

Chapter 4

# The Mechanisms for Direct Control of Research



*Photo credit: National Institutes of Health*

# The Mechanisms for Direct Control of Research

At the laboratory bench level, each researcher controls his or her own activities, deciding which questions to answer and how to go about answering them. Controls are also part of the normal procedures of a research field or discipline—for example, the peer review system that governs the contents of disciplinary journals. Other, more formal control takes place at the laboratory or institutional level, through set policies or such mechanisms as review committees. And finally, legal and administrative regulation of research occurs at all levels of government, most likely in response to public opinion or public protest. This chapter looks at the administrative mechanisms for control or influence at all stages of the research process.

In an idealized model of scientific freedom, a scientist sets his or her own research agenda, performs the research without fear of repercussion or criticism, and describes the work to anyone and everyone. Sissela Bok characterizes such freedom as “freedom of limitless thought and unfettered speech. For scientists in some fields, that freedom has traditionally been perceived to encompass autonomy of action as well as responsibility for how the work is conducted. Biologist David Baltimore observes that contemporary research in molecular biology, for example:

... has grown up in an era of almost complete permissiveness. Its practitioners have been allowed to decide their own priorities and have met with virtually no restraints on the types of work they can do.<sup>2</sup>

In many research facilities and in many laboratories, open communication has been routine,

Zoologist Alexander Faberge describes the “open traditions” in one field:<sup>3</sup>

Not only is it normal to discuss one’s ongoing research, but also to give away one’s research material in the form of genetic stocks, with the verbal understanding that the giver should be given time to publish first. Such genetic stocks, or cultures of organisms, sometimes take years of work to prepare, and are placed in culture collections, freely available.

“It would be an unheard of matter,” Faberge continues “to keep genetic stocks private . . .” These and similar aspects of the sharing of research data are discussed in a 1985 report from the National Academy of Sciences (NAS) which notes that, in general, access helps in reanalysis and verification.<sup>4</sup> In fast-moving areas, the sharing of research data may jeopardize a researcher’s patent rights or the commercial return on a discovery, so there are significant forces against openness. Nevertheless, the NAS committee concluded that without data sharing, scientific understanding and progress would be impeded.

Even in early modern science, however, communication of ideas was not totally open. Inventors delayed or repressed publication out of fear of ecclesiastical or political displeasure. Because the community of science rewards priority, researchers have also delayed sharing data until credit is assured, usually through publication. Historian David Hull attributes such secretiveness to science’s “intrinsic competitive nature.”<sup>5</sup> Technological skills and knowledge regarded as applied have not always been tightly controlled by their possessors; skills were assumed to be the prop-

<sup>1</sup>Sissela Bok, “Freedom and Risk,” *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W. W. Norton & Co. 1979), p. 110

<sup>2</sup>David Baltimore, “A Biologist’s Perspective,” *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W. W. Norton & Co., 1979), p. 37.

<sup>3</sup>Alexander C. Faberge, “Thoughts on the Origins of Secrecy and Openness in Science,” American Association for the Advancement of Science, annual meeting, New York City, May 1984.

<sup>4</sup>National Academy of Sciences, Committee on National Statistics, *Sharing Research Data* (Washington, DC: National Academy Press, 1985)

<sup>5</sup>David Hull, “Openness and Secrecy in Science: Their Origins and Limitations,” *Science, Technology, & Human Values*, vol. 10, spring 1985, pp. 8-9

erty of those who exercised and developed them.<sup>6</sup> Although *unqualified* sharing (especially before publication) has never been the norm, until several decades ago, scientists exercised relatively few restraints on their communications to others.

Contemporary attitudes to openness in university science are also influenced by the concept of academic freedom in general. In the United States, “academic freedom” has stood for personal freedom of the academic, rather than the collective freedom of the Nation. Because of this emphasis on the individual, some academics have regarded regulation more as a limit to which they are obliged to submit. Limits have been, therefore, equated with “responsibilities.”<sup>7</sup> But, Walter Metzger points out, “academic freedom and scientific freedom are different species of freedom. . . .”<sup>8</sup> The former is an ideology of a profession, across the disciplines, with common duties; the latter is the ideology of various professions in a discipline (e.g., science). And the latter need not be connected to a university.

Historian Carroll Pursell takes a more pragmatic view. Science, he observes, is always “regulated” in the sense that it is given shape, direction, and impetus by something. There is, he writes, “a tendency to take it simply as the working of some invisible hand until the public (in the form of government, mobs, or whatever) takes a more visible hand. This is, of course, nonsense.”<sup>9</sup> Communities have, for example, never tolerated (for very long) any researcher who tackles topics outside the boundaries of accepted moral behavior or social beliefs or who knowingly

puts the community at risk through hazardous, dangerous procedures (e.g., experimenting with explosives in Times Square). Such “moral regulations”—enforced through social condemnation or disapproval—have been the predominant controls on research for centuries, other than those which arose in connection with military research. Neither Federal nor local governments in the United States had formal laws, rules, or policies by which the subjects or procedures could be controlled.

This environment changed for American scientists in the 1940s. When the United States entered World War II, the scientific community joined in the war effort and, just like millions of other people, scientists relinquished to the Government their personal autonomy over how they did their work. They accepted government control over agenda, over process, and—in the case of information considered to be of military importance—over dissemination even to their colleagues. When almost everyone in science was working behind the secrecy fence, the communications restrictions did not seem so onerous. There was a comradeship and free exchange that participants recall as frequently greater than in the structure of university departments. Within the Manhattan Project, for example, Robert Oppenheimer successfully convinced General Leslie Groves not to implement irrevocable application of “compartmentalization.” Groves wanted to keep scientists from sharing information with their colleagues in other parts of the project; Oppenheimer argued that some decompartmentalization was necessary for progress at both the laboratory and the individual level. The perspective argued by Oppenheimer was that the scientists were the best judge of how to get to their goal. He also believed that the creative scientist required intellectual “elbow room” for the cross-fertilization that could be vital in a new field. Each individual had to feel free to pursue research whatever way he or she wished.

<sup>6</sup>Ernan McMullin, “Openness and Secrecy in Science: Some Notes on Early History,” *Science, Technology, & Human Values*, vol. 10, spring 1985, pp. 14-23.

<sup>7</sup>Walter P. Metzger, “Academic Freedom and Scientific Freedom,” *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 102.

<sup>8</sup>Ibid., p. 107.

<sup>9</sup>Carroll Pursell, [Department of History, University of California, Santa Barbara, personal communication, 1985.

## MECHANISMS FOR INDIVIDUAL OR RESEARCH GROUP CONTROL

At the level of individual choice, then, researchers in a democratic system decide what line of research to pursue, how to test their hypotheses, which data to gather and how to gather it, and when and to whom to tell about their results. The scientists simply seize on personal freedoms available to all citizens.

The amateur astronomer provides an excellent example of how little externally imposed controls can affect a researcher who is working outside conventional institutional settings for research, academic or otherwise. There are approximately 10,000 amateur astronomers in the United States, many of them engaged in the search for new astronomical bodies, or in recording astronomical phenomena. Almost all work at their own expense, in return for the reward of discovery, the joy of creative activity. Such an individual can decide what to do, can build his or her own equipment according to any schedule, and can elect to tell everyone or no one\* about the results. To achieve recognition and acceptance by the community of professional astronomers, however, a researcher must adhere to the standards and norms that govern conduct in the field and must subject that work to review by colleagues, usually through the journal peer review system.

\*A participant in a 1984 seminar series sponsored by the American Association for the Advancement of Science pointed out that when an idea is in a researcher's head and not written up, then of course there is no real dissemination subject to regulation. Once it becomes more than an idea, then the law can regulate it as speech. If you tell enough people (as legally defined), then that is considered to be publication and the government can step in (in the case, for example, of information relevant to national security interests). This issue arises in conjunction with interpretation of the Export Administration Act of 1985, which permits restrictions on "information and knowhow (whether in tangible form . . . or in intangible form). . . ." The question for future cases will be can this be construed to mean knowledge in a scientist's head.

