Country Report USA

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I. A brief History of the Development of American Law and Ethics With Respect to Protection of Human Research Subjects

For practical purposes, the history of protection of human research subjects in the United States begins with the Nuremberg Trial and Code. Though the trial, of course, addressed NAZI experiments during the Second World War, the prosecutors and the primary ethical witness at the trial (Dr. Andrew C. Ivy) were Americans, and the code they attempted to articulate drew heavily on American ideals. In the two decades following Nuremberg there was a growing awareness in the United States of the ethical challenges posed by human subjects research. Though the United States was largely spared the ravages of the Thalidomide Tragedy, publicity attending the disaster led to 1962 amendments to the Food, Drug and Cosmetic Act requiring informed consent from research subjects for testing of investigational drugs. Disclosure of several research scandals, including one in which indigent elderly patients had been injected with live cancer cells in the Brooklyn Jewish Chronic Disease hospital, led to the creation of a Public Health Service Policy in 1966 that became the forerunner of federal human subject protection regulation. One of the most important precipitating factors in stimulating federal regulation was an article published by Harry K. Beecher, an influential American physician-researcher, in the New England Journal of Medicine in 1966 exposing twenty-two examples of unethical research. This was followed by disclosures in the early 1970s of research scandals involving injection of mentally retarded children at the Willowbrook State School in New York with the hepatitis virus and of a forty year study of black men in Tuskegee, Alabama, which denied the research subjects

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2 Radiation Experiments, supra note 1, at 75-78.
3 Id. at 98.
4 Id. at 99-101.
5 Id. at 101; Vanderpool, supra note 1, at 8-9.

E. Deutsch et al. (eds.), Forschungsfreiheit und Forschungskontrolle in der Medizin © Springer-Verlag Berlin Heidelberg 2000
known treatments for syphilis in order to observe the progression of the untreated disease. In 1974 both Congress and the Department of Health, Education and Welfare (which later became the Department of Health and Human Services) took action in response to the public outcry brought on by these disclosures. Congress created a National Commission for the Protection of Biomedical and Behavioral Research, which lasted from 1974-1978. One of several documents published by this Commission was the Belmont Report, which remains the primary document establishing the ethical framework for regulation of human of human subjects in the United States. DHEW published rules to govern protection of human subjects in research it funded in 1974. These rules were revised in response to the recommendations of the National Commission in 1981, and were republished in 1991 as the Common Rule, discussed below.

It is difficult to evaluate the role that the Declaration of Helsinki has played in American developments. The original 1964 declaration came at a crucial time in the development of American human subjects protection policy, was well-received by the American research community, and seems to have had some effect on later developments. American developments, however, seem to a considerable degree to have charted their own course following the promulgation of the first federal human subjects protection rules in 1974, and the Helsinki Declaration is rarely referred to in contemporary American discussions unless international research projects are involved.

II. Federal and State Regulation of Research Involving Human Subjects in the United States

A. Federal and State Jurisdiction

For purposes of legal oversight, research involving human subjects in the United States falls into two categories--research subject to federal regulation and research exempt from federal regulation. The federal “Common Rule”, published jointly by the FDA and the federal Department of Health and Human Services in 1981, and reissued in 1991 as a Common Rule for fifteen federal departments and agencies,