

Participant Considerations

Safety and Protections



Video Transcript –

Tasmeen Singh, MPH, NREMT-P: The government makes sure that there is a lot of protection for children. So there's no study being done out there in kids that isn't being well watched. Any hospital that's doing research has an institutional review board or an ethics board that reviews the research in detail to make sure that there's nothing going on that would harm the children. So research these days in kids is really pretty safe.

Every parent wants to know: **Who is watching out for my child in a study?**

The answer is...lots of people.

"...there are individuals whose only concern is making sure that the safety of the child is protected..."

Dr. William Rodriguez, Pediatrician

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. They review studies both before they start and throughout the study. They are also known as Research Ethics Boards (REB) or Ethics Committees (EC).

Safety Measures

There are safety measures in place to protect children while they are in a study.

- There are many, clearly defined government rules for protecting human subjects in clinical research with special protections for children (<http://www.dhhs.gov/ohrp/policy/populations/children.html> will take you to the Office for Human Research Protections for more information about Special Protections for Children as Research Subjects).
- Each study has a research team responsible for running the study and making sure people are safe.
- Some studies have a Data and Safety Monitoring Board that regularly monitors safety. This impartial Board oversees studies and says if a study should be changed or closed at any time for safety issues.
- Some studies have a Medical Monitor, usually a doctor or nurse not associated with the study, who reviews side effects that occur in a study.

Be comfortable

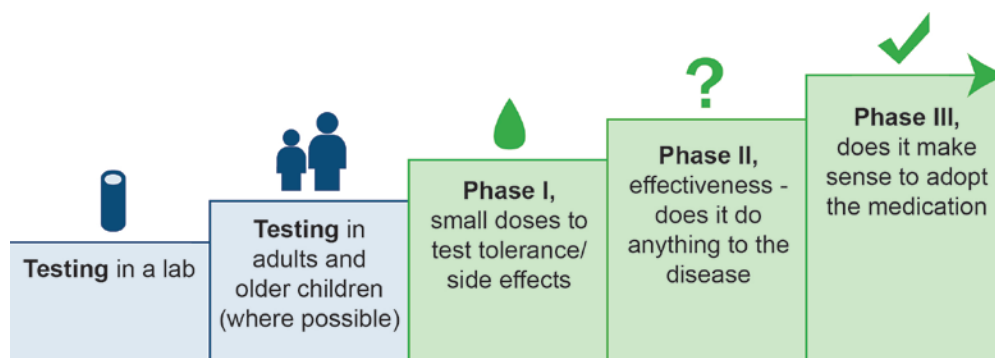
As a parent, you must be comfortable with what your child will be doing in a study.

- 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.**

"The only way to really find out if whether or not a proposed new medication is safe and whether or not it is effective is to test it."

Dr. David Wendler, Bioethicist

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:



"It is critically important that practice is predicated on scientific evidence."

Dr. Joe Wright, Pediatrician

"The whole point of the study was not to know whether your child was receiving the drug or not...you might hesitate to give it to them [if you knew what they were on]."

Jose, father of child in heart defect study

Rights of Families in Studies

You're being asked to enroll your child in a study.

You've seen a lot of information; you've talked to the research team. You know you have rights but would like to know a little more about them.

When you are thinking about joining a study, remember that you have the right to:

- Join a research study only if you want to. You should never feel pressured or forced to join.
- Be told about all the known or possible risks and benefits of the treatments in the study.
- Full and complete information about what the study means for your child, what is expected of you and how the study will be done.
- Ask questions about the study before you start and as the study goes on.
- Know about any costs to you or your insurance company.
- Know about other treatment options, if any exist, and their risks and benefits.
- Privacy and to know about how your personal information will be shared and protected.
- Be given a copy of the signed and dated written **informed consent** form when one is required.
- Know about any new information that the researchers may learn about the treatments while the study is going on.
- Leave a research study whenever you want. You should never be pressured to stay in a study. You cannot lose access to your regular medical care if you leave a study.

These rights are in place to make sure that you feel that your child is protected and that you have control over the decisions made about medical care and being in a study.

"...just [make] sure that at least you as a parent are comfortable, that you understand to the extent that you want to understand, that you're able to make the decision that you think is right for you and for your child."

Dr. David Wendler, Clinical Bioethicist

You Can Say No at Any Time



Video transcript –

David Wendler, MD: As a parent, you're the only one who can determine whether or not a particular study is appropriate for your child.

Erica: They wanted him to be a part of the study before he's two, because the goal of the project was to work on them before two or at two years old.

David Wendler, MD: So you have to decide, maybe this is a study that's okay for most kids, but because of fears your child has, your kid's sports schedule, you live too far away from the center-there could be all sorts of different reasons why it might not be appropriate for you or your child. And I think for the most part what we know is, we know that researchers understand those differences.

Erica: I discussed it with my husband. From the minute I told him the tests they would have to do-they'd have to do kidney function, liver function, all these tests, to make sure all the organs are intact; and if I had decided to put him on the trial, then they would do the blood work to find out if anything was different, anything was happening with the normal function of these vital organs-he just said no.

David Wendler, MD: You can say no, and that's not going to influence the care your child is going to get, or anything that your child would have received otherwise.