### Agenda Controls

In research groups, internal factors may not only direct but also constrain research. At any given point in the development of a scientific speciality, for example, there exists some finite set of research topics that are considered by the members of the speciality to be legitimate, interesting, and feasible.<sup>10</sup> If peers do not consider an area to contain "interesting" questions and hence to be intellectually stimulating or professionally rewarding, then researchers may suspend research out of concern for their professional reputations. Influence on the researchers to control or restrain their own work may also come from the social environment, as when the public raises questions about the morality of a project. Other research topics may receive little attention and no funding because peers consider them to be outside the boundaries of "legitimate" science; research on parapsychology often falls into this category. Researchers working on new chemicals for introduction into commerce or on new pesticide formulations may tend to shape their investigations so that the chemical will withstand scrutiny and secure approval under such Federal environmental regulations as the Toxic Substances Control Act or the Federal pesticide laws.

The cost of instrumentation and the internal allocation of resources can be devices for dramatically controlling the research agenda. The major experimental facilities for high energy particle physics research, for example, are few in number and because the demand for time on the accelerators far exceeds the time available, laboratories

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<sup>10</sup> Daryl E. Chubin and Terence Connolly, *Research Trajectories and Science Policies: Local and Extra-Local Negotiation of Scientific Work*. *Scientific Establishments and Hierarchies Sociology of the Sciences*, vol. 6, Norbert Elias, et al (eds) (Hingham MA: Reidel Holland, 1982), p. 20.3.

### **Box A.—NIH Study Sections as a Mechanism for Control of Agenda , ,**

The peer review system, whereby scientists advise the Federal Government on how to allocate research funds, is representative of a two-pronged mechanism for control of the research agenda: decisions on funding particular proposals both set the current agenda for research and affect the direction of a field or discipline. The multi-level process used by NIH provides a good example of such controls.

A research proposal submitted to NIH is first scanned by an officer in the Division of Research Grants, who refers the proposal to the most relevant of 65 chartered Study sections and to the most appropriate Institute of NIH. Each study section is composed of approximately 18 scientists and a full-time, nonvoting executive secretary who is an NIH scientist. The executive secretary nominates members of the study section for selection by the NIH Director. Study section members serve a 4-year term and meet 43 times a year to review over 100 proposals per session.

The study sections assign to each proposal a priority score based on scientific merit. Reviewers are not aware of the total budgetary request on the proposal. The relevant Institute then receives the ranked proposals and passes the funding decision on to its advisory council, which is composed of both scientists and public figures. Because Institutes with larger budgets are able to fund more projects, some critics charge that high quality research can go unfunded in areas where social and political decisions have resulted in a certain disease priority for lesser quality research may be funded in more "glamorous" disease categories. The study sections also conduct workshops to report on the status of the field, thereby providing long-term planning information to the Institute and sending signals to the scientific community about areas of potential interest to the granting agency.

adopt specific criteria for selecting experiments and assigning priorities to them. The International Committee for Future Accelerators of the International Union of Pure and Applied Physics recommends four criteria be used for selecting experiments and determining their priority: 1) scien-

tific merit, 2) technical feasibility, 3) capability of the experimental group, and 4) availability of the resources required.

At the individual level, research may be restricted not only by mechanisms driven by political, economic, or professional concerns but also by personal values. Especially when alternatives are limited, individuals "feel forced to choose among projects they would normally not consider, the moral questions . . . become more immediate and controversial."<sup>11</sup> The decision not to participate in military-supported or weapons-related research, therefore, may be also a decision to alter one's lifetime research agenda. This decision is a personal one, an individual rather than a collective control.<sup>12</sup>

In each of these instances, the regulatory force may actually be outside the research group, but the group or the individual chooses to suspend a line of research in response to either moral or economic pressure.

### **Controls on Procedures**

Within each scientific field or research specialty, the social influence of tradition and "standard practice" also govern aspects of the research process. Even though these practices are voluntary, they carry the authority of social norms. On occasion, they may later form the basis for institutional or governmental regulation.

Many controls are linked to the formal principles and rules that govern admission to a profession. Since antiquity, the medical profession, for example, "has formalized principles and rules of conduct for its members in prayers, oaths, and codes."<sup>13</sup> Universal codes adopted by more than one scientific field may relate basic ethical and moral principles to research practice. The Nuremberg Code of 1947, for example, serves as the model for many international and national codes pertaining to clinical research in general and to such topics as organ transplantation.<sup>14</sup> Another

<sup>11</sup>Rosemary Chalk, "Drawing the Line: Science and Military Research," unpublished manuscript, May 1983, p. 24.

<sup>12</sup>Ibid., p. 22.

<sup>13</sup>Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Inquiry in Clinical Investigation," Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 136.

<sup>14</sup>Ibid., p. 132.

important code has been the World Medical Association's Declaration of Helsinki (1964, revised 1975).

In some research areas, laboratory groups have not refrained from imposing voluntary clinical moratoria—prohibiting researchers from, for example, using on patients a procedure still considered to be experimental. Such a moratorium can last weeks, even years.<sup>15</sup> It is linked to perceptions of the risks associated with premature use of a procedure and to the incomplete nature of the research process, however, not to the topic.

The most dramatic instance of a voluntary moratorium on basic research was, of course, that imposed by molecular biologists in the 1970s. Recombinant DNA regulation arose first in the form of a moratorium called by researchers in the field. What began in private discussions was dramatically brought to public attention when, as described in chapter 2, biologists proposed a voluntary suspension of certain types of genetic research. This extraordinary step was followed by the 1975 Asilomar meeting, when researchers from the United States and elsewhere, discussed the appropriateness of continuing the moratorium. After that meeting, action moved to the Federal Government level—to legislation and the formal development of National Institutes of Health (NIH) guidelines for the research.

### Communication Controls

Through the centuries, individuals have also exercised self-restraint in dissemination of research

<sup>15</sup>Judith I. Swazey and Renee C. Fox, "The Clinical Moratorium: A Case of Mitral Valve Surgery," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969).

results, either by withholding the information altogether or by delaying dissemination for a short period of time. British mathematician John Napier, who had experimented with a new form of artillery around 1600, "took great pains to conceal the workings of his invention."<sup>16</sup> In 1947, Massachusetts Institute of Technology professor Norbert Wiener refused to supply a paper of his to an industry scientist engaged in military research.<sup>17</sup> In the 1980s, many biologists assert that researchers in certain areas are refraining from sharing information and substances with colleagues, 'a

The science community as a whole may support an investigator's desire to avoid premature disclosure, especially when data are incomplete or not yet published in a refereed journal. Such delay may also be linked to the researcher's desire to maintain professional security through temporary but exclusive control of knowledge. A dramatic example of group self-censorship occurred before World War II when a group of physicists tried to limit the publication of scientific research relating to nuclear fission. By the middle of 1940, most physics journals had agreed informally "to delay the publication of any article that might help a knowledgeable scientist build an *atomic* bomb."<sup>19</sup>

<sup>16</sup>Cited in Chalk, *op.cit.*, p. Q.

<sup>17</sup>Norbert Wiener, *The Atlantic Monthly*, letter to the editor, January 1947; reprinted in *Science, Technology, & Human Values*, vol. 8, No. 3, summer 1983.

<sup>18</sup>Biologists interviewed by Sandra Panem "uniformly agreed that there was more free information exchange in the 1960s than currently." Sandra Panem, "The Interferon Dilemma: Secrecy v Open Exchange," *The Brookings Review*, winter 1982, p. 20.

<sup>19</sup>Michael M. Sokal and Janice F. Goldblum, "From the Archives," *Science, Technology, & Human Values*, vol. 10, spring 1985, p. 24.

