

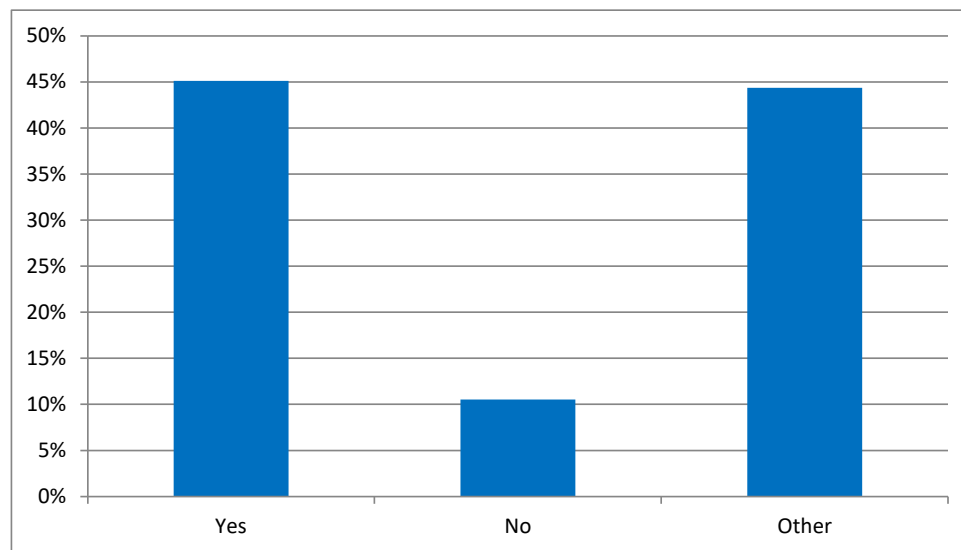
Clinical Research Ethics Question of the Month: Consent by a Conflicted Parent

By Norman M. Goldfarb

Researchers have identified a previously unknown but fairly common viral disease in certain developing countries: infant maternalitis, in which an infant is born with a serious allergy to the mere presence of his or her mother. For reasons that are not understood, even awareness of the mother's presence can provoke the condition. You are a member of an IRB reviewing a study protocol for a painless, inexpensive test that would, with 100% accuracy, identify infants with this disease so they can be separated from their mothers before the disease appears. After that, the condition becomes permanent and untreatable. The protocol requires consent by both parents. Will you vote to approve the study?

Results

When making your vote, will you consider only the welfare of the child or also the welfare of the mother?



Because this question was poorly phrased for the 133 respondents, it is restated clearly here:

When making your vote, will you consider only the welfare of the child and not also the welfare of the mother?

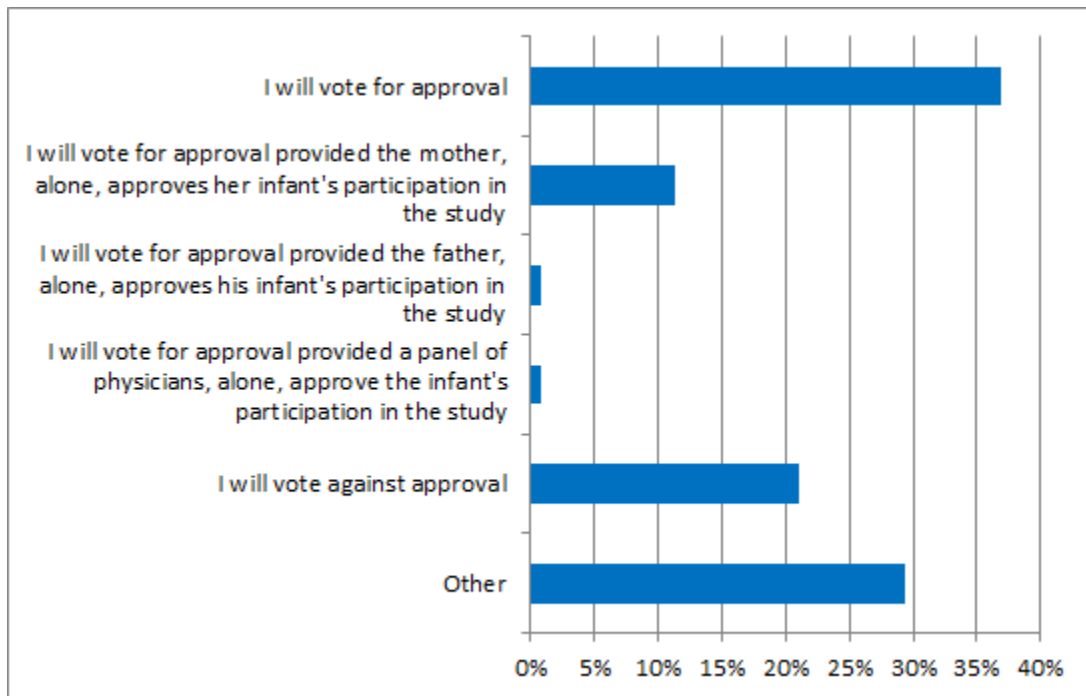
Most of the respondents in the "Other" category would consider the welfare of both child and mother. (Some would also consider the welfare of the father.) It is therefore fair to say that a lot of respondents would have answered "yes" to the restated question and a lot would have answered "no."

One respondent pointed out that, since the central question is about maternal bonding, both mother and child are, in essence, subjects in the study.

One respondent pointed out that the study is of a diagnostic test, not a treatment. The use of the test's results is a separate question.

One respondent pointed out that the test would be useful to the parents in case they want to have another child.

Leaving aside any regulatory requirements, how will you vote?



Thirty-seven percent of respondents would vote for approval, 21% would vote against approval, and 12% would vote for approval provided the *mother*, alone, approves her infant's participation in the study. Only 1% would vote for approval provided the *father*, alone, approves her infant's participation in the study.

Most of the respondents in the Other category who commented would vote for approval if both parents approve the infant's participation (which should have been one of the options).

Some respondents said that counseling or other social services should be provided for families whose child was found to have infant maternalitis.

One respondent stated that the mother should sign a consent form acknowledging that her child could be taken away from her.

Some respondents would want to know the risk of harm to the child, mother, father and/or family caused by separation.

One respondent raised the issue of the father's relationship to the child, which could vary by culture if, for example, the parents are unmarried.

One respondent pointed out that a cure or ameliorating treatment might be found, perhaps in the near future.

Seventy percent of respondents were parents. Of those, 90% were mothers and 10% were fathers. No correlation was found between their parental status and their responses.

Should an IRB ever consider the welfare of anyone but the patient and the general population?

Seventy-four percent of respondents said that IRBs should consider the welfare of people other than the patient and the general population.

Applicable Regulations

Since the subjects in the study will be infants, assent is not an option.

CFR 50 Subpart D presents four scenarios for pediatric studies:

50.51. Clinical investigations not involving greater than minimal risk.

50.52. Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

50.53. Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.

50.54. Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Because this study of a painless diagnostic test does not appear to involve greater than minimal risk, the requirement for parental permission is:

Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for clinical investigations to be conducted under 50.51 or 50.52. (21 Part 50.55€(1))

The regulations do not address the question of *which* parent can give permission. Nor do they address the question of *indirect* risk, e.g., how the results of a diagnostic test will be used.

Discussion

Many respondents stated that the mother alone should make the decision and many stated that both parents should make the decision, but only a few stated that the father alone should make the decision. No respondents voiced concern that the mother's decision might be biased because she is the one who would be separated from the child. On the contrary, a few respondents stated that the possible impact on the mother is a good reason why she should be the one to give permission for her child's participation in the study.

According to the regulations, only one parent would be required to give permission for their child to participate in this study. However, in this case, it would be reasonable for the IRB to require permission from both parents. With this study, the mother's role is complicated because participation in the study would also affect her personally. On one hand, a separate "consent" from the mother might be a good idea because of the study's potential impact on her. Few mothers would accept the idea that they would place their interests above those of their child. Nevertheless, the impact on the mother might make it more difficult for her to objectively assess the best course for the child.

The father's situation is not much better. Not only does he have to weigh the potential impact on the child and the mother, but also on himself. Among other things, his

relationship with the mother might not survive the decision.

A joint decision by the mother and father, well supported by a qualified counselor, might be the best approach. Given the potential damage to the parental relationship, the IRB might require both parents to firmly and independently support a decision to give permission for their child to participate in the study. This scenario thus provides a good example of how an IRB's ethical responsibilities extend beyond the regulatory requirements.

This scenario raises the question as to whether consent should be required from someone who is not, technically, the study subject. Many pediatric studies can affect the lives of the parents, as well as the child. While the regulations require that parents approve their child's participation in a study, should their consent also be required for their own indirect participation? If so, would this logic extend to the entire community in some cases?

Next Month's Question

The zombie apocalypse has arrived and is threatening the survival of the human race. Researchers have developed a treatment that might restore zombies to normal health and non-infectivity. There is a reasonable probability that the treatment will work as a cure but not as a protective measure. Failure of the treatment would be fatal for the subject. Potential study participants will not have the capacity to give consent. To the contrary, they will vigorously resist participation. No other possible treatments are known. There are no functioning governmental authorities, so the fate of humanity rests on your IRB. Time is of the essence. As a member of the IRB, will you vote to approve the study?

Read the full question and give us *your* answer at:
<https://www.surveymonkey.com/r/DRD6LTH>

Please send your ethical conundrums to ngoldfarb@firstclinical.com.

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