



# ETHICAL DIMENSIONS

Issue #28

## The Cancer Patient and IRB-Approved Research

Winter 1999

Mrs. Garcia, age 57, has been battling complications from metastatic liver cancer on the oncology unit for three weeks. Her husband and children know that she will die shortly. Mr. Garcia is not angry about his wife's current medical treatment or even the fact that she was struck by cancer. He is angry about the research protocol into which Mrs. Garcia was briefly admitted one month ago. The experimental therapy seemed to leave Mrs. Garcia in an even more weakened and compromised condition. Mr. Garcia has brought his wife's case to the ethics committee, through the offices of the medical center's chaplain. At a special committee meeting he admits that his wife signed a consent form for participating in the research protocol. He insists, however, that the physician who spoke with them about the "treatment" prior to the form being signed misled them. Mr. Garcia claims that the physician made the whole thing seem like just another step in the treatment plan to extend Mrs. Garcia's life as much as possible. Mr. Garcia tells the committee that his wife signed the form but never read it, assuming that the form was just a "formality." He wants the ethics committee to do something about the physician and his "research" so that other patients are not harmed like his wife. As Mr. Garcia leaves and the members begin their discussions, the ethics committee chair informs them that the protocol and consent form were approved by the medical center's IRB.

This case can be considered from the perspectives of individual ethics, institutional ethics, and societal ethics. Respond to the statements below using the following scale:

- 1 Strongly Agree     2 Agree     3 Not Sure     4 Disagree     5 Strongly Disagree

### Individual Issues

- The principles of autonomy and nonmaleficence (do no harm) were violated in this case.  
 1    2    3    4    5
- It is impossible for a physician to engage in medical research and remain a proper caregiver.  
 1    2    3    4    5
- Mr. Garcia would be praising the physician in this case if the therapy had improved his wife's condition.  
 1    2    3    4    5
- The physician in question may be (legally) liable for failure to get informed consent and for battery.  
 1    2    3    4    5
- Mr. Garcia should not complain about the therapy because his wife surely benefited from medical advances gained through the hardships of former patients.  
 1    2    3    4    5

### Institutional Issues

- The IRB, not the ethics committee, should handle this case.  
 1    2    3    4    5
- The ethics committee would overstep its proper role if it were to consider ethical issues or problem cases in medical research.  
 1    2    3    4    5
- IRBs are effective in reviewing and troubleshooting research protocols that are approved and underway.  
 1    2    3    4    5
- IRBs are only meant to ensure that the informed consent form satisfies federal and state requirements.  
 1    2    3    4    5
- In most institutions, the ethics committee and the IRB have a close, working relationship through which cases such as this one can be resolved.  
 1    2    3    4    5

### Societal Issues

- It is more important to advance medicine through research than to ensure the autonomy and safety of every patient who comes into contact with medical research.  
 1    2    3    4    5
- It is more important to ensure the autonomy and safety of every patient who comes into contact with medical research than to advance medicine through research.  
 1    2    3    4    5
- Patients must assume responsibility for their actions, including signing forms they do not read and failing to inquire adequately about the treatment they are receiving.  
 1    2    3    4    5
- Intentionally misleading a patient upon enrollment into a research protocol should be a felony, and unintentionally misleading a misdemeanor.  
 1    2    3    4    5
- Medical research in this country is well supervised and regulated through the IRB system.  
 1    2    3    4    5



OPINIONS AND FEELINGS ARE FREQUENTLY A PERSONAL TRIUMPH OVER GOOD THINKING  
YOU DEFINE REALITY BY WHAT YOU KNOW, WHAT YOU BELIEVE, AND WHAT YOU DO ABOUT IT.