## REGULATIONS IMPOSED BY INSTITUTIONS

The attitudes and policies of research organizations can regulate the agenda, procedures, and communication of a project, through both informal guidelines enforced by social pressure and formal rules enforced by threat of dismissal or penalty. Although the extent and stringency of rules may vary, most organizations have specific ex-

perimental protocols and safety procedures and have policies on what subjects are not acceptable. A research group may decide deliberately to take up or drop a specific line of research for political or moral as well as scientific considerations. Those decisions—whether to pursue certain topics, or how to disseminate results—can reflect such fac-

tors as: 1) fear of social criticism or protest, 2) accommodation to the pressures of the surrounding social or political climate, or 3) a desire to protect property rights (e.g., when a team delays publication until assured of patent protection or keeps a project secret in order to assure first publication).<sup>20</sup>

As a result of discussions from the Vietnam era, some U.S. research laboratories or universities decided not to allow classified research to be performed on their campuses. Ohio State University, which accepted over \$5 million in defense contracts research in 1982, now bans any campus research on offensive weapons.<sup>22</sup> Other universities impose procedural restrictions—e.g., whether classified work may be accepted with any entailing restrictions on publication<sup>23</sup>—or have placed such work off-campus and attempted to insulate it from the research environment of undergraduate or graduate students.

To enforce such administrative policies on acceptable research topics or procedures, organizations employ a variety of mechanisms, ranging from informal guidelines and review committees, to formal administrative rules. In most cases, these controls are enforced through social pressure or reprimand. Many universities have adopted guidelines for the acceptance of externally sponsored research which govern, for example, the terms of university-industry cooperative projects, the use of human subjects in experiments, or the handling of dangerous biological materials. Such policy documents may govern with a velvet glove, however. As the Harvard University guidelines note, “The pursuit of truth in the academic community is impossible without a measure of mutual trust between its members, and no set of detailed principles and criteria can be a substitute for this

trust.”<sup>25</sup> The Harvard report further points out that:

... the principal means by which the faculty exercises control over the quality of the scholarly activities of its members is through its role in recommending the selection of its own members and through the professional standards that it and the University apply in the selection process.<sup>26</sup>

To administer such rules on a routine basis, universities and private laboratories set up institutional committees to review safety procedures, to decide which topics to pursue, or to review the quality or process of publication. Committees are dominated by members of the institution and are appointed and funded by the institution. Many exist as a direct result of Federal regulations tied to grant or contract funds. Institutional Animal Care and Use Committees, Institutional Review Boards, and the Institutional Biosafety Committees, for example, are all required of institutions receiving funds from the Public Health Service, NIH, or other compliant agencies. Institutional review boards, which are (administratively and financially) local committees of the institution, nevertheless must include both scientists and non-scientist members from the local community, all of whom “examine and pass judgment on the risks and benefits of a proposed study and on the adequacy of the consent proceeding as described in the research protocol.”<sup>27</sup>

Some institutional committees govern the administration of a specific research program. For example, in 1977, the Monsanto Co. and Harvard University set up a special independent advisory committee to oversee aspects of their \$23 million research agreement. The five-person committee, established out of concern for the public interest, assures that “both sides honor their contractual promises to protect academic freedom—namely, the right to publish—and to develop any products that may emerge in a manner consistent with the public good.”<sup>28</sup> The Health Effects Institute,

<sup>20</sup>As described in, for example, James D. Watson, *The Double Helix* (New York: Atheneum, 1968).

<sup>21</sup>Robert C. Cowan, “Degrees of Freedom,” *Technology Review*, August-September 1985, p. 6; also see Dorothy Nelkin, *The University and Military Research: Moral Politics at MIT* (Ithaca, NY: Cornell University Press, 1972).

<sup>22</sup>*Kansas City Times*, Jan. 13, 1983, p. A-7.

“Chalk,” *op. cit.*, p. 13.

<sup>23</sup>As described in, for example, Nicholas H. Steneck, “The University and Research Ethics,” *Science, Technology, & Human Values*, vol. 9, fall 1984, pp. 6-15.

“*Report of the Committee on Criteria for Acceptance of Sponsored Research in the Faculty of Arts and Sciences* (Cambridge, MA: Harvard University Press, October 1983), p. 3.

“*Ibid.*”

“Swazey,” *op. cit.*, p. 139.

<sup>28</sup>Barbara J. Culliton, “Harvard and Monsanto: The \$23-Million Alliance,” *Science*, vol. 195, Feb. 25, 1977, p. 759.

a private research firm, insulates scientists from pressure by using two independent committees, one that creates the research agenda, another that reviews finished work.<sup>29</sup> In the national laboratories, visiting committees, composed of scientists from other institutions, are used to evaluate the quality of work in the lab.

Institutional restraints on communication may result not just in suspension of publication but also deliberate, albeit temporary delays. At a 1984 seminar on secrecy in science, many university deans of research remarked that it was not unusual for them to receive requests to delay the submission of a Ph.D. dissertation to University

<sup>29</sup>*Science*, Feb. 15, 1985, p. 729.

Microfilms, Inc. (a general clearinghouse for U.S. theses and dissertations) and that it was not unusual for graduate schools to cooperate—as a matter of policy—by granting 1-year delays.” Typical reasons for such requests were: 1) to allow the student time to seek patent protection, 2) to allow time for first publication in a journal of record, 3) to provide a degree of protection for industrial sponsors of research, 4) to protect the safety and welfare of informants used in the research, or 5) to protect militarily-sensitive information.

<sup>30</sup>“Openness and Secrecy in Scientific and Technical Communication,” seminar, Vanderbilt University, Nashville, TN, Sept. 24, 1984.

## CONTROLS BY PROFESSIONAL ORGANIZATIONS IN SCIENCE AND ENGINEERING

Professional codes or industry association guidelines may act as a regulatory force on the research conduct of members. These rules are voluntary standards that reflect private consensus on public matters. They are enforceable primarily through the social pressure of membership in the association and hence are effective only when such membership is useful or necessary to acquiring or maintaining employment in the field or in acquiring a government grant or contract.

In some scientific fields these rules may form the foundation for State licensing procedures—as in the case of physicians or engineers. In other fields, the codes may pertain to accepted procedures in the field or to testing. The American Psychological Association, for example, has issued guidelines for research psychologists who use animals, as have such groups as the Society for Neuroscience, the Society of Toxicology, and the International Society for the Study of Pain.<sup>31</sup> The American Psychological Association has also developed a set of Ethical Principles in the Conduct of Research with Human Participants. The American Anthropological Association and the American Sociological Association adopted new codes of ethics for research in 1971. The Evaluation Re-

<sup>31</sup>*Science*, vol. 228, May 17, 1985, p. 830

search Society has established professional standards for evaluation research. The American Chemical Society developed the Chemists' Creed and Professional Employment Guidelines, which set standards for practice in research settings. Most scientific societies have, at minimum, guiding principles for the conduct of research. Some have extensive and detailed guidelines for agenda, procedures, and communication of research results.

Recent concern about the leakage of militarily sensitive information to the Soviet Union from the U.S. western allies has led the Federal Government to request the specific cooperation of the scientific and technical societies in regulating communication. The Government has asked societies to restrict access to certain meeting sessions—that is, the session would be neither classified nor open to all meeting participants. The American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility has identified examples of “self-imposed restrictions” in a few professional societies that exclude non-U.S. citizens from meeting sessions dealing with militarily sensitive topics.<sup>32</sup> The Society for the

<sup>32</sup>Robert L. Park, “Intimidation Leads to Self-Censorship in Science,” *Bulletin of the Atomic Scientists*, vol. 141, No. 3, spring 1985, pp. 22-25.



Advancement of Material and Process Engineering and the Society of Manufacturing Engineers, among others, have voluntarily censored themselves, limiting attendance at their meetings (or at specific meeting sessions) to U.S. citizens only.<sup>33</sup>

<sup>33</sup>Janice R. Long, "Scientific Freedom: Focus of National Security Controls Shifting," *Chemical & Engineering News*, July 1, 1985, p. 9.

At least half a dozen professional societies are either reconsidering or reformulating their policies on restricted meetings.\*

\*The AAAS is distributing a survey to determine the extent and pervasiveness of this trend.

