Making Informed Decisions

As a patient or parent, at some point you will likely face the need to make important medical decisions, and it is absolutely essential that you have full understanding of the procedure or treatment (and the alternatives) before making your decision. Some examples of medical choices that you could encounter may include whether to undergo a surgical procedure, a new medical treatment or participate in a research trial. In all instances you need to give your ***informed consent*** before any new treatment, surgery or research begins.

What is informed consent?
Informed consent is a communication process between patients and physicians, such that fully informed patients can participate in choices regarding their health care.

When should informed consent be obtained?
The goal of informed consent is for patients to have an opportunity to be informed participants in their health care decisions. Informed consent should be obtained for participation in all research studies as well as for any experimental or major therapeutic or diagnostic procedure for which disclosure of major risks involved would assist a patient in making a decision whether or not to undergo the proposed procedure.

Written informed consents obtained for research studies are signed by the participant (or legal guardian), the investigator, and a witness. A copy of the signed consent form is given to the participant.

What are the components of informed consent?
Complete informed consent should include a discussion of the following:

- The nature and purpose of the proposed treatment or procedure
- Reasonable alternatives to the proposed treatment or procedure
- The relevant risks, benefits, and uncertainties related to the proposed treatment or procedure and for each alternative
- The risks and benefits of ***not*** receiving or undergoing the proposed treatment or procedure
- Assessment of patient understanding
- Acceptance by the patient

In order for the patient's consent to be valid, he/she must be considered competent to make the decision at hand and his/her consent must be voluntary. The patient should have an opportunity to ask questions to develop better understanding of the treatment or procedure, so that he/she can make an informed decision to proceed with or to refuse the proposed treatment or procedure.

Assent for older children and adolescents
Health care decisions regarding older children and adolescents should include, whenever feasible, the ***assent*** of the patient as well as the participation of the parents and the

physician. Though consent must still be obtained from their legal guardian, minors should be given serious consideration within their developmental capacities for participation in decision-making and for their assent.

Assent from a minor should include the following:

- Helping the patient achieve a developmentally appropriate awareness of the nature of his/her condition.
- Describing for the patient at his/her level what to expect with the proposed procedure
- Assessing the patient's understanding of the situation and the factors influencing his/her response
- Obtaining an expression of the patient's willingness to accept the proposed care.

The web pages listed below include issues to consider and practical questions to ask as you go through your decision-making process.

Clinical Research

Surgery Considerations for Girls with Classical CAH

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Clinical Research

Overview

Clinical research is crucial to the advancement of medicine, and if you are considering participating in a research trial, you are making a very important contribution to the medical field and to future patients. That being said, it is necessary for you to protect yourself and/or your child. Any treatment that is considered experimental should take place under the auspices of an **Institutional Review Board (IRB)**-approved protocol.

An **IRB** is an independent oversight committee within a medical institution, comprised of lay persons as well as health care professionals. Each IRB has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects. In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. An IRB performs critical scientific, ethical, and regulatory oversight functions for research conducted on human subjects.

Any IRB-approved research study must obtain ***written informed consent*** from all participants (or their legal guardian).

Participating in Clinical Trials

Questions to Ask the Research Team before you consent

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Making your Decision

(Adapted from the Children's Hospital Boston website)

It's important to gather information from people like the principal investigator and research coordinator, family members and friends, your child's regular doctor, and resources such as this presentation and website. If the research study involves your child, then depending on your child's age and ability, his or her opinions will also be important - and your child's assent may be necessary.

In the end, your decision about medical research is likely to be influenced not only by the information you gather, but also by the unique characteristics of you/your child and your own family values. There is no absolute "right" or "wrong" answer about participating in research, only the answer that seems right for your family situation.

Questions to Ask the Research Team before you Consent:

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The following questions come from materials developed by Children's Hospital Boston to help parents decide about their child's participation in research. Many of these questions and considerations are applicable to for adult participation as well.

Purpose and Nature of the Study

1. What is the purpose of this study?
2. What are you trying to learn?
3. Will I receive the results of the study? If so, when?
4. Is this study being done in one place, or in many places?
5. Is it a small research study or part of a large study?
6. Have there been similar studies that used the same drugs, devices, etc.? What happened in those studies?

Eligibility and Participation

1. Why is my child eligible to participate in this study?
2. How many children will be in the study?
3. If my child is not eligible for this study, is there another study you know of that he or she might participate in?

What Does the Study Involve?

1. How long will the study last?
2. What procedures, medicines, and tests will my child have as part of the study?
3. How will these procedures, medicines, and tests differ from those my child would receive if he or she were not part of the study?
4. If my child enrolls in this study, will he or she have to stop any of the drugs or other treatments he or she is currently receiving? Will being in the study mean that there are some drugs or other treatments that my child won't be able to have?

