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Health, Education and Human Services Division

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March 25, 1996

The Honorable Dan Miller
House of Representatives

The Honorable John Porter
House of Representatives

In your June 6, 1995, letter, you expressed concern that the costs of complying with the growing number of federal regulations may be affecting research sponsored by the National Institutes of Health (NIH). NIH is the federal government's primary agency charged with conducting and supporting biomedical research. NIH grant funds may be spent on compliance activities required by a variety of regulations, thereby reducing funds available for research.

In fiscal year (FY) 1995, NIH received over \$11 billion in federal funds. Over 80 percent of these funds were devoted to NIH's Extramural Program, supporting biomedical research at 1,700 organizations around the nation. Most of the funding was awarded to colleges, universities, and medical schools. In addition, NIH supported more than 2,000 research projects conducted in its own laboratories through its Intramural Research Program.

Researchers, including NIH grantees, are expected to comply with regulations issued by many federal agencies. These regulations were promulgated for a variety of reasons, such as promoting safety or protecting the environment, and apply to a variety of entities, including research facilities. For example, the Occupational Safety and Health Administration sets standards for worker protection and the Environmental Protection Agency regulates airborne emissions, including those from laboratories, following the provisions of the Clean Air Act. State and local governments also issue regulations in their jurisdictions that apply to researchers as well as to others. In addition to regulations established by other federal agencies, NIH establishes procedures that its grantees must follow in conducting research, ranging

GAO/HEHS-96-90R Regulatory Compliance for NIH Grantees

from requirements to establish biosafety committees when recombinant DNA technology is used to certifications of compliance with civil rights laws. The specific regulations and procedures governing any particular scientist or laboratory are related to the type of research being performed, among other things.

As agreed with your staff, we are providing a list of federal regulations affecting researchers such as NIH grantees, that was developed by the Council on Governmental Relations, an organization of research universities. We are also providing a list of the types of regulations those in the research community we met with perceive to be most burdensome and costly to implement. You asked us to explore the possibility of quantifying the costs of regulatory compliance and determine the feasibility of estimating the amount of NIH grant funds spent on activities with no purpose other than complying with regulations. However, as discussed with your staff, given the limitations of available data, we could not determine how much of these funds are spent on regulatory compliance.

To do our work, we interviewed representatives from seven professional organizations representing the scientific and academic research community. We obtained reports and other materials from these organizations regarding the impact of federal regulations on research. In addition, we met with NIH officials, researchers, research administrators, faculty and senior officials at three universities, and other interested parties. (See table 1 of the enclosure for a complete list of the organizations we contacted.)

We performed our review between August 1995 and January 1996 in accordance with generally accepted government auditing standards.

In summary, we found that both researchers and administrators are increasingly concerned with the growing number of regulations with which they must comply. While recognizing that many regulations serve valuable purposes, they also reported that compliance activities are placing an inordinate burden on the research community. Although confident that compliance costs are high, members of the research community were unable to provide cost data directly attributable to compliance activities. Moreover, even if such data could be obtained, they may not be useful because they may be unreliable and may not be representative.

ALTHOUGH CONCERNED ABOUT GROWING
REGULATORY BURDEN, RESEARCH COMMUNITY
SUPPORTS REGULATORY GOALS

Nearly all those we interviewed told us that the number of regulations affecting biomedical research has grown substantially and that the regulations impose an increasing burden on research organizations. For example, regulations implemented in the last 10 years have included additional protections for workers handling hazardous materials. (See table 2 in the enclosure for the Council on Governmental Relations' list of federal regulations affecting the research environment). While different regulations were cited as most burdensome or costly by different researchers and administrators, there was consensus that the overall increase in regulations is straining the resources available in the research community. Consistently, the time and attention of staff that must be dedicated to compliance activities are viewed as coming at the expense of scientific endeavors.

However, those that we spoke with also support the goals of almost all the regulations we discussed with them, believing that they serve important purposes. Four of the five principal investigators we spoke with concurred that some of these regulations are legitimate and necessary. For example, one principal investigator explained that regulations regarding the disposal of hazardous materials are absolutely necessary. Similarly, the administrators and other scientists we spoke with agreed that some regulations are needed, but they are also concerned that some regulatory requirements or methods of implementing regulations result in an inordinate burden or cost. The same principal investigator who commented on the necessity of the hazardous disposal regulations also expressed concern that the labelling requirements and paperwork related to the storage of laboratory chemicals are excessive.

Members of the biomedical research community reported that different regulations are burdensome and costly to their institutions. The areas of regulation most frequently reported as costly or burdensome include environmental protection rules, protections for human subjects, animal care and use rules, and conflict-of-interest disclosure requirements. For example, several researchers and administrators told us that chