



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 an individual 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 participating in research. Therefore, you have been asked to make decisions on behalf of this person.

Research Risk

Basically, you are being asked to weigh the risks and benefits of participating in a research study. “Risk” means the chance of harm that might happen. For example, there could be the risk of being upset about sensitive personal issues being discussed in the study. The



risk for participating in surveys and interviews are usually small, but they can be important. Sometimes a study also has behavioral interventions. They usually pose little risk but you need to understand those risks.

Research Benefit

Likewise, you are asked to evaluate the benefits to the patient for participating. A benefit might be that the new intervention would actually help treat a social or behavioral problem. Researchers 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 problems or interventions and other people 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 individual would do if he or she could still make independent decisions.

For example, a research intervention might hold out a likelihood of benefit for a certain behavioral health problem but might take a very large amount of time. However, you know that the individual



would want to advance science and be of possible benefit to others. In this case, you might decide to agree to the individual’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 participating in research based on what you

think is best for the individual, 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 intervention might hold out a promise of effectiveness, but the participant is so indifferent to the problem that even this improvement will make no difference in quality of life. In this case, you might decide to not agree to the research if you follow the best interests of the individual approach.



Being a legally authorized representative is a serious role and the individual’s research investigator 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 research investigator for more information until you feel confident that you are making the best decision you can under the circumstances.