
Report on a Research Death Faults Review Board

A report on the death of a healthy volunteer in an asthma study at Johns Hopkins University found that the university's research review board was inadequate to handle its thousands of studies and that some researchers had adversarial relationships with federal regulators.

The report, by an external panel appointed by the university's president, also said researchers may have used "subtle coercion" to solicit participants in medical studies, which are overseen by the federal Office for Human Research Protections. "Our interviews suggest that many people at Hopkins believe that oversight and regulatory processes are a barrier to research and are to be reduced to the minimum rather than their serving as an important safeguard," said the report, which was issued on Wednesday. However, the authors praised corrective steps taken by the university after the volunteer, Ellen Roche, 24, died in June after inhaling a chemical to induce asthmatic symptoms. The government shut down most of Hopkins's 2,400 federally financed experiments for five days, an action the university called unwarranted. Regulators are allowing the studies to resume one at a time. The report, by a five-person committee led by Dr. Samuel Hellman, dean emeritus of the University of Chicago School of Medicine, in many ways echoed observations by an internal Hopkins study and the federal office for research protection. But the Hellman panel, appointed by the university's president, William R. Brody, in July, drew some significant distinctions. For example, the university's internal committee reported last month that there was no coercion in Ms. Roche's participation in an asthma study. But the external report found the possibility of subtle coercion, including signs around the asthma studies center recruiting volunteers and saying staff members could participate in work hours. Ms. Roche worked at the center. The external committee also echoed criticisms from the federal office that the university's review board was "grossly inadequate" to handle the thousands of studies at the university. But the committee commended the university's plans to expand the number of internal review boards to four from three. The committee's report faulted the asthma study's lead researcher, Dr. Alkis Togias, for not properly sterilizing the chemical Ms. Roche inhaled, hexamethonium, and for not seeking approval from Food and Drug Administration to use it. Dr. Togias also prepared a participant consent form that was misleading about risks and did not report adverse symptoms in another participant, the report said. Previous studies made similar observations. The university posted "selected comments" from Dr. Togias on its Web site, www.hopkinsmedicine.org. In his comments, Dr. Togias agreed with some of the criticisms, but disputed others as "unduly dismissive" of his research methods. The university has accepted responsibility for Ms. Roche's death and suspended projects led by Dr. Togias, who remains on the staff.