## MECHANISMS FOR GOVERNMENT REGULATION

Federal, State, and local governments use legislation, executive (e.g., Presidential) directives, agency rulemaking, and so forth, to exert control on the conduct and dissemination of research. Such mechanisms differ from entity to entity.

A comparison of two Federal agencies that regulate biomedical research demonstrates how different mechanisms can constrain research. The Food and Drug Administration (FDA) closely monitors drug research and applies its program of control—e.g., in requiring the assurance of consent by subjects involved in clinical trials—uniformly throughout the United States. Tighter requirements for the use of human subjects were instituted in 1962. This organizational approach is tied to FDA's principal mission of regulation aimed at protecting the consuming public; its enforcement power to regulate research comes from the fact that it must approve the marketing, advertising, and distribution of all drugs sold in the United States. The principal regulatory efforts of this agency are thus directed at research in the pharmaceutical industry.<sup>34</sup> In contrast, NIH, as an organization that supports and conducts basic research, applies a philosophy of encouraging academic freedom and imagination in the research it supports through its extramural projects grants program.<sup>35</sup> The NIH approach uses a system of decentralized, institutional review committees that operate under generalized ethical guidelines. NIH also "takes direct responsibility for the protection of research subjects under its own system of na-

tional review of project applications."<sup>36</sup> Its principal regulatory effects are felt in the university research labs, although the regulations on molecular biology research or on the use of human subjects in experiments have also been applied to some industry research.

Because of the variety of mechanisms and enforcement in the executive branch agencies, new fields often face a thicket of duplicative or even conflicting requirements. The December 31, 1984, *Proposal for a Coordinated Framework for Regulation of Biotechnology*<sup>37</sup> issued by the Office of Management and Budget is evidence of increasing concern about this problem. In May 1984, the White House Cabinet Council established a working group on biotechnology to review Federal regulatory rules and procedures relating to the biotechnology industry. All three affected agencies (FDA, Environmental Protection Agency, and U.S. Department of Agriculture) would review biotechnology products and processes. Under the *Framework*, review would proceed on a case-by-case basis, each with its own staff, consultants, and expert scientific advisory committees. The Recombinant DNA Advisory Committee (RAC) would continue to oversee rDNA experiments related to biomedical research and the National Science Foundation (NSF) would form a review committee to examine the potential environmental effects of basic research experiments employing rDNA. All five advisory committees would report to a parent committee, the Biotechnology Science Board, which would receive summaries of all recombinant DNA, recombinant RNA, or cell fusion applications and may undertake itself,

<sup>34</sup>Alexander M. Schmidt, "The Politics of Drug Research and Development," *The Social Context of Medical Research*, Henry Wechsler (ed.) (Cambridge, MA: Ballinger Publishing Co., 1981), pp. 233-262.

<sup>35</sup>William J. Curran, "The Approach of Two Federal Agencies," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969), p. 449.

<sup>36</sup>Ibid.

<sup>37</sup>49 *Federal Register* 50856-50907.

or request that the agency committee review, a specific proposal. In addition, the Board would evaluate review procedures and committee reports, conduct evaluations of broad scientific issues relating to this research, develop guidelines, and provide "a forum for public concern." As of this writing, NIH is in the process of reviewing comments on the proposed regulations, and no final rule has been issued.

Such coordination, is unusual, however. Normally, government regulation of research is administered through a number of uncoordinated and therefore potentially conflicting mechanisms. These include: national or local commissions to review general procedures and policies; tax credits; legislative review and veto; moratoria; controls of acquisition or possession of materials needed for research; interpretation of regulations; contract provisions; and publication or communication review or classification.

## Agenda Controls

### Governmental Review Commissions

The Government may set up a commission or board to review research, either with an eye to improving research procedures or to resolve some dispute. An example at the local level is the Cambridge Experimentation Review Board, which ruled on the safety of rDNA research in the 1970s at the request of the Cambridge City Council. At a national level, the NIH RAC approves experimental procedures and must consider any proposed changes in the NIH Guidelines for Research Involving recombinant DNA Molecules. The NIH committee, composed of both scientists and non-scientists, meets several times a year to examine special cases of recombinant DNA research, petitions for exemption, and proposals for changing the *Guidelines*. The Committee must also recommend to the Director of NIH any proposed change in the guidelines.

National commissions have been used to formulate guidelines for research, but most have not had any power to restrict or delay actual research—e.g., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established by Congress in 1974 to develop guidelines for such research.

## Tax Credits

Legislation offering tax credit or similar financial incentive to encourage and discourage research is passed usually to provide incentives for private funding on designated topics (e. g., research on alternative energy sources). In 1980, Congress gave small businesses and universities the opportunity to obtain patent rights on inventions developed with Federal funds.<sup>38</sup> In response to the energy crisis of the 1970s, over 30 States passed laws to promote solar energy. Most of these laws provide tax incentives (income or property tax reductions) to stimulate private sector research, development, and commercialization of solar systems.<sup>39</sup> Congress has been similarly active in passing legislation that promotes research on alternative energy systems. And the 98th Congress enacted the Orphan Drug Amendments to the Food, Drug, and Cosmetic Act<sup>40</sup> in order to stimulate private research and development (R&D) of drugs for rare diseases.

The Internal Revenue Code also currently allows businesses the option of deducting or amortizing expenditures for research and experimentation over a period of 60 or more months. The Economic Recovery Tax Act of 1981 (Public Law 97-34) provides a 25 percent tax credit for incremental research expenditures made after 1981. That legislation reflects a deliberate attempt by Congress to reduce tax burdens in order to stimulate research. It includes tax credits for laboratory equipment leases, and for portions of payments to universities to perform basic research.<sup>41</sup> These provisions are set to expire at the end of 1985. To stimulate research by private industry, Congress has tried to lower the cost of private R&D through a combination of tax policy, direct spending, and patent legislation.

Social science research was specifically excluded from the areas of research spending for which a tax credit is allowed. Bills introduced in the 98th

<sup>38</sup>35 U.S.C. Section 200 (1980).

<sup>39</sup>W. Rogers, *Energy and Natural Resources Law* (St. Paul, MN: West Publishing Co., 1978), p. 31.

<sup>40</sup>21 U.S.C. Sections 360aa-360ee.

<sup>41</sup>Wendy H. Schacht, "Industrial Innovation: The Debate Over Government Policy," Issue Brief 84004, Congressional Research Service.

Congress, which would have created additional incentives for corporate investment in research and development, also excluded social science research from their definition of “qualified research” for which a corporation may take a tax credit.

The Congressional Budget Office estimates that the Federal Government gives the high-technology research system approximately \$1.5 billion in the form of tax credits.<sup>42</sup> There are currently three major tax-related mechanisms that high-tech research industries may employ: 1) straight deductions, year by year, of research expenses such as salaries and equipment [Internal Revenue Code, Section 174]; 2) the R&D tax credit, which expires in 1985 and allows a company to deduct from its taxes 25 percent of amounts that exceed the previous 3-year average of amounts the company spent on research [Public Law 97-34]; and 3) the funding of research through R&D limited partnerships, possible through several provisions of the tax code.

#### Legislative Review

Congress has several times attempted to control specific research projects or types of projects through legislative review of proposals or projects. In 1975, Representative Robert E. Bauman of Maryland introduced an amendment to the NSF authorization bill (H.R. 4723) which would have allowed Congress to review all NSF proposals prior to the final awarding of the grants. The Bauman amendment passed the House, but was deleted in Senate Subcommittee and therefore not included in the final bill. The strongest argument against the amendment was the burden that would be placed on Congress to review thousands of grants. A second argument was that Members of Congress are not scientists and therefore are not necessarily competent to judge specific research proposals. What might sound frivolous and inconsequential to a layperson can be of major importance to scientific development. A third argument was that consistency would require Congress to oversee the grants made by all other agencies, including the Department of Defense (DOD). Other arguments included the added length of time to receive a grant, the politiciz-

ing of the award decisionmaking process, and the possibility of making NSF more conservative (and possibly less innovative) in its effort to please Congress. In 1983, the Supreme Court effectively ruled in *INS v. Chadha* (103 S. Ct. 2764) that legislative vetoes, such as proposed in the Bauman amendment, were unconstitutional.