Control Groups and "Arms" of the Study

1. Will all children in the study receive the same drugs, devices, procedures, or will there be different groups ('arms') of the study that are treated differently?
2. Is it possible that my child will not receive the experimental treatment even if he or she is in the study?

3. How will you decide which children will receive the experimental treatment, and those who will not?

4. What is 'randomization?'

5. If my child is in the study, and does not receive the experimental treatment, what will happen to him or her?

6. During the study, will I, the research team, or other health care providers know what arm of the study my child is in? Will we find this out after the study is over?

7. Is it possible that my child will receive a placebo?

8. During the study, will I know if my child is receiving a placebo? After the study, will I find out if my child was receiving a placebo? Will the research team and other caregivers know?

9. In an emergency, can the research team or my child's caregivers find out which arm of the study my child is in?

Possible Risk of Harm

1. Does the study involve any risks of short-term or long-term harm?

2. What are these risks?

3. How likely is it that these risks or harms will happen to my child? What happens if they do occur?

4. Will any of the procedures or tests that are part of the study hurt, or cause my child discomfort? If so, how much, and for how long? How will pain be prevented or reduced?

5. How will being in the study affect my child's daily life?

6. Could my child's condition get worse during the study? What will happen if it does? Who will take care of my child? Who will pay for the treatment?

7. Is it possible that my child will be injured during the study? If my child is injured, what will happen? Who will treat my child? Who will pay for the treatment?

Possible Benefits

1. Do you know whether this study will help my child?

2. Do you know whether this study is better for my child than current standard treatment?

3. Is it possible that being in the study will improve my child's health?

4. Will this study help in learning about my child's condition?

5. What are the possible short- and long-term benefits, if any, of the study?

6. How likely is it that my child will experience these benefits?

Alternatives

1. What other options are available if my child doesn't participate in the study?

2. Are there other research studies for which my child might be eligible?

3. What are the risks and benefits (both short-term and long-term) of these alternatives?

4. How do the possible harms and benefits of the study compare with the possible harms and benefits of the other options available to my child?

If Your Child Participates

1. Who would I contact with questions if my child does participate in the study?

2. Who should I tell about any side effects my child has?

3. After the study has begun, who would I contact in an emergency?

4. If I wanted to take my child out of the study, who would I contact?

5. How would I remove my child from the study in a safe way?

6. What would happen to my child after he or she was taken out of the study?

7. Is it possible that the study might be stopped? If so, why?

Ongoing Medical Care

1. Who will be responsible for my child's medical care during the study?

2. Will my child still see his or her personal doctor during the study?

Ongoing Responsibilities

1. How many times will we have to visit the hospital or doctor's office during the study? How long would each visit be? Would we have to come during work and school hours?

2. Will I, or my child, have to fill out any paperwork during the study? How much? What else will I, as a parent, have to do?

Financial Issues

1. Will it cost me anything for my child to be in the study?

2. Will my costs - such as the cost of parking - be reimbursed?

3. Will I, or my child, receive any payment for being in the study?

4. Who is sponsoring or paying for the study?

5. Do any members of the research team have a financial interest in the outcome of the study? Do you, or any others on the research team, own stock in the company testing the drug or

medical device? Are you, or any of the others, paid any money by the company making the medicine or medical device?

6. What 'conflict of interest' policies are in place at this location?

Confidentiality

1. Who would know that my child was in a research study?

2. Who would be able to look at the record of my child's participation in the research?

3. What would happen to any specimens (such as blood or tissue) that were taken from my child during the study?

Protections for Those in the Study

1. What is an Institutional Review Board, or 'IRB'? What standards must be met before an IRB will approve research that involves children?

2. How will you monitor my child's safety during the study?

3. Are there other individuals who will also be monitoring the safety of the study?

4. What will happen if the risks of the study seem to be greater than expected?

Making the Decision

1. Who can I contact to ask questions before I decide?

2. Who can help me understand the 'informed permission' form?

3. How much time do I have to decide whether or not my child should participate?

4. What are some reasons why it might make sense for me to allow my child to be part of this study?

5. Why would I have my child participate in the study rather than choose one of the other options?

6. What are the most important things I should consider when deciding whether to allow my child to participate in this study?

7. How can I find out more about research - and about this study in particular?

Your Child's Role in the Decision

1. How old does my child have to be before he or she must also agree to be in the study?

2. How much should my child be told about the study?

3. What if my child says he or she does not want to participate? What if he or she changes his mind later, and doesn't want to be in the study any more?