

SCIENCE,  
TECHNOLOGY,  
AND SOCIETY

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AN ENCYCLOPEDIA

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very hot. The remark of one leading historian of science during this period is also revealing. Charles Gillespie observed vis à vis the spread of the purportedly Western institution of science, "The hard trial will begin when the instruments of power created [in] the West come fully into the hands of men not of the West. . . . And what will the day hold when China wields the bomb; and Egypt: Will Aurora light a rosy-fingered dawn out the East? Or will Nemesis?" (Durbin, p. 5). The ethnocentric trajectory of the history of science established by Whewell and perpetuated by Sarton continued with little deflection well into the waning twentieth century. The attitude of governmental funding agencies underscores the point. In the mid-1950s the National Science Foundation chose "to downplay sociology and establish a research program uniting only the history and philosophy of science" (Durbin, p. 41). Of the three disciplines, sociology would lead most directly to a contextualized approach to science, whereas the history and philosophy of science, as they were then and in some respects still commonly are practiced, fostered an internalist, decontextualized approach.

Even while following the basic pattern of modern historiography by paying closer attention to the contexts—cultural, economic, political, and so forth—that make scientific discovery possible, historians of science still conceive of science as a modern, Western phenomenon. Dobbs, shortly before her death, remarked on the "Whiggishness" of much contemporary history of science. She might have added that "Whig" is and always has been a rather euphemistic formulation. To say that something is "Whig history" is to say that it is history written as if the events of the past were but prelude and preparation for our present. It is a way of ratifying the institutions and viewpoints of the present by explaining how the past leads inevitably to "us." "Whig history" is, in other words, a euphemism for that less favored word, propaganda.

See also **Science in History**

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Peter John

## HUMAN SUBJECTS IN MEDICAL EXPERIMENTS.

The need to protect individuals subjected to human experimentation gained worldwide attention after world War II. The Nüremberg trials—at which an American military tribunal adjudicated cases from 1946 to 1949 against physicians in the Nazi party accused of inhumane and unnecessary medical experimentation on humans—signaled the harm that can come to human subjects if science and medicine do not receive oversight. The

process of producing national regulation in the United States, however, was tempered by a widespread institutionalized belief that American physicians and researchers would never allow or participate in the unethical research practices in which the Nazis had engaged. Consequently, responses to specific incidents in American research, which had received public attention, have propelled U.S. federal regulation.

In spite of sensational cases that have shown otherwise, the image of U.S. research as ethically sound and nonexploitative has been the dominant vision of American science. It is clear that American physicians and researchers had a set of normative ethics that dictated four accepted conditions for conducting research on humans: (1) prior experimentation on animals, (2) willingness to self-experiment or to experiment on one's own family, (3) therapeutic benefit and/or absence of injury, and (4) consent or absence of coercion of the subject. Using this perspective, researchers were able to argue for self-regulation and against external control of research during the decades after World War II and continue to mobilize this argument against further regulation today.

In contrast to this image of self-regulating scientific practices, many American researchers, particularly physicians, have a long history of involuntarily using marginalized groups for human subjects research. Experimentation has systematically occurred using slaves, prisoners, mentally institutionalized people, and orphans. Criticism of these practices has even come from within the ranks of researchers; in 1966, American physician Henry Beecher published a whistleblowing article in the *New England Journal of Medicine*. The article, which cited research studies published in medical journals, served to highlight serious ethical breaches being made by some American medical researchers and to accuse the medical profession of complacency in regulating research.

Beecher's article catalyzed the scrutiny of medical research and led to mass media coverage of major research projects like the Tuskegee syphilis study on African American men; the Willowbrook State Hospital

(NY) study, in which mentally institutionalized children were injected with a live hepatitis virus; and the panoply of invasive studies on inmates at Holmesburg Prison (PA). These cases and others spurred the U.S. Public Health Service to issue preliminary guidelines to protect human subjects in 1969 and to develop them further in 1971. These federal guidelines specified the requirement for "informed consent" from all human subjects participating in all Public Health Service-funded research and for institutional review of research protocol prior to study commencement. In addition to these correctives initiated by the U.S. Department of Health, Education, and Welfare (now, Health and Human Services), the U.S. Congress created ad hoc advisory committees and conducted congressional investigations and hearings during the early 1970s to examine the extent of the problem.

### *The Belmont Report*

The U.S. Congress passed the National Research Act of 1974 to establish the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was charged with recommending ethical guidelines that could shape federal regulation of human subjects research. Although the National Commission produced seventeen reports regarding a variety of issues in human experimentation, its most important and famous recommendations were published in 1979 in the *Belmont Report* (1979).