In the 99th Congress, Representative Robert G. Torricelli of New Jersey introduced a bill entitled the “Information Dissemination and Research Accountability Act” (H. R. 1145), which has similar evaluative intent. The purpose of the bill is to “promote the dissemination of biomedical information through modern methods of science and technology and to prevent the duplication of experiments on live animals.” It calls for a National Center for Research Accountability, located within the Library of Medicine, which would provide for a comprehensive, full-text literature search before any research proposal involving the use of live animals could be approved. Thus, all animal research proposals would be funneled by the potential granting agency through the Center prior to approval. The President would appoint 20 persons to serve as members of the Center. Critics of the bill claim that the process would unnecessarily prolong the already extensive grants review process and would duplicate the peer review process. In addition, the duplication of research that the bill intends to eliminate is often an important and required aspect of research in that it enhances validity and reliability. Proponents of the bill feel that it will prevent the unnecessary use of animals in research.

#### Moratoria

The most dramatic device used by government to control research is the legally enforceable ban or moratorium. Moratoria on science—or the proposal of same—are effective ways to focus attention on a serious issue or to express a political perspective that the researchers appear to have been ignoring. The 1974 act prohibiting experimentation on human fetuses (see box B) is an example of such a ban. In 1975, the Department of Health, Education, and Welfare prohibited the funding of research on in vitro fertilization without review by the agency’s Ethics Advisory Board.<sup>43</sup>

<sup>42</sup>Congressional Budget Office, *Federal Support for R&D 2nd Innovation*, April 1984, pp. 76-83.

<sup>43</sup>Michael Gold, “Research Off-limits,” *Science* 8.5, vol. 6, April 1985, p. 36.

### Box B.—Fetal Research

The controversy over research on fetuses or fetal tissue illustrates the implementation and effect of various mechanisms for government control of research.

Between **1970** and **1972**, advisory groups within the National Institute of Child Health and Development debated NIH policies on the review and funding of human fetal research. Reports of abuses by researchers in other countries had led to pressure on NIH to declare a moratorium on any research with the living fetus before or after abortion, lest such abuses be repeated in the United States. Congressional debate and legislation (National Research Act, Public Law **93-348**, Section **2130**) created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced recommendations that became the core of the Federal regulations. The Commission intended the existing independent, local institutional review boards (IRBs), with the addition of a national Ethics Advisory Board, as the means for control and consideration of fetal research. The fetal research guidelines were adopted as Federal regulations on July 29, 1975, but an Ethics Advisory Board was not chartered until 1977 or convened until 1978, so a de facto moratorium existed during this time on both fetal research and in vitro fertilization.

The Ethics Advisory Board was allowed to die in 1980 and its absence means that the privately supported IRBs are still the only locus of practical control. Supplementing the Federal regulations are **25 State statutes** and the Uniform Anatomical Gift Act (passed in all **50 States** by **1973**). That act governs research on dead fetuses generally by including explicit language to that effect. Department of Health and Human Services (DHHS) regulations cover only DHHS funded research or research institutions; other research is governed by State statutes, when they exist. They range from strict (no research except that of therapeutic value to mother or fetus) to those more liberal than the Federal regulations.<sup>1</sup>

In summer 1974, the National Commission for the Protection of Human Subjects declared a national moratorium on all fetal research, which remained in effect until the Commission issued interim regulations in **1975**.

In several cases in Boston in the 1970s, State-level protest also attempted to halt fetal research. Because the research in question used dead fetal tissue obtained from abortion procedures, antiabortion groups charged that publication of findings based on research using such tissue was unethical. In response to the public protest, the **1974** session of the Massachusetts legislature passed "An Act Prohibiting Experimentation on Human Fetuses," which treated such research as a felony offense punishable by up to 5 years in prison. The law (amended in **1976**) applies only to fetal tissue and does not prohibit experimentation on live fetuses in efforts that might be considered "beneficial" to the fetus. Many legal scholars consider the law to be imprecise and, because of that imprecision, to have the potential for producing a "chilling effect" on researchers. On the other hand, opponents of the research have pushed for stronger legislation that would make violation a criminal offense. Controversy has continued with the introduction of legislation in Congress proposing a national moratorium on research on live fetuses.

Rules restricting federally funded research on human fetuses, set in place in **1974**, specify that individual research proposals must be reviewed by a federally appointed Ethics Advisory Board. When the Ethics Advisory Board was allowed to lapse in 1980, the effect was a de facto ban. No research in this area can be done until it is reinstated. Four succeeding Secretaries of DHHS have failed to limit the moratorium. In January 1984, the NIH sent a request to DHHS for reestablishment of the board, but as of this writing, the Secretary has not acted on the request.

<sup>1</sup>John C. Fletcher and Joseph D. Schulman, "Fetal Research: The State of the Question," *Hastings Center Report*, vol. 15, April 1985, pp. 6-11.

A moratorium was proposed in 1976 on all R&D surrounding laser isotope separation of uranium. The proposal was to suspend all projects in the United States, "pending the results of efforts to achieve agreement with other industrialized nations to halt their work in this area." <sup>4</sup>The proposers acknowledged the complexity of implementation (and improbability of success) of such a moratorium, but used the proposal itself as a way to further public discussion of the policy on proceeding with the research. The Lilienthal-Acheson proposals in 1946 for regulation of atomic energy would have entailed a similar ban on research in certain sensitive fields .45

## Controls on Procedures

### Acquisition or Possession of Materials Used in Research

Research may be regulated through controls on the acquisition or possession of the chemicals or other substances necessary to do the research. For example, the Environmental Protection Agency (EPA) is authorized by the Toxic Substances Control Act (TSCA) to regulate the approximately 60,000 chemicals subject to the act, at all stages of their development.<sup>46</sup>TSCA recordkeeping and reporting requirements apply to research on chemicals and additional regulatory requirements apply when the chemicals are introduced into commerce .47

Federal regulations control the possession, use, and disposal of radioactive substances, including their use in research. Handling of nuclear and radioactive materials is governed primarily by the Nuclear Regulatory Commission (NRC), under the Atomic Energy Act of 1954.<sup>48</sup>The NRC has regulatory power over any materials made in a reactor. It does not have any jurisdiction over accelerator materials or over naturally occurring radioactive materials, although some States do regulate these substances. If the research institution is located within an "agreement" State, the investigator must be licensed by the State radia-

tion control agency. If the institution is within a "nonagreement" State, it must apply to NRC for a license. All research must comply with Federal and State OSHA regulations, which regulate exposure to toxic substances in laboratories.

For research using radioactive substances, then, there are various degrees of licensing and permits, depending upon what is done and the substance in question. Regulatory jurisdiction varies from State to State and between the Federal Government and the State. In addition, there is a tiered system of control based on the quantity of material in question. (NRC has established categorical exemptions from certain regulatory requirements for certain low-level radioactive materials. ) The requirements for a license pertain to the personnel and their qualifications, the facility, uses of the material, estimated human exposures, recordkeeping and reporting systems, and disposal practice .4' Large institutions conducting a lot of research may apply for a broad license, which delegates considerable decisionmaking power to the institution's Radiation Safety Committee. In all cases, radiation safety officers must be approved by the licensing agency and NRC must know and approve the qualifications of such individuals. Most research institutions have a radiation safety officer, even if they do not have a radiation safety committee. Licenses can be very precise, authorizing one investigator to use a specific material for a specific period of time.

There are also regulations for disposal of radioactive waste. All Federal institutions must comply with the Clean Air and Clean Water Act, if applicable. In addition, the institution must apply for a discharge and disposal permit from the State air pollution agency and/or the State water pollution agency. Both Federal and local regulations may apply to disposal as well.

