Ohio Pediatric Research Association
Presents

A Guide For Parents Of Pediatric Research Patients

7200 Poe Ave. Suite 200
Vandalia Ohio 45414
(937) 424-9294

www.ohiopediatricresearch.com

Addresses

Vandalia Location	***Kettering Location***
7200 Poe Ave. Suite 200 *Vandalia OH 45414*	*1775 Delco Park Dr.* *Kettering OH 45420*

Hours of Operation

Monday thru Friday
8:30am-5:00pm

Phone Numbers

Vandalia *(937) 424-9294*
Kettering *(937) 299-2339*
Fax *(937) 236-2431*
Emergencies after hours:
(937) 424-9294

Ohio Pediatric Research Association Mission Statement

The mission of Ohio Pediatric Research Association is to conduct clinical trials involving infants, children, adolescents and the adults who care about them in order to provide patient access to emerging health care, promote provider expertise and competency in the pediatric and general health field and to improve global health care.

Why Do Research in Kids?

You may wonder why children are included in research since it involves uncertainty and may have risks. Why not just ask adults, who can decide for themselves if they want to join a study?

The simple truth is...children are not little adults.

Clinical studies are important

Why? Because they can help us:

- Understand the differences in children as they grow and develop.
- Identify the best dose of medicines to prevent harmful effects or under-treatment.
- Produce chewables, liquids or tablets that are easier for children to take.
- Find treatments for problems that occur only in children, like prematurity.
- Find treatments for certain diseases or conditions that occur in both children and adults but which act differently in children and adults, like arthritis or heart disease.
- Understand how medicines are used in and filtered out of the body in children of all ages.

- Find treatments for new or existing diseases to improve the health of children in the future.

For example, vaccine studies help children stay healthier. Vaccines help protect the children who receive them and protect those people around them who are not vaccinated. Vaccines are responsible for controlling what were once common childhood diseases that killed and injured many children. Vaccines have virtually wiped out included polio, measles, mumps, ruebella (German Measles), chicken pox, pertusis (Whooping Cough), diphtheria, tetanus, rotovirus and haemophilus influenza in the United States.

Ohio Pediatric Research Association has a long standing relationship with vaccine research. Since 2001 we have participated in numerous vaccine studies that have been approved by the FDA and made available to children to improve their health. For more information you can visit www.cdc.gov/vaccines to help answer any questions.

Research Versus Care

Clinical research can look a lot like regular, or standard, medical care. Sometimes it is hard to tell the difference.

Here are some of the ways they may be similar:

- The researcher and your healthcare provider can be the same person.
- The setting may be your regular clinic.
- The treatments may seem the same.

Research is done to help find out if a treatment or procedure is good for a large group of people with a certain disease or condition. Research helps to answer questions for the *future* health of those populations. Standard medical care; however, focuses on *individual* needs.

When considering enrolling your child in a study, make sure you understand the difference between the regular care your child gets at the doctor and what's involved in research. Even when the office and healthcare providers are the same as your regular healthcare team, find out what makes it a research study.

Make sure you ask:

- How is this different from standard care?
- Will I see different doctors and nurses for the study?
- Will I go to a different hospital or clinic for the study?
- Will the doctors and nurses ask me a lot more questions about my child's condition?
- Will there be more paperwork or additional tests when we are in the study?
- Will there be more rules and deadlines in the study?

Here is an example of how some things in a clinical study are the same as in regular care, while some are different.

	Standard Care	Research
Visit with physician or nurse	✓	✓
Paperwork to enroll (consent)		✓
Eligibility screening		✓
Baseline testing	✓	✓
Medication or procedure	✓	✓
Interim questionnaires or forms		✓
Follow up testing	✓	✓

Safety and Protection

While research can have risks, there is a lot that goes on "behind the scenes" to ensure safety before families are invited to be in a study.

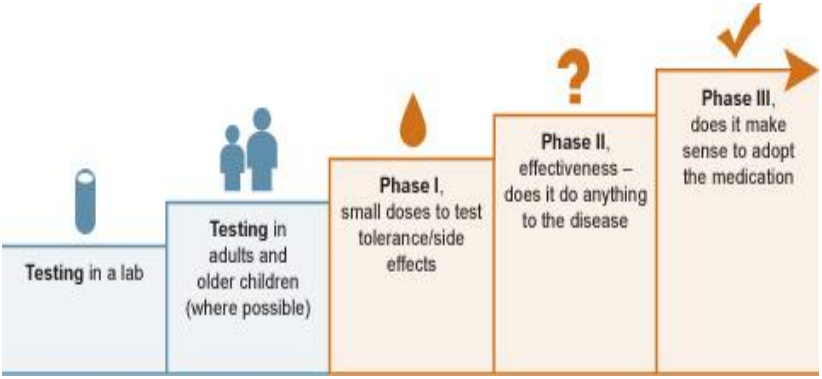
- Many people review a study in detail before a single person is enrolled. These people include:
    - the scientists who focus on identifying the **right treatment**,
    - the statisticians who help to design the **right study** with the **right number of participants** to get good results, and
    - the medical investigators (nurses, doctors, pharmacists, psychologists, and technicians) who will make sure that the study is done in the **right way** with the **right participants**.
- **Informed consent documents** are developed to describe why a study is being done, what will happen and risks and benefits.
- **Institutional Review Boards** (IRB) are *independent* committees that review research plans and consent forms to make sure that people in a study are informed and protected when in studies.