The *Belmont Report* identified three ethical principles to govern human subjects research: respect for persons, beneficence, and justice. The report then matched three applications to the respective ethical components: informed consent, risk/benefit assessment, and selection of research subjects. Defining "respect for persons" in terms of individuals as autonomous agents, the National Commission intended informed consent procedures to maintain and reinforce individuals' autonomy through the three ingredients of information, comprehension, and voluntariness. The second ethical principle of beneficence is described in two somewhat conflicting parts: "do no harm" and maximize possible

benefits while minimizing possible harms. In the report, risk/benefit assessment was offered as the best way to ensure beneficence. The National Commission stressed the importance of measuring the risk of the research to the individual compared with the benefit of the research to the individual and, more broadly, to society. Finally, the third ethical principle identified by the National Commission is that of justice. They defined it in terms of "fairness of distribution." Concerned with the distribution of the benefits and the burdens of medical research, the National Commission discussed the need for fairness (but not equality). This principle and its application created a "right" to participate in medical research and were closely linked with respect for persons. Justice was not understood in terms of groups or a burden of participation; rather, it was understood that no one who could benefit from a research protocol should be denied access to participation.

### **Institutional Review Boards (IRBs) and the Common Rule**

The task of transforming the recommendations framed in the *Belmont Report* into federal regulation fell to the Public Health Service. The 1981 regulation became known as the Common Rule (45-CFR-46) because it was designed for intramural and extramural research funded by the Department of Health, Education, and Welfare, but it was applied to human subjects research in all of the government's departments and agencies. In brief, the regulation requires a more vigorous system of institutional review than was then in place.

According to the Common Rule, an institutional review board (IRB) must consist of five members, who cannot all be of the same sex or profession. At least one member must represent specific scientific concerns, and at least one member must represent specific nonscientific concerns. One member of the IRB must not be affiliated with or related to someone affiliated with the institution for which he or she serves on the IRB. Finally, IRB members must not vote on their own research protocols or research in which they have a vested interest.

Outlined in the Common Rule, the most important functions of IRBs are to ensure that risks are minimized and reasonable for the anticipated benefits, subjects are selected equitably, informed consent is sought and documented, and data monitoring is performed for safety. In order to operationalize informed consent for IRBs and investigators, the Common Rule specified that informed consent must include statements about (1) the research's purposes; (2) the procedures involved in the study; (3) a description of "reasonably foreseeable" risks; (4) disclosure of alternative nonexperimental procedures or treatments; (5) assurance of confidentiality; (6) any compensation that will be given to the subject should they be harmed during the study (however, compensation is not required); and (7) a statement that participation in the study is voluntary, the subject will not be penalized for not participating, and the subject has the right to end participation at any time. The regulation also specifies that informed consent must be presented in language understandable to subjects and that it does not and should not waive subjects' rights.

Although the Common Rule applies to all federally funded research, the regulation is relatively weak for behavioral and social sciences because it creates a variety of systematic exemptions for institutional review and often dictates expedited review of those protocols. The strength of the *Belmont Report* and the Common Rule was concentrated in human subject research in the biomedical sciences.

### **Vulnerable Populations**

The Common Rule, with the recommendations outlined in the *Belmont Report*, identifies three specific groups as vulnerable and in need of further explicit regulation: (1) pregnant women and human fetuses, (2) prisoners, and (3) children. The first group is characterized as a vulnerable population as a result of the thalidomide disaster, which received attention throughout the United States and Europe in 1962. Thalidomide was a drug that had been prescribed for nausea and insomnia in pregnant women in the early 1960s. It soon became apparent that women who took thalidomide during the first trimester of

their pregnancies gave birth to severely deformed infants. Because thalidomide poses no threat to women who are not pregnant, this tragedy highlighted the need to categorize pregnant women and fetuses separately in biomedical research and in the approval of new drugs. The Common Rule specifies that studies can only be done on pregnant women and fetuses when potential risks have been assessed through studies performed on pregnant animals and nonpregnant women. The regulation allows research that exposes a fetus to risk only if the study will have benefit to the woman or fetus. There is also an explicit clause that states that it is not permitted to provide any inducements, financial or otherwise, to women to terminate their pregnancies.