If an institution is found to be in violation of the laws governing radioactive materials, civil monetary penalties can be imposed, and its license suspended or revoked; in addition, the organization would probably receive damaging press coverage. At large institutions, safety precautions may 'be emphasized, therefore, because of the consequences of a single mistake, primarily the sus-

<sup>4</sup>Barry M. Casper, "Laser Enrichment: A New Path to Proliferation?" *Bulletin of the Atomic Scientists*, January 1977, pp. 28-41.

<sup>45</sup>The complete text of the plan was contained in a State Department document, Publication 2498 (1946).

<sup>46</sup>15 U.S. C. Section 2601

<sup>47</sup>15 U. S.C. Section 2607

<sup>48</sup>See especially Title 10 of the Act

<sup>49</sup>10 CFR Parts 30-32.

pension of all of the institution's research using radioactive materials.

Department of Transportation regulations enacted under the Hazardous Materials Transportation Act govern shipments of certain research materials (e. g., radioactive materials, etiologic agents, poisons, corrosives, flammables) by requiring specific carriers, containers, or handling practices .50

Federal laws prohibiting the possession of narcotics act to restrict research in a number of fields, Researchers who wish to use controlled or illegal substances as a legitimate part of their research must first register with the Department of Justice; they are then investigated by the Drug Enforcement Administration and their research is validated by FDA. If approval is granted, the researcher must request the drug from the National Institute of Drug Abuse. If the research also involves human subjects, additional reporting requirements must be fulfilled. According to the Drug Abuse staff of FDA, the administration of these regulations used to be very time-consuming, but recent streamlining of the approval process and an apparently diminished interest in research involving controlled substances have reduced the number of requests and the time required to process them.

#### Requirements for Procedural Review Committees

Various Federal and State commissions have been given principal responsibility to implement legal regulations that apply to research procedures—in the case of the rDNA commissions, requirements for physical containment of the biological materials used in the research. By focusing on a very specific step in the research process, the Federal Government was able to establish standards of protection for workers and the community and as well as to set criteria for researcher (and institutional) accountability.<sup>51</sup> Once the rDNA guidelines were set (with the aid of the scientists), the discussion moved back to the sphere of the policy makers and administration *officials*, who were under political pressure from environmental and public interest groups.

<sup>50</sup>49 U.S. C. Sections 1803 et seq. and 49 C.F. R. Parts 100-179, "Dorothy Nelkin, "Threats and Promises: Negotiating the Control of Research, " Holton and Morison, op. cit., p.199.

Regulation may also occur at the very end of the research process, as in EPA regulation of field testing of new insecticides or for agricultural research involving rDNA. In a recent case involving insecticide-producing soil bacteria, the EPA has required the company to apply for an experimental use permit and to submit more research data on various aspects of the bacteria (e.g., its longevity in soil and its effect on nontarget species), an action that has the effect of restricting or delaying the use and dissemination of results from the project.

The Federal Government may also require that an institution set up review committees to monitor, approve, and shut down projects. The three principal types are Institutional Biosafety Committees (IBC), Institutional Review Boards (IRB), and Institutional Animal Care and Use Committees.

IBCs are mandated by the NIH *Guidelines for Recombinant DNA Research* and have served as the major locus of responsibility for oversight of that research since 1978. The latest NIH regulations<sup>52</sup> stipulate that an IBC must have "no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. " At least two members must have no affiliation with the institution apart from their membership on the IBC and should be chosen to represent the interest of the surrounding community with respect to health and protection of the environment. Unless exempt from review under the *Guidelines*, all rDNA research must receive IBC approval. Certain categories of research considered to be of questionable or high risk must be referred to the NIH Recombinant DNA Advisory Committee for approval before work can be initiated. There are currently 301 IBCs registered with the Office of Recombinant DNA Activity of NIH. Approximately 250 are academic IBCs; the rest are industrial. Compliance by industry is voluntary.

"Basic DHHS Policy for Protection of Human Research Subjects"<sup>53</sup> requires that all research in-

<sup>52</sup>49 *Federal Register* 227, Nov. 23, 1984.

<sup>53</sup>CFR 46,

volving human subjects conducted by the Department of Health and Human Services (DHHS) or funded in whole or part by a Department grant, contract, cooperative agreement or fellowship, undergo review by an IRB. (See box C.) As with an IBC, IRB membership is specified in the Federal regulations. The IRB must have five members and, per the *Guidelines*, “be sufficiently qualified through experience and expertise of its members, and the diversity of the members’ backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.” According to the Office for Protection from Research Risks, the office responsible for the implementation of the IRB regulations, there are currently over 5,000 operating IRBs in the United States. A 1979 study by Jeffrey M. Cohen and William B. Hedberg determined that, in 1 year, a typical IRB was in session 41 times and reviewed 278 proposals, involving approximately 80,000 potential research subjects.<sup>54</sup> That IRB cost the university \$36,000 during the year, or about \$130 per proposal.

Institutional Animal Care and Use Committees (IUCAC) are required of all institutions that receive Public Health Service (PHS) funds for research involving animals. Under revised PHS policies released May 1, 1985, those committees, which must have lay members, will have the responsibility for reviewing research plans and monitoring compliance. Prior to the establishment of these guidelines, nearly 1,000 institutions already had animal assurances through PHS. It is not known how many new committees will have to be established once the guidelines take effect. The new guidelines also require that all animal facilities must also be accredited by the American Association for the Accreditation of Laboratory Animal Care, a voluntary association that certifies animal handling facilities, or must conduct an assessment based on the NIH *Guidelines for the Care and Use of Laboratory Animals*. Accreditation is a necessary condition if an institution wants to receive PHS funds for research involv-

ing animals. By January 1, 1986, each institution receiving PHS funds must submit an “assurance of compliance” (containing such documents as descriptions of the facilities and membership and procedure of the local IUCAC) to the NIH Office for Protection from Research Risks.

### Contract Provisions

The provisions of research grants and contracts are used to enforce such things as limitations on spending, allocations of funds among budget categories, requirements that organizations be accredited or meet certain accreditation standards, and requirements that research designs or procedures be approved by the monitoring committees described in the previous section.

In the case of recombinant DNA research, the Asilomar recommendations were adopted by NIH, which then issued a set of guidelines covering research in designated categories. It applied to all recombinant DNA research funded by NIH. Today, the amended NIH *Guidelines for Recombinant DNA Research* set forth the generic requirements for safety in recombinant DNA research. These safety requirements apply through contract provisions to all recombinant DNA research in the United States which is conducted at or sponsored by an institution that receives any support for rDNA research from NIH.<sup>55</sup> Failure to comply can lead to termination of NIH funding or other NIH sanctions. Although limited to institutions funded by NIH, the *Guidelines* have been adopted or followed by virtually all Federal agencies, State and local agencies, and private organizations.

### Communication Controls

Reporting requirements in contracts can include regulations on the “deliverables” of a project, usually through prepublication review. Such contractual provisions are currently being invoked in order to restrict the flow of information believed to be linked to national military security or related to the Nation’s ability to compete in world markets. Contract provisions have been used, for example, to prohibit foreign nationals from be-

<sup>54</sup>Jeffrey M. Cohen and William B. Hedberg, “The Annual Activity of a University IRB,” *IRB*, May 1980, pp. 5-6.

<sup>55</sup>45 *Federal Register* 77384, Nov. 21, 1980, and 77409.