Be comfortable

As a parent, you must be comfortable with what your child will be doing in a study.

- Even with efforts to make your child safe, remember there may still be risks. Make sure you understand the possible risks and benefits and understand how they apply to your child.
- Get familiar with the study team, whose job it is to protect your child.
- Find out what resources are available to help you understand your rights.
- **Ask questions**.

Clinical Studies don't just "happen". Before your child is even asked to participate, the procedure or medication being researched has likely been through a series of steps:



Will My Child Benefit from the Study

Parents who are asked to enter their child into a study will want to know, "Will being in this study help **MY** child?" It is very important to understand that research is done to gain information about a disease, condition, drug or treatment that will benefit children in the future. It is different from regular medical treatment that is given to help a specific child.

A clinical study may offer closer monitoring or additional testing for your child, which may not be part of regular care. Sometimes a study asks parents to keep a diary or to bring a child in to be seen more often, such as weekly visits. Children in a clinical study will be watched closely for side effects and to understand how the treatment is working.

Whatever the reason, remember that clinical studies are designed to test if a drug or procedure works and is safe. There may be benefits for your child, but there may not be.

What If I Want To Say No?

No one has to be part of a clinical study. And no one should be made to feel that way. It's about making an informed decision, your own decision - *yes or no*. Each decision is individual and no decision is wrong.

Parents and children say "no" for different reasons. It may be that a child will miss too many activities or school. Or that the risks seem too high, or the benefits too low. Perhaps there is too much travel or a parent can't take time off from work. Whatever the reason, it is your decision. And your child will not be treated any differently if you say "no".

Sometimes parents say "no" because they are unsure what happens in clinical studies. Be careful that your decision to say no is not based in the fear that comes from not knowing. If there is something you don't know, ask about it. If there is something you don't trust, talk with the research team about it. They may be able to ease your fears or explain something in a better way. This will help you feel comfortable that nothing will change in the care that your child gets, **no matter what the decision**.

Feeling Connected

The most important thing is that you feel connected and part of the team, and that you feel you are doing what is best for your child. You need to know your child is safe and will receive the best care.

- Feel comfortable asking questions.
- Get to know your study team. They should earn your trust, be respectful, fair and supportive of you and your child.
- Learn what happens if you withdraw from the study or when the study ends. Will you still get the medicine or medical care?
- Ask how the study team can help you if you need childcare, an interpreter, transportation or need to take time off work.

- And always remember: **it is okay to ask**.

Questions You Should Consider Asking

It is difficult enough to decide to enroll in a study as an adult, but it is even harder to make that decision for a child, especially if the child is sick. Clinical study documents have a lot of information, but there are questions that you may still have. And you need to ask them...**and ask them again** if the answers aren't clear to you.

Here are some more questions:

- What will happen and how much time will it take?
- How will it affect other family members?
- Are there costs?
- How do I know what questions to ask?
- What if I have questions during the process?
- Will I get reimbursed for my time and travel?

Before you make your decision, ask questions. Ask them again. Get the answers you need to feel that the decision you make is the right one for you...and your child.

Do Kids Have a Say?

Parents have to give legal consent for their child to join a research study, in almost all cases. So you've read the information and asked the questions of the study team. You think you might want to enroll your child. Now it's time to think about how your child feels about being in a study.

- At what age should you ask a child if they want to enroll?
- What if your child feels differently than you about enrolling?
- How do you reach an agreement about what is best?

There is a process called "**assent**." In most cases, this means that children are given basic facts about a research study and are asked to be part of the decision. Children can be asked to give assent from as young as six or seven. Sometimes they can be older or, depending on the study, assent may not be required.

All kids are different.

Some kids may want to be part of the process, others may not. Some may be uncertain or fearful. Others may wonder about pain...or how it will affect school and friends. Some children may be too young to be involved while others can understand as an adult would.

Kids as young as 2 or 3 won't be involved in the decision process, but when children get to 14 or 15, data suggest they understand a lot about the process. That leaves a group of children in between that understand at different levels...some may understand very little, while others focus on what is going to happen to them. At any age, the important thing is that they are comfortable and their questions are answered.

What seems to be true for all kids, though, is that their input should be valued.

Sometimes a parent and child can't agree. But often disagreements can be worked out with the help of the study team. In fact, there are advocates and ethics experts involved in most studies who can help with just these situations. It's about talking...you and your child. And remember that the study team is there to help.

Your Principal Investigator
Julie S. Shepard, MD, MPH

Dr. Julie Shepard has conducted clinical research since 2001 and has been the principal investigator for more than 70 studies. Dr. Shepard graduated from Yale University and Columbia University Medical School. She is board certified in Pediatrics and has practiced medicine for over 20 years.

Research terms you need to know:

Assent*-the term used when a child agrees to be in a study.*

Blinding/Masking*-when patients and doctors don't know which study treatment the child is getting.*

Informed Consent*-a parent's guide to learn key facts about a research study.*

Investigational Review Board (IRB)-*a group of experts who monitor clinical studies to make sure people are safe.*

Placebo*-a pill, liquid or powder that has no active medicine in it.*

Protocol*-the document that describes a study while it is being done, how it will be conducted and how results will be analyzed.*

Randomization*-Since researchers don't know what treatment is better this is a way to determine who gets what… like flipping a coin.*