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e-Ethics

Ethical and Organizational Aspects of Human Subjects Research

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On 6 July 1885, a dog believed to be rabid attacked nine-year-old Joseph Meister. Joseph's mother asked Louis Pasteur to administer a series of inoculations that had been tested only on eleven dogs. Weighing the possibility that Joseph might contract rabies from the vaccine against the certainty of the boy's death if the dog were rabid, Pasteur gave twelve immunizations using a compound created by Dr. Emile Roux. Joseph did not develop rabies, and the experimental vaccine was refined and remains in use.

Whether or not we participate in medical research, we benefit from a long history of human experimentation to ensure the safety and efficacy of drugs, devices, and procedures. Ancient records describe testing poison on condemned prisoners. Before creation of a systematic method for conducting research, physicians often engaged in self-experimentation. World War II marked a watershed in the increase in U.S. government-sponsored studies and in development of research ethics. Scientists mobilized to find therapies for malaria, infections, and other military maladies. After the troops were home, this war against disease continued in medical laboratories.

Another wartime carryover was the notion that a few can be sacrificed for the good of many.

This mentality as applied to scientific research was denounced when Nazi doctors, who maimed and killed during medical experiments, were tried at Nuremberg. The Nuremberg Code (1946) specifically condemns performing research on the mentally disabled, and characterizes voluntary consent as "absolutely essential."

Tenets of the Nuremberg Code regarding human subjects research did not take hold in the U.S. until the 1960s, when *The New England Journal of Medicine* revealed abuses by respected scientists at prominent U.S. institutions. The National Institutes of Health (NIH) subsequently initiated a system of peer review known as Institutional Review Boards. Researchers must now obtain approval from an IRB before enrolling individuals in studies supported by the federal government or subject to federal law.

Many think of the IRB as a type of ethics committee. But unlike hospital ethics committees, IRBs interpret and apply specific

laws regulating human subject research. Moreover, IRB membership and activity are defined by law, and IRB records are monitored by the Federal Drug Administration (FDA) and the Office for Human Research Protections (OHRP).

Maintaining the safety of human research subjects is the primary task of IRBs. Federal law defines *research* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)). *Human subject* is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (45CFR 46.102(f)).

In applying these definitions, IRBs balance the legitimate but different ethical obligations and loyalties characterizing medical research and practice.

In pure research, researchers study human subjects with the goal of obtaining knowledge that is generally true, but not applied to any single research subject. In pure therapy, physicians treat individual patients with the goal of cure, or at least, alleviation of symptoms. When research involves experimental treatment,

these distinctions are less clear, and protecting human subjects is more complex.

For example, even though a researcher/physician carefully explains that an experimental drug may not benefit a human subject, and may even cause side effects, because of the relationship already established with the subject as patient, some participants report, "My doctor would not recommend me for this study if she did not think it would help." This impression, known as the "therapeutic misconception," demonstrates how allegiances and responsibilities may be unintentionally compromised or purposely manipulated. The fact that research may involve experimental therapies for incurable diseases introduces additional complexities, such as weighing the desperation of critically ill patients against the possibility of unknown and dangerous side effects.

Last year, the widely reported death of Jesse Gelsinger, an eighteen-year-old participant in gene therapy research, brought public pressure to bear on protecting human subjects in much the same way that publicized research abuses generated commitment to ethical codes and peer review a generation ago. The consent form Gelsinger signed omitted information about deaths of monkeys in previous experiments. Characterizing his son's death as "a preventable tragedy,"

Jesse's father testified in Senate hearings that disclosure would have made a difference in deciding to volunteer for the study. In the wake of a media blitz about Gelsinger's death, the NIH received hundreds of "adverse event" reports from gene therapy researchers that should have been filed much earlier, raising concern about federal oversight of IRBs.

The NIH has since created a special federal IRB for genetic research. In an effort to better inform and protect all clinical research subjects, the NIH and FDA created a web site for current information (www.clinicaltrials.gov). The Office of the Inspector General recommended improvements in research regulation, including mandatory education for researchers and IRB members, increased audits of IRB procedures and records, and imposition of individual and institutional fines for violations.

Mechanisms for monitoring human subjects research change over time, but the central ethical commitment remains: protecting individuals while promoting the social good of curing disease. The Advocate Health Care Institutional Review Board, chaired by Advocate's Chief Ethics Officer, can be reached at (847) 723-1469.



e-Ethics provides discussion of important ethical issues in clinical care and organizational life. In specific cases, fuller ethical analysis may be required. The discussions in E-ethics should not be construed as legal advice and do not necessarily represent official positions of Advocate Health Care.

To list an event in the E-ethics calendar, contact Mary Ann Clemens at (312) 266-2222 ext. 240 or mac@prchfe.org.



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