Prisoners were also identified as a vulnerable population owing to historical events. Following the Second World War and until the late 1970s, prisoners became an important population for biomedical research. Investigators argued that prisoners were an ideal population because they live in a controlled and controllable environment, so that prison experiments could take on laboratory conditions. However, prisoners had been grossly mistreated in many experiments and had been coerced into participating by the promise of better living conditions while in prison and shortened prison sentences. The Common Rule recognizes that incarceration may limit prisoners' ability to give voluntary consent. As a way to counteract this threat, the regulation limits the type of research that can be performed on prison populations to studies that are explicitly about prisoners, that investigate illnesses that are prevalent in prisoners, or that improve prisoners' health or well-being. Much of the federal regulation aims to respect the rights of prisoners as citizens and to eliminate the assumption that prisoners could pay their debt to society by participating in research studies.

The final group identified as vulnerable by the Common Rule consists of children. The regulation specified for protecting children has two main parts. The first element is that assent from children and written permission from parents is necessary for children to take

part in research. The second part of the regulation restricts research on children who are wards of the state to studies related to their status as wards or to studies in which the majority of children included are not wards. This latter provision is a corrective for studies like those done on children at Willowbrook.

Many other groups have been discussed as potentially vulnerable in the context of human subjects research. Mentally disabled individuals may have a reduced capacity to give informed consent, yet, at this time, there is no explicit policy for including or excluding this group from research protocols. Military personnel and students have also been flagged as potentially vulnerable populations because, like prisoners, it is not clear that they are able to give truly voluntary consent. Severely ill populations may also be vulnerable because there is the possibility of creating a therapeutic misconception when there is little chance for benefit to patients, yet they consent believing that their health or quality of life will improve. One final group that can also potentially be characterized as vulnerable is the economically disadvantaged. This group may be compelled to participate in studies in order to receive financial compensation or access to health care.

### **Cross-National Comparison**

In 1964, the World Medical Association issued its *Declaration of Helsinki*, in which international guidelines for human subjects research were detailed. Physicians wrote the declaration as a means of creating and supporting principles of research ethics that transcended national boundaries. The hope was that the declaration would prevent research atrocities from happening in the future through a system of accountability, but it had no particular legal status. Nevertheless, it has served as a model for many industrialized countries as they struggled with creating regulation.

The United States was the first government to regulate human subjects research, and many other industrialized nations were influenced by the U.S. policy. Although the content of the guidelines—specifically, the

use of research review committees (e.g., IRBs)—is quite similar among industrialized countries in North America, Europe, and Asia, the only country other than the United States that gave the role of oversight and development of regulation to the government, rather than some other organization, was New Zealand, where the public's attention had been directed to research misconduct. In the case of New Zealand, one study conducted from 1966 to the mid-1970s consisted of leaving cervical cancer untreated to observe the natural history of the disease. Investigations shocked New Zealanders when it revealed that many women participating in the study died unnecessarily.

Some commonalities in regulation in industrialized countries are based on the tasks or composition of the review committees. Most national guidelines' only incentive for submitting research protocols to be reviewed is the threat of losing research support for noncompliance. The United States, Australia, and Denmark are most serious about trying to create disincentives for not following the guidelines. Another common feature of review committees is that there is little monitoring after the initial review of the research protocol. Denmark is the only country to continue review by having spot-checks for on-going projects. In addition, review in most countries is generally decentralized and located in individual institutes. New Zealand and Denmark have a slightly different system, in which there are regional committees, rather than institutional ones. Finally, most nations require lay members to sit on the review committees, but these members are often in the minority. In New Zealand and Denmark, lay members need to account for half the composition of the review committee, and some need to be members of the groups being studied.

By contrast, developing countries in Africa, Asia, and Latin America have little to no regulation governing human subjects research, and many multinational pharmaceutical companies are using populations in developing countries as a means of escaping some of the restrictions imposed by industrialized countries. The Declaration of Helsinki

is meant to give international guidelines in these contexts, but there is no monitoring to ensure compliance. Further investigation needs to address human subjects research in developing countries, particularly in the light of trends in globalization.

### **Current Climate and Agitation for Change**

The human subjects research landscape in the United States has shifted significantly since the Common Rule was enacted in 1981. One example of this change is manifest in the effects that advocacy groups have had on research practices and federal policy. The women's movement impressed upon the National Institutes of Health (NIH) the necessity of including women in clinical trials and resulted in policy requiring studies to include women or justify their absence from all medical research. Also, the AIDS movement succeeded in changing the conditions for access to AIDS research and in altering the power relations for access to research design decisions. These advocacy groups and others have had profound impacts on increasing the rights of human subjects.

