Deborah G. Johnson's Commentary on "Complex Concerns"

Commentary On
Complex Concerns

This case raises several of the toughest issues in research ethics. Part 1 focuses on issues that arise in the design of the research project, and Part 2 focuses on issues that arise in the implementation of the study. The questions at the end of Part 1 point to the general ethical dilemma posed by all research using placebos: the role of compensation in research (What is an appropriate amount of compensation?) and the question whether children or their parent/guardian should receive compensation for the child's participation. The first question raised at the end of Part 2 has to do with the appropriate response of the individual who is serving both as a researcher and a clinical doctor to a child who is a potential subject for the study. The last questions point to difficulties in determining the age at which a children can consent for themselves and the subtleties of representative consent, in this case consent for the child by someone other than a biological parent. I don't think I can "answer" these questions; I hope only to articulate what is at issue and why the issues are morally problematic.

Several of the ethical dilemmas posed in this case are not specific to research on children; they arise, as well, in research involving fully competent adults. In this case, the ethical issues are made even more complex and difficult because of the involvement of a child. Moreover, in most research involving children, the child is represented by a parent, but in this case there is further complexity because the child is represented by a guardian, a foster parent.

Let me first consider the issues that would be raised even if no children or representatives were involved. When, if ever, placebo studies are justified is one such issue. Drug tests are morally problematic because they put participants at risk. Since the effects of the drug are not known, there is risk of adverse effects. Indeed, independent of the use of placebos, all researchers have to ask whether the knowledge they will gain is worth the risk to which they expose their research

subjects. It is for this reason that poorly designed research is unethical; it puts individuals at risk with little likelihood that good will come from it.

In this context, research involving placebos might be seen as morally preferable to other research because half the subjects will not, in fact, be put at risk. The problem is that in most placebo studies, the drug or therapy being tested is thought to have a positive effect, and yet those receiving the placebo have no chance of receiving this benefit. They are, in effect, being used to prove a point. Of course, it might be argued that this practice is morally neutral since those who receive the placebo are neither being benefited nor put at risk. But this argument is problematic too. The participant's life expectancy might be increased by receiving the experimental drug, or, worse, the subject may be denied a known but moderately effective drug in order to prove the greater effectiveness of the new drug. In cases where a known or moderately effective drug is going to be denied to a participant, or where there is some evidence of a positive effect from the drug to be tested, it would seem that placebo studies have a heavier burden of justification. The value of the knowledge to be obtained must be great enough to overcome the potential harm to the subjects who will not receive positive treatment.

Another issue that arises independent of the involvement of children surrounds the doctor's quick dismissal of Mary's concerns about the risks of participation in the study. That is, even if Mary weren't representing Liz but were herself considering participation in research, the doctor's response to her concerns about the risks would be disturbing. Generally it is recognized that consent to participate in an experiment is valid only when the person is informed and not coerced. To be informed means, among other things, to understand the risks involved; not to be coerced means to freely choose to participate. The latter entails at a minimum that the person has not been threatened with negative consequences for refusal to participate. In this case, the doctor did not threaten Mary, nor did he misinform her. Rather, there is a subtle problem here because Dr. Kid is both the doctor and part of the research team. In relation to Mary, Dr. Kid is an expert, and Mary has put Liz in his hands. In order to ensure that Liz will get good treatment, Mary will want to maintain a good relationship with Dr. Kid. One can't help but wonder if this situation doesn't pressure Mary to agree to Liz's participation in the study. And, while there is no doubt that Dr. Kid is more knowledgeable than Mary, it is not clear that he has the expertise to determine whether participation is a reasonable risk for Liz. Indeed, the fact that he is committed to finding subjects for the study seems to disqualify

him from deciding whether Liz should participate. He has a bias in favor of participation. So, while the doctor should discuss the consent form with Mary, he should take care not to let his interest in the study sway her.

Also related to the matter of a valid consent is the question of the appropriate level, if any, of compensation for participation in the study. As already mentioned, one of the criteria for valid consent is that the consent not be coerced. There should be no threat of negative consequences for refusal to participate. This case raises the more subtle issue of whether the promise of compensation might also undermine a valid consent. In other words, the ideal is that individuals freely consent. We can imagine types of compensation that exploit the vulnerabilities of individuals or groups of individuals. If we allow researchers to pay subjects large amounts of money for participation, we are likely to find that poor people will readily participate. But the larger the compensation, the more it will seem that poor people are being exploited. High levels of compensation for participation take advantage of the subjects' circumstances and entice them into doing something they would prefer not to do if their circumstances were better.

So much for the issues that are independent of the involvement of a child. As noted earlier, the issues in this case are compounded by the fact that the potential subject of the research is a child - a child represented by a foster mother, not a biological mother. Children are considered a special class of research subjects because they are thought to be incapable, themselves, of giving a valid consent. They do not have the capacities and experience essential for giving a valid consent. On the other hand, children's bodies differ significantly from adult bodies. So, if research is not done on children, knowledge of how to treat or prevent their illnesses may never be acquired. The point is nicely illustrated in this case insofar as it focuses on study of a drug, Eradovir, which is known to be effective in adults, but has not been tested for treatment of pediatric AIDS. The only way to find out how Eradovir affects pediatric AIDS is to do a study.

If studies are to be done involving children and if children are not capable of giving a valid consent, then the next best thing would seem to be to have parents consent on behalf of their children. Parents, it appears, are more likely than anyone else to understand the best interests of their children. The questions at the end of Part 2 raise two issues about representative consent. The first has to do with whether a foster mother can adequately represent the interests of a child, and the second question has to do with whether the child can or should be involved in the decision

to participate.

Both issues are extremely important but both seem to be difficult to deal with in general terms. From a public policy point of view, it seems reasonable: 1) to allow some research on children to be done; 2) not to allow children to consent themselves, unless they have reached a certain age or demonstrated the ability to understand the risks involved; and 3) to assign a representative to represent the best interests of the child when parents cannot do so. I admit that the age at which a child has the ability to represent him- or herself varies from child to child. The law draws a somewhat arbitrary line about the age at which children are old enough to make decisions for themselves, but a line has to be drawn for the protection children. In any case, it is a good thing for the child to be involved in the decision making about participation both because it is likely to help with participation and because it will help the child develop into an adult.

The question whether the foster mother can adequately represent the best interests of the child can be answered in a similar way. It would be unrealistic to claim that foster parents will always act in the best interests of their children, but it is important to remember that it would also be unrealistic to claim that biological parents will always act in the best interests of their children. In reality, there is a good deal of variation among foster parents as well as biological parents. Indeed, it is difficult to say what a parent or a foster parent ought to do in this case.