If you have questions about your rights as a legally authorized representative of a UK research study volunteer, you may call the University of Kentucky Office of Research Integrity at (859) 257-9428 or toll free at 1-866-400-9428.
You are what is called a "legally authorized representative" of a patient who is or might become a participant in a research study. Basically, you are being asked to weigh the risks and benefits of participating in clinical research. "Risk" means the chance of harm that might happen. There could be risks from medication side effects or risks from certain medical procedures. Sometimes doctors will tell you about these risks as "very rare" or "common" or sometimes they will give you information to help you understand the level of risk. For example, they might tell you that a side effect has happened to 10% of research subjects in the past.

This means that the participant whom you represent does not have the capacity to make an independent decision about treatment or about participating in research. Therefore, you have been asked to make decisions on behalf of the patient. Being a legally authorized representative is a serious role and the patient's research doctor takes it seriously as well. One other thing – sometimes choosing to participate can mean that you must spend considerable time bringing the participant to appointments and waiting for procedures to be done. Be sure to ask about how much time you or other family members will need to spend during these visits.

The substituted judgment approach means that you are being asked to make the decision based on how you think the participant would do it. In other words, you express exactly what you think the patient would do if he or she could still make independent medical decisions. For example, a research treatment might hold out a promise of effectiveness, but the participant is so ill that even this improvement will make no difference in quality of life. In this case, you might decide to refuse treatment.

Risk and Benefit

You have to weigh the risks against the benefits. That is, "this much risk for that much benefit." The benefits should outweigh or offset the risks. From this study, patients might benefit from the knowledge gained from the study. Therefore, you have to weigh the risks against the benefits.

Two Approaches

When you are asked to make a decision, there are two ways to go about it: (1) the "substituted judgment" approach and (2) the "individual's best interest" approach.

For example, a research treatment might have a small likelihood of benefit or might have serious side effects. If the participant would want to advance science and be of possible benefit to others, you might decide to agree to the patient's participation. In this case, you use the substituted judgment approach.

The individual's best interest approach takes a different turn. In this situation you make the decision using the substituted judgment approach. If the patient's participation might make no difference in quality of life, you might decide to refuse treatment. In this case, you use the individual's best interest approach.

The individual's best interest approach takes a very different turn. In this situation you make the decision using the substituted judgment approach. If the patient's participation might make no difference in quality of life, you might decide to refuse treatment.

The individual's best interest approach takes a very different turn. In this situation you make the decision using the substituted judgment approach. If the patient's participation might make no difference in quality of life, you might decide to refuse treatment.