Erica: My care didn't change. No way. Didn't. They greeted me the same. Like I said, any new information that would come up, they would tell me about it. The greeting, the warmth, everything remained the same. It's not like because you said no, they're going to turn their back on you and say, "Okay, she didn't come and be a part of this study, so let her stay with her child." No. It was the same.

You get to say no. And you can say "no" at any time. It is your right.

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.

Clinical studies come in many different forms.

- Some are brief...some take a lot of time.
- Some are for children who are sick...others are for perfectly healthy children.

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".

"If you're not comfortable with your child being maybe seen a couple of extra times at the doctor's office - maybe they'll have to give blood, which is an uncomfortable thing for a child - then it's not for you."

Jose, father of child in heart defect study

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.

"Being afraid is like when you do not ask the question and something happens to your child. Then you should be afraid."

Sharda, mother of child in kidney disease study



You have taken an important first step by seeking more information here. Make sure you have ALL the information you need to make the best choice for you...and your child. This will help you feel comfortable that nothing will change in the care that your child gets, **no matter what the decision.**

Minority Interests and Questions



Video transcript –

Renee Jenkins, MD: People perceive health entities for the most part as being discriminatory. And if I am poor or an ethnic minority, then people don't really care about me and what they want is their ends met and if I can help them accomplish that, then so be it. But does that provide me any safety? See, I don't think people always trust that. And they really have to trust that the research that they are going to participate in is safe, that they have been fully informed, and that their children will benefit in some way or if they are not going to benefit that that has been clearly explained to them. You basically have to tell them what the routine treatment is and that they are able to get that routine treatment even if they don't participate in your project, if at any time they want not to participate that they can bow out of it without any repercussion from their health provider.

Sharda: He didn't make us believe or make us feel like it was just a study. That she was going to go through the study and whatever happens happens. And then that is it after that.

Bianca: They cared. It's not like you just come in, they take your blood and that's it. They actually take the time to have a conversation with you and ask you what's going on in your life and they make sure that emotionally your feeling okay, not just physically.

Sherry: The doctor should also encourage you to speak with other parents, and that's what Dr. Trachtman did with us and he called me up with other parents that were in the study to talk to them also.

Sharda: As a parent don't be afraid to ask doctors what when why or how this is going to affect your child. Don't ever be afraid cause you have all rights and your not doing anything wrong, you're not being rude, you just want to know what's best for your child.

Sherry: You need to get everybody involved. And the more you get involved, the more you will feel comfortable that what you are doing is a good thing and the more involved you are the more people you could help and the more people could help you.

It is amazing that human beings are so much alike. Only one-tenth of one percent of our genes varies from one person to the next. But even with these tiny differences, there are still people with different appearances and different health conditions. Illnesses affect each of us differently - as individuals, as families, as racial and ethnic groups, and as communities.

That's why it is important to include all types of people in clinical studies.

"It's important to have a group that reflects what we look like in the United States. So that when they say this is what's going to happen, you can say safely that's what happens in all of the people that we study, and you have a real sense of the impact of differences for ethnic minorities."

Renee Jenkins, Pediatrician, American Academy of Pediatrics President, 2007-2008

Getting Information

All parents care about their children, no matter what their educational level, how much money they have, what language they speak, or where they live. However, if you are a member of a minority group, what's important to you - or what concerns you - may be different from what is important to another parent.

- Some parents find it hard to ask medical people questions.
- Some may be concerned that research means "experimenting" or that doctors and nurses doing research only care about using children to help themselves.
- Some parents have had a bad experience at the hospital or clinic and think something bad could happen to their child also.
- Most parents have problems understanding the words or ideas in the long consent forms given to them for the study.
- Others may be uncomfortable with a study team that is 'different' from them or doesn't speak their language.

- Many parents may not know what a clinical study is.

These are very real and important concerns. And no one should feel uneasy about being in or asking any questions about a clinical study.

The doctors and nurses know that you are worried about your child and may be unsure about joining a study. They are glad when you ask questions and take control of your child's healthcare. No one expects parents to understand the medical terms, or even understand at first what a study is about. **Just ask questions until you get the answers that you understand.**

"I think one of the crucial things is just to get to know those people [the research team], make sure that you're comfortable...making sure that they're willing to answer your questions."

Dr. David Wendler, Clinical Bioethicist

Remember that much work has been done to make sure people are protected in studies - especially children. But even with these safeguards, there still may be risks. **Be comfortable** with the study documents and ask if things are not clear.

"...we really trusted him [the study doctor] and I mean he always been doing the right thing for us. And as far as the paperwork was concerned he was there with us."

Sharda, mother of child in kidney study

Role of Community

Sometimes you may wish to talk with your family or friends about joining a study. They too may be unsure of what a study is or what happens. So while you talk to your family and friends, also do your homework and get informed. Remember that one day, another parent might ask you to help them with their decision and you will want to be as informed as you can to help them.

Reach out to others who may help you make decisions. Bring family members or church friends with you to talk about the study. There are parent advocates and community advocates who can help you understand the role of the research and what it means for you and your child.

"So you need to get everybody involved and the more, the more you get involved the more you will feel comfortable with what you're doing."

Sherry, mother of child in kidney study

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.**

"...sometimes it's not easy because maybe [parents] might feel like they're not gonna be treated the same way and they're fearful of saying no. But what my advice to you whenever you get information that you're not sure of to just go read...go back and ask the same doctor..."

Erica, mother of child who did not enroll in clinical study