The second type of change that is an important context for understanding the dynamics of human subjects research is increasing privatization and globalization of research sites. Within medical research, privatization involves a shift away from a reliance on academic centers as the primary producers of scientific knowledge to a market model characterized by outsourcing as the key principle to the distribution of labor. An example of privatization can be found in recruitment for medical research. Traditionally, recruitment for medical studies has relied upon the use of physicians' personal pools of patients. With the advent of privatization, monetary inducements, direct advertising, and centralized databases listing eligible subjects have become commonplace. Another example is the appearance of for-profit IRBs that are being used by academic as well as private institutions. Globalization is affecting medical research through the use of multisite studies and the selection of sites in developing nations.

A final example of change in the U.S. human subjects research is at the level of federal oversight of research sites, such as universities and hospitals. Since the early 1990s, the government has fully or partially suspended research in over 40 research organizations. The most well-known cases are the full suspensions of human subjects studies at Duke University in 1999 and at Johns Hopkins University in 2001. Hopkins's suspension came after a federal investigation following the death of a healthy 24-year-old woman participating in an asthma study. Following closely behind the death of a 19-year-old man who died in a gene-therapy experiment at the University of Pennsylvania in 1999, this Hopkins death signaled the need for government intervention to provide better protection of research subjects.

Although the Common Rule has been updated and revised since it was issued in 1981, little has actually changed in terms of its jurisdiction or scope. As a result, policymakers have been aware of the need to revise the regulation for almost a decade. The response by policymakers has been to appoint ad hoc committees and to create offices within the Department of Health and Human Services to study the ethics of human subjects research and to provide recommendations for new policy and regulation. Some updates to the regulations have been made regarding subjects' privacy and financial conflicts of interest for researchers and institutions.

These committees and reports have all recognized the need for change in the current system of human subjects research protection. From the Institute of Medicine's 2002 recommendation to create ethics review boards (ERBs) that complement IRBs, which are often more concerned with the scientific merit of the study than with debating ethics, to the Secretary's Advisory Committee on Human Research Protections Committee debating stem cell research policy, there are many facets to the national discussion about what needs to be done to better protect human subjects. Although many groups are poised to enact new regulation, there has been little movement toward actual change.

It is expected that the U.S. government will make amendments to the Common Rule in the light of the changing situation with human subjects research; it remains unclear, however, when these changes will occur and what they will be.

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Jill A. Fisher

## HUMANITIES AND SCIENCE.

The sciences and the humanities, and the more specific disciplines within them, each produce knowledge using different practices. Over the course of the twentieth century, movements bringing the practices of the humanities to bear on the sciences have gained momentum. These movements are as diverse as the rhetoric of science, which analyzes modes of argumentation in scientific work; cultural studies of science, which inquires about how science and culture interact; the philosophy of science, which addresses epistemology and how we come to know truth through science; and the history of science, which develops narratives about major scientific events. All these combinations seek to make science understandable according to a humanistic discipline's terms. These interdisciplinary movements interrogate science about how scientific knowledge is produced and distributed. Production and distribution are frequently interrelated. This interrelation is addressed by one of the most recent interactions between the science and humanities. Science, technology, and society

(STS) studies include scholars in both the sciences and the humanities, in order to establish a socially conscientious perspective on scientific knowledge production and distribution. Before the sciences and humanities existed in relative harmony, however, they clashed on a number of historic occasions. This essay describes two such occasions. The first is the "Two Cultures" lecture delivered by Sir Charles P. Snow in 1959, a lecture that garnered a great deal of rancorous commentary. The second instance is the no less inflammatory Sokal hoax of 1996, when a leading cultural studies journal unwittingly published an article intended to be a parody. The article, written by a physicist, used caricatured versions of theoretical terms from the humanities to culturally analyze a similarly unrigorous version of physics. How science produces knowledge, and to what end, has in recent history frequently resolved into the question of whether science is constructed or essential; that is, whether it is only the product of social interactions and institutional interests, or whether it progressively reveals bedrock reality. The examples that follow demonstrate that even though the conflict between constructed versus essential has been considered a major debate in science-humanities interaction, describing the conflict exclusively in this way is a bit misleading. These examples explore some of the political and economic stakes of disciplinary formation, in both the sciences and the humanities. Humanities programs that address sciences can do so because science is embedded in culture; that is, the production and distribution of scientific knowledge seems so stable and enduring and truth-creating *because* it is held in place culturally, not in spite of its cultural basis. With this point in mind, when interdisciplinary movements identify science as "socially constructed," such a designation cannot be a way to dismiss humanities' intervention in the sciences, as disciplinary purists take it to be. Before turning to our two illustrative occasions, let us take a (necessarily broad) overview of how a divide developed between the sciences and humanities in the