The Ellen Roche Case—
Research with Healthy Volunteers

Ellen Roche was a 24-year-old healthy technician at a university asthma and allergy center. A researcher called her one day to ask her to participate in an asthma study because she had participated in studies before.

Asthma is a serious disease that is on the rise, especially in urban areas. The purpose of the study Roche volunteered for was to better understand how asthma affects the body. First, she took a drug designed to mimic the effects of asthma. Next, she inhaled a chemical (hexamethonium) that was supposed to block nerves the researchers believed were involved in asthma attacks.

The consent form called the hexamethonium a “medication” that had been “used during surgery, as a part of anesthesia”—giving the impression that it was approved by the Food and Drug Administration (FDA) as a medicine and was, therefore, safe. There was no mention that inhaling the chemical was experimental.

The day after receiving the experimental treatment, Roche developed a cough and started to feel ill. Four days later, she was hospitalized with a fever and abnormal chest symptoms, and the study was placed on hold. The air sacs in her lungs collapsed, then her lungs became stiff, and, finally, her other organs stopped working. Less than a month after the treatment, Roche died. If she had completed the study, she would have received up to $365.

Research involving humans must be reviewed by an institutional review board (IRB). The IRB determines whether studies are both scientifically sound and ethical. The university’s IRB had reviewed and approved the original research proposal.

One of the biggest criticisms of the IRB is that it did not request more careful review of the chemical. Many critics believed that researchers should have reevaluated the study when the first subject had troubling symptoms (before Roche’s treatment). That subject reported mild shortness of breath and coughing, but the symptoms got better on their own.

Before the experiment, the scientist who led the study looked at research going back 50 years and did not find any sign that hexamethonium would be harmful. However, after Roche’s death, investigators found earlier papers that warned about possible toxic effects. The chemical was also not approved by the FDA for the way it was used in this study. The role of the FDA in approving studies at research universities is not clear, but many people felt that the researchers should have sought the FDA’s opinion.

The U.S. Office for Human Research Protections stopped all research at the university for several days, until the university came up with a plan that included funding for more IRBs. Until then, the university had only two committees that were responsible for reviewing 2,400 proposals. The university accepted responsibility for the death and reached a financial settlement with Roche’s family four months later.

About 50,000 individuals participated as subjects in research at the university the year Roche died. The university was one of the most highly regarded medical centers in the nation. It had conducted trials for 100 years without any deaths of healthy volunteers. In an article about the case in the February 28, 2002, issue of the New England Journal of Medicine, the dean of the medical school expressed the difficulty of balancing the potential for learning new information that can help improve human health and the risks of harming people involved in experiments: “At a certain point some patient is going to die in clinical trials. There is no question about it.” But, he noted, the alternative is “not to do any clinical investigation...and still have children on ventilators after polio.”
Reflection Questions

1. Aside from its focus on asthma, how is this case similar to or different from the experiment conducted in class?

2. What is the role of an institutional review board (IRB)?

3. Some ethicists noted that because Roche was an employee at the university, she may have felt unduly induced* to volunteer. A doctor called to ask her if she wanted to take part because she had participated in other studies. Do you think this is a concern? Why or why not?

4. How does this case illustrate the challenge of balancing research that may have health benefits and the risks that research participants face?

*Undue inducement refers to a situation where people are pressured into doing something harmful by the use of incentives. When inducements distort a person’s judgment, leading them to agree to do what they would not otherwise do, the inducements are considered undue.