

## Second Opinion: Breaking the Rules of Medical Research

Tuesday, August 28, 2001; Page HE07

"Heavy Drinking Found Among Medical Residents," proclaimed a headline in the Health section two years ago. Since the residents in question were pediatric residents, this was pretty scary stuff. How would you like to have your kid treated by a physician in training who is drinking too much?

The story was based on what seemed to be a blue-ribbon study of 115 pediatric residents in a large, unidentified urban hospital. The researchers were from Harvard Medical School and Boston's Children's Hospital. The findings were published in the Archives of Pediatric and Adolescent Medicine.

"Alcohol problems are present among pediatric trainees at disturbing rates," concluded the researchers. So alarming were the results that the journal's editor added a special note: "This article is a wake-up call for those who are unaware of (or close their eyes to) the serious problem of alcohol abuse in residents (even pediatricians!)."

Turns out the study was deeply flawed.

For starters, the study did not have approval from the hospital's institutional review board (IRB), the watchdog ethics group that oversees all human research studies in academic centers. None of the participants in the study had given their consent. They did not even know they were in a study. At the time, they were taking a mandatory course on substance abuse and were asked to fill out a survey on drinking behavior. The first thing the residents knew of the study was when the findings were published in late 1999.

To make matters worse, the conclusions of the study were also flawed. The survey asked such questions as, "Have you ever gotten into physical fights when drinking?" It did not primarily focus on current drinking patterns. Yet the published article made it sound as though these physicians were having major alcohol-abuse problems as they worked long hours in the hospital taking care of sick children.

"I felt betrayed," said one unwitting participant. "Here you're giving so much to the hospital and you get labeled at risk of falling down drunk on the job. It wound up unfairly maligning us."

The following year, the authors of the study apologized. In a letter to the journal, the researchers wrote: "We did not seek approval for publication from the residents themselves. We now recognize that this was an error."

They have also set up safeguards for future research. The alcohol-abuse prevention course now has a policy that residents be notified in advance that their responses on surveys may be used for research purposes.

"The most painful part," wrote the researchers, was that the residents "felt we had damaged the reputation of the residency program. Nothing could have been further from our intent, and we are most sorry."

Certainly, alcohol abuse is a serious issue for physicians and nurses and other health care workers. But the residents in the study were not the "heavy drinkers" depicted in The Post headline.

In the scheme of recent research disasters, this is a minor one. None of the study participants died. They suffered no bodily harm. They weren't given unproven and potentially dangerous agents. They weren't exposed to a toxic substance so that researchers could better understand the course of a disease.

The residents were not sick or underage, which would have made them more vulnerable to scientific exploitation. They were hardly naive about academic medicine or the value of research. After all, they were doctors!

But their experience illustrates some of the fundamental problems in the current state of research on "human subjects."

IRBs in many academic medical facilities are not equipped to protect volunteers in research studies. Procedures for evaluating and approving studies are often loose. There is confusion about what kinds of studies need approval. Do epidemiological studies -- like the residents survey -- require the same safeguards as a clinical trial of an experimental drug? The individual investigator has the primary responsibility for making sure volunteers understand the nature of the research and give their consent before the study begins. But IRBs don't always have the staff or institutional support to see that these ethical standards are met.

An article this month in the British Medical Journal found that only about 60 percent of studies on child health in 1999 had documented approval from IRBs or signed consent forms. These studies were published in five leading U.S. medical journals, including the Journal of the American Medical Association and the New England Journal of Medicine.

The public image of human research is tarnished. This month, the Maryland Court of Appeals condemned medical scientists at Baltimore's Kennedy Krieger Institute for exposing children to lead poisoning in a research project. Earlier, all federal research at Johns Hopkins was briefly halted by government regulators after a young, healthy volunteer died in an asthma study.

It's time for researchers to go back to the Hippocratic drawing board: First, do no harm to human subjects.

*Abigail Trafford can be reached by e-mail at [trafforda@washpost.com](mailto:trafforda@washpost.com). Join her on [washingtonpost.com](http://washingtonpost.com) for a Health Talk discussion of health topics in the news Tuesday at noon.*

© 2001 The Washington Post Company