

Questions to ask before making a decision for another person:

Understanding the research study:

- > Why is the research being done?
- > Why are the researchers asking this person to be in the study?
- > How is this research study different from regular medical care?
- > What other choices are available?
- > Where can I find help to make this decision?

Evaluating risks and possible benefits:

- > What will happen during the research study?
- > What are the risks of being in the study?
- > Will this person benefit from the research?
- > How long will the study last?
- > If this person recovers his/her ability to make a decision about being in the study, can he/she change the decision that I made?

Considering the possible costs of taking part in the study:

- > Will there be any cost to this person, or to me?
- > Will this person be paid for taking part in the study? Will I be paid?
- > Who pays if this person is unexpectedly injured in the study?
- > Will being in this study affect this person's health insurance now or in the future?

Leaving the study:

- > What happens if I want to take him/her out of the study early?
- > Can the researchers take him/her out of the study against my wishes?

After the study ends:

- > What will happen after the study ends?
- > Will the researchers share what they've learned from the study?
- > What will the researchers do with information learned about him or her in the study?

SURROGATE DECISION-MAKING



Participating in research is a choice.

Be informed. Ask questions. Get answers.

Health research makes new treatments possible. Researchers try to learn about human health and find ways to prevent and treat diseases and conditions. Researchers also look at how a disease or condition affects the well-being of a person, their family, or their caregivers. Research studies often include subjects who have the disease or condition being studied. Sometimes this means including persons who cannot make their own health decisions. In these cases, researchers will ask a “surrogate” or “proxy” decision-maker to decide if being in a study is the right choice for that person. A surrogate acts in the best interests of the person who cannot make the decision for him/herself. A surrogate makes decisions based on what the other person would want, even if that is not what the surrogate would choose for him/herself.

Participating in research is a choice

Protections are in place for the safety of all research subjects and to ensure all subjects are treated with respect. Institutional Review Boards (IRBs) oversee research studies. An IRB decides if it is necessary to include research subjects who cannot decide to take part for themselves and who must rely on a surrogate decision-maker.

Why am I being asked to make this decision?

You are being asked to make this decision as a “surrogate” for someone who cannot make a decision for him/herself. As a surrogate, you will think about what the person would want. Use that information to decide whether he/she should or should not take part in the research study.

You may have questions about what taking part means and what sorts of choices you will face. You might ask yourself,

- > Would this person want to participate in this research study?
- > Will taking part in this research help this person?
- > Or, is the research being done only to learn about his/her condition?

Use the information here to help you make decisions. Ask as many questions as you need. Make sure you feel comfortable with your decisions.

What are the risks and benefits of research participation?

Research is not the same as regular medical care. Instead, research tries to answer a question. Being in a study may involve some risk for research subjects. The research team will take steps to protect a subject’s safety, privacy, and personal information. A study might not benefit an individual subject, but taking part may help other people in the future. Researchers may publish the results of a study to share what they learn with others. However, personal information about research subjects will not be part of any publication.

The research team will go over an Informed Consent Form with you. They will explain the study goals, procedures, and possible risks and benefits. You will have time to read through the consent form before making your decision.



How do I make this decision for someone else?

Consider what that person would want, even if this is not what you would choose for yourself. Think about how he/she might feel about the research goals and procedures. Also, think about what will happen to the person during the course of the research, and how he/she will feel during the study.

In making this decision, you might consider his/her:

- > Personal values (beliefs about how best to live his/her life)
- > Religious or cultural beliefs
- > Past decisions or statements

If he/she can communicate with you, talk about the study together.

It’s normal to feel nervous or unsure when making these sorts of decisions. Talk about your concerns and choices with someone you trust, such as:

- > Another doctor, nurse, or therapist
- > A primary care provider
- > Family members or close friends
- > Spiritual advisers

Remember – you can change your mind at any time, even after someone begins to take part in a study. If you decide that taking part is not the right choice for this person, leaving the study will not change his/her regular medical care and services.