Study Case 3. Research with Healthy Volunteers—The Ellen Roche Case

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.

Questions

- What is the role of an institutional review board (IRB) in a research?
- Should informed consent for a healthy person participating as a volunteer in a research project be different than that for a patient consenting to receive an approved medical treatment?
- What kind of information should Miss Roche have received as part of the informed consent process? Does she have a right to ask questions of the investigators?
- Are there special issues to consider when a researcher asks his students or employees to volunteer as research subjects? Do you think students might feel coerced or induced to participate undertaken by employers or peers? How can such risks be minimized?