



Advice to Legally Authorized Representatives of Adult Participants

*University of Kentucky
Institutional Review Board*



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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.

see blue.
in everything we do.

You are what is called a "legally authorized representative" of a patient who is or might become a participant in a research study.

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.

Research Risk

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.

Research Benefit

Likewise, you are asked to evaluate the benefits to the patient for participating. A benefit might be that the new experimental drug would actually help treat the patient's medical problem. Doctors call this kind of benefit a "direct" benefit to the individual. There is



another kind of benefit that is indirect. In this case, the benefit might be that a lot can be learned about promising medications or procedures. Also, other patients might benefit from the knowledge gained from this study.

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.

Two Approaches

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

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 have a small likelihood of benefit for the patient and may have serious side effects, but you know that the patient would want to advance science and be of possible benefit to others. In this case, you might decide to agree to the patient's participation using the substituted judgment approach.



The individual's best interest approach takes a very different turn. In this situation you make the decision

about a treatment or about participating in research based on what you think is best for the patient, independent of what he or she might have decided if there was no impairment in decision-making. In other words, you act almost as parent for a child where you look out for the safety and overall well-being of the patient. In using this approach, you can consider all aspects of well-being.

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 not agree to the research treatment if you follow the best interests of the individual approach.

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 waiting during these visits.

If you are having difficulty in making this decision, ask the participant's doctor or the research doctor for more information until you feel confident that you are making the best decision you can under the circumstances.