### Box C.—Research on Human Subjects

Until the 1960s—with the exception of the Nuremberg Code (1947)—there were no legal decisions from the courts and no Federal or State laws concerned directly with how humans were used in experiments (again, with the exception of violations of criminal law). NIH and PHS first began in **1953** to develop formal standards for human experimentation, but these efforts were not productive. The turning point was the increased volume of clinical investigations funded by the Federal Government (the shift in research performer) and government regulation of experimental drugs (manufacturing, distribution, and safety) in interstate commerce through FDA. Another factor was the thalidomide tragedy abroad, which triggered the 1962 Kefauver-Harris Amendments to the U.S. Food and Drug Act. Congress, in debate and not in the original bill, added the requirement to the law that subjects or patients be informed that they were to receive an experimental drug not fully licensed by the Federal Government and that their consent be obtained prior to receiving it. In **1966**, the U.S. Surgeon General issued the first PHS Policy and Procedure Order for extramural research on human subjects.<sup>1</sup> This Order required all institutions receiving PHS funds to review projects for the potential of abuse and it led to the formalization of the current system of IRBs.<sup>2</sup>

At present, most categories of human subjects research funded by Federal money or conducted at institutions that receive Federal subsidies are subject to some form of review or regulation. Federal agencies with oversight in this area specifically list those categories that are exempt or not subject to regulation; but, research conducted without direct or indirect Federal funding is not subject to human subjects regulations. In addition, some populations may not be adequately protected by existing regulations.

All research funded in whole or in part through DHHS by direct award, cooperative agreement, or fellowship, then, is subject to human subjects regulations [45 C.F.R. 46, Section 46.101]. Indirectly, all research conducted at or sponsored by institutions which do not receive DHHS funds are not legally required to comply, but according to Charles McKay, of the NIH Office for Protection from Research Risks, 96 percent of the 500 major institutions conducting research apply DHHS regulations to research not funded by DHHS. Compliance is indicated through a statement of assurance. Regulations of FDA cover clinical investigations with regard to products specified in the Food, Drug, and Cosmetic Act for marketing. These include drugs, biological, blood and blood products, devices, and food additives. In addition, the U.S. Department of Agriculture (USDA) regulates clinical investigations of food additives. For the Department of Defense, the Veterans Administration, and 20 other agencies, varying degrees of regulations are tied to direct or indirect use of their funds. All use IRBs and informed consent practices. There is an effort underway by the Office of Science and Technology Policy and near completion—to have cross-agency uniform regulations very similar to the existing DHHS regulations.

Despite these efforts, research on human subjects does take place under conditions or in institutions exempt from DHHS regulation. DHHS itself exempts educational research, test development, interview and observation research, and research involving specimens and/or medical records, as long as the information taken from these sources is recorded in such a manner that subjects cannot be identified or that the information revealed would place the subject at risk. The Department of Justice has exemptions in their coverage of prison research, and has legal prohibitions against regulation of research on recidivism and probation. The Department of Defense exempts epidemiological research from regulation. Industrially related research (e.g., academics doing consultative work designing systems to improve worker efficiency) is not subject to regulation. All product marketing research (testing of products not FDA or USDA regulated) is exempt from DHHS regulations; some of it is covered by consumer safety laws, but those only apply after the product is on the market. Moreover, the regulatory intent is to protect the public rather than the subjects.

<sup>1</sup>Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Injury in Clinical Investigation," *Limits of scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 138.

<sup>2</sup>William J. Curran, "The Approach of Two Federal Agencies," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969).



One of the solutions to criticism has been to sharpen the procedures for ensuring that subjects have knowingly and willingly consented to participate in an experiment. There is now an extensive body of law and regulatory controls, and literature, debating the social and moral aspects surrounding the question of informed consent to human experimentation. Today, the United States regulates research to protect the physical or psychological health or the privacy of the human subjects used in research under guidelines established by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Research Act of 1974 instructs the Commission to: 1) "identify the basic ethical principles which should govern research involving human subjects and to recommend guidelines and mechanisms for assuring that such principles are observed; 2) "to clarify the requirements of informed consent to research in the cases of children, prisoners, and the institutionalized mentally infirm;" and 3) "to investigate the use of psychosurgery and recommend policies for its regulation."<sup>8</sup>

ing employed on a research project.<sup>56</sup> More recently, the Federal Government has used grant and contract terms as a means of directly controlling dissemination of research results, <sup>57</sup> by requiring that the researcher or institution allow prepublication review by the sponsoring or interested Federal agency. Contracts for classified work, of course, routinely include such provisions but some agencies have begun to invoke prior approval provisions previously considered to be *pro forma* (or have considered revising their standard contracts to include such provisions). The purpose of requested delays or review is to allow the opportunity for either classification or alteration (editing and censorship).

In one such case in 1980, NSF refused to fund parts of a cryptology proposal submitted by a computer scientist because of the national security implications of his work. A later decision awarded the funds to the researcher with the stipulation that he take responsibility for seeking prior constraint as required by the content of his work. NSF eventually drafted new language for all its contracts to require that a grantee take responsibility for notifying the cognizant NSF Program Director if data, information, or materials developed in the course of research appear to require classification. NSF retains the option—after review of the information—to defer dissemination, distribution, or publication.

<sup>56</sup>*Scientific Freedom and National Security*, Issue 5 (Washington, DC: American Association for the Advancement of Science, March 1985), p. 7.

<sup>57</sup>*Interim Report of the Committee on the Changing Nature of Information* (Cambridge, MA: Massachusetts Institute of Technology, Mar. 9, 1983), Section 4.5.

The mechanism of classification (or the threat of the possibility of classification) can also be used to delay publication. This tactic has been used by the National Security Agency to delay journal publication of a number of scientific articles on cryptography.<sup>58</sup> From 1982 to 1985, Federal regulations on the export of technical information have been used to bar certain foreign nationals from attending otherwise open society meetings and have been used to require researchers to withdraw unclassified technical papers scheduled for presentation at professional society meetings because foreign nationals might attend those meetings.<sup>59</sup>

In addition to contract provisions, there are nine major legal mechanisms by which the U.S. Government can restrict formal and certain informal communication of scientific and technical information.

1. **The Arms Export Control Act of 1976** and the resulting International Traffic in Arms Regulations and U.S. Munitions List, administered by the Department of State, authorize control of the export and import of defense articles and defense services, including export of technical data related to defense articles.

2. The Export Administration Act of 1979, implemented through the Export Administration Regulations, Commodity Control List (CCL), and Militarily Critical Technologies List (MCTL), and administered by the Department of Commerce,

<sup>58</sup>*Ibid.*

<sup>59</sup>*Free Trade in Ideas: A Constitutional Imperative* (Washington, DC: American Civil Liberties Union, May 1984); Long, *op. cit.*, see especially the table of meetings that have been restricted.

authorizes control of the export of tangible goods, including technical data, in the interest of national security and foreign policy and, to a lesser extent, to protect the domestic economy. MCTL designates arrays of technical information, expertise, or equipment that DOD believes would make a significant contribution to the military potential of another country if exported. The unclassified version of this list is over 200 pages long; the classified is reported to be over 700.<sup>60</sup> Both the CCL and the MCTL were not intended to be control documents, but rather to be reference lists of the sensitive technologies,

3. Executive Order 12356 of 1982 authorizes classification of information, including that pertaining to "scientific, technological, or economic matters," that is "owned by, produced by or for, or is under control of U.S. government" for national security purposes. The order contains a specific exemption for "basic scientific research information not clearly related to national security,"

4. The Atomic Energy Act of 1954, as amended, places explicit controls on scientific information and defines restricted data. The act is not limited to nuclear physics nor even to activities of the Federal Government; its language is sufficiently broad to allow the extension to "privately generated" knowledge as well. A 1981 amendment allows the Secretary of Energy to adopt regulations on the dissemination of unclassified information regarding either the design of facilities or their security measures.<sup>61</sup>

5. The Invention Secrecy Act of 1951 authorizes the defense agencies to review applications submitted to the Patent and Trademark Office

<sup>60</sup> Long, op. cit.

<sup>61</sup>Harold C. Relyea, "Shrouding the Endless Frontier—Scientific Communication and National Security: The Search for Balance," *Striking a Balance: National Security and Scientific Freedom*, Harold C. Relyea (ed.) (Washington, DC: American Association for the Advancement of Science, 1985), p. 85

and, if publication of the patent is deemed harmful to national security, to declare the invention secret for a period of 1 year (with restriction annually renewable). The justifications for the Invention Secrecy Act (1951) are to allow defense agencies to review applications for patents submitted to the Patent and Trademark Office, with the goal of catching inadvertent violations. If publication of a patent is judged to be potentially harmful to national security, then a 1-year, renewable secrecy order is issued.<sup>62</sup>

6. The Freedom of Information Act contains provisions allowing but not requiring agencies to exempt certain types of information from mandatory disclosure.

