database contains 4000 studies at 47,000 sites, mostly government and university sponsored studies. The web site has links to resource information, such as Understanding Clinical Trials, Glossary, Genetics Home Reference, and NIH Health information.

## Ped-Onc Resource Center

***www.ped-onc.org/treatment/clintrial.html#find***

This page lists web addresses for online databases as well as clinical trials at major cancer centers, including Memorial Sloan Kettering, St. Jude, and MD Anderson.

# Notes

# A PARENT'S GUIDE TO
# CLINICAL TRIALS

Childhood cancer patients enter clinical trials more often than do adult cancer patients. A child diagnosed with cancer is usually referred to a major treatment facility, such as a children's hospital, because childhood cancer is rare and is best treated by the specialists at these facilities. Clinical trials in childhood cancer are among the most organized and extensive in the world. There is no question that this has led to a tremendous increase in the survival of some types of childhood cancers. This collaboration between the child, their family, physicians, and scientists has served as an example for other childhood and adult diseases. This said, the collaboration must continue if the overall survival of all children with cancer is to improve.

It is important to understand the clinical trial process, as well as available optional treatments for your child before entering into a study. In order to assist families with this, the American Childhood Cancer Organization has prepared this booklet to explain the process and structure of clinical trials. Helpful links for more information can also be found at the end of the booklet.

## About the American Childhood Cancer Organization

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AMERICAN childhood CANCER ORGANIZATION

American Childhood Cancer Organization
6868 Distribution Drive
Beltsville, MD 20705
855-858-ACCO (2226)
www.acco.org