7. Executive Order 12333 on Intelligence, issued December 4, 1981, allows for the covert collection of information by agents posing as academics.

8. A number of DOD directives on national security and classification based on 10 U.S. C. 140c allow that agency to restrict information developed by scientists under DOD contract. Directive 5230.25 outlines the conditions under which DOD can withhold classified data from general public dissemination in accord with export control laws. An October 1984 memorandum on "Publication of the Results of DOD sponsored Fundamental Research" sets forth policies on publications. And Directive 5230.24 (November 1984) requires all newly created technical documents in DOD to carry statements defining distribution and indicating how requests for the document should be handled.

9. The Immigration and Nationality Act may be used to refuse admission to or deport foreign scholars from U.S. research activities.

<sup>62</sup>Ibid.

## THE ROLE OF THE COURTS IN THE REGULATION OF RESEARCH

Statutory law governs the role that the judicial branch may play in the regulation of research: the courts respond to and interpret existing government action. The Federal courts have no jurisdiction other than to interpret the laws enacted by

Congress or regulatory actions taken under Federal, State, or local statutes.

The courts have frequently been used, however, in environmental disputes to require Federal agen-

cies to perform, commission, or use research to support environmental policy decisions. The intent—through lawsuit—has been to force the agencies to increase or, in some cases, to improve their use of research. The effect, at least in the 1970s, was to strengthen the quality and increase the amount of environmental science research. Environmental lawsuits are, however, just part of a general shift in the use of the judicial system to affect social policy.<sup>63</sup> More dramatic use of the courts occurs when, after a plaintiff has filed suit, the court issues an injunction that prohibits the research from going forward at all. In the case study presented in chapter 7, the Supreme Judicial Court of the Commonwealth of Massachusetts at first issued a temporary restraining order against a municipal public health order that had attempted to stop research at a local laboratory; that court later ruled to uphold the city's right to impose such a ban.

In May 1984, Federal District Judge John Sirica, in effect, put a moratorium on all field tests of genetically modified microbes being conducted by the University of California.<sup>64</sup> The experiments in question involved tests of genetically engineered bacteria (*Pseudomonas syringae*) designed to prevent frost formation on plants. In September 1983, a group of plaintiffs led by Jeremy Rifkin and the Foundation on Economic Trends claimed that NIH was violating National Environmental Protection Act (NEPA) requirements for an envi-

<sup>63</sup>Donald L. Horowitz, *The Courts and Social Policy* (Washington, DC: The Brookings Institution, 1977).

<sup>64</sup>Marjorie Sun, "Rifkin and NIH Win in Court Ruling," *Science*, vol. 227, Mar. 15, 1985, p. 1,321.

ronmental impact statement. NIH claimed that its approval process more than satisfied the NEPA requirements.<sup>65</sup> On April 12, 1984, Rifkin filed a motion for injunction to prevent the researchers from proceeding with a field test experiment scheduled for May. On May 16, Judge Sirica granted the motion for a preliminary injunction and ordered that: 1) NIH be enjoined from approving experiments involving the intentional release of recombinant DNA, and 2) that the University of California be enjoined from proceeding with the experiment until final resolution on the case. In subsequent court action, the U.S. Court of Appeals for the District of Columbia ruled (February 27, 1985) that experiments could proceed if their potential environmental effects were properly evaluated. NIH must now prepare environmental assessments.

Recently, an additional legal action has introduced controversy into what has usually been a quiet region of the scientific community, agricultural research. In 1979, attorneys filed a lawsuit, on behalf of 17 farm workers and the California Agrarian Action Project, that charged the University of California with unlawfully spending public funds on mechanization research that displaced farm workers.<sup>66</sup> (For a full description of the case, see app. A.)

<sup>65</sup>Judith A. Johnson, "Recombinant DNA: Legal Challenges to Deliberate Release Experiments," U.S. Congress, Library of Congress, Congressional Research Service, Science Policy Research Division, report No. 85-502, Jan. 7, 1985.

<sup>66</sup>Philip L. Martin and Alan L. Olmstead, "The Agricultural Mechanization Controversy," *Science*, vol. 227, Feb. 8, 1985, pp. 601-606.

## MECHANISMS FOR SOCIAL CONTROL OUTSIDE OF GOVERNMENT

Public opinion can be a potent force for pressuring government to enact regulation or enforce more stringently existing rules. It is most often expressed through the mechanisms of public meetings, picketing, protest, violence, or political action organizations. For example, recent activities by animal rights organizations have included break-ins, vandalism, and theft of animals, data and equipment from laboratories using animals in their research; in some cases, direct threats have

been made to the lives and safety of investigators and their staff. More moderate groups have used the traditional policy arena to seek change, lobbying Congress and State legislators for stricter laws. In summer 1985, DHHS Secretary Margaret Heckler suspended funding for a head trauma study utilizing anesthetized baboons at the University of Pennsylvania after members of the Animal Liberation Front (ALF) illegally raided the University lab, stealing videotapes and destroy-

ing equipment. DHHS officials contend that while the research protocol was considered to be scientifically justifiable, the laboratory had violated its animal welfare assurance to NIH, and that the decision to suspend funds was unconnected to the sit-in conducted by ALF at the NIH Bethesda Campus.

A number of church groups, in the United States and abroad, have recently provided an additional mechanism for expression of social control on research. Through conferences, newsletters, and "pastoral letters," religious organizations have attempted to educate their members, raise public awareness about the theological and ethical dilemmas posed by research, or to sway public action concerning regulation of specific areas of research. In 1979, for example, the World Council of Churches sponsored a World Conference on Science, Faith, and the Future at which scientists, theologians, trade unionists, businessmen, and politicians met to discuss the nature of science and of faith. More recently, the Episcopal Diocese of Massachusetts convened a Biotechnol-

ogy Study Group to develop a study guide for use in churches. The guide addresses the implications of new developments in gene therapy, genetic engineering, and fetal research. Theologians have also taken more direct approaches in registering their concern, such as the 1983 "Theological Letter Concerning the Moral Arguments Against the Genetic Engineering of the Human Germline Cells," a letter signed by representatives of virtually every major church organization in the United States. Most recently, the House of Bishops of the Episcopal Church adopted an official position on genetic engineering that "encourages . . . research directed to an increase in human understanding of vital processes, recognizing that human DNA is a great gift of God . . ." <sup>67</sup> In addition, the Bishops asked that Congress ensure that FDA or an appropriate agency seek advice from ethicists and the lay public to assure that use of genetic engineering is ethically acceptable. <sup>68</sup>

<sup>67</sup>Cited in *Science*, vol. 230, No. 4724, Oct. 25, 1985, p. 423.

<sup>68</sup>*Ibid.*

## SUMMARY

There have always been measures of control imposed on the scientific community. Most often the controls have been in the form of self-restraint, imposed by the scientific community through peer review and peer pressure. These controls have been shaped by scientific and technological criteria as well as by the social values and norms apparent in the ethical codes and standards adopted by most scientific societies. It is only recently in the history of science that so many institutions and social forces have influenced in so many ways the conduct of science.

As described in this chapter, research can be directly controlled at all stages of the scientific process. Forces can affect the agenda, the process, and the dissemination of results. These forces

can be exerted informally, through professional and peer pressure; formally, through institutional mechanisms; or legally, through Executive orders, legislation, and agency rulemaking. Finally, the courts can be used as a mechanism for interpretation of legal controls.

The value of this "cobweb" of direct control lies in its democratic and pluralistic nature. The danger of this system, however, lies in the potential for uncoordinated and potentially conflicting mechanisms for direct control. The potential complexity of this approach to regulation may be exacerbated when compounded by the many levels and forms of indirect control of research, to be examined in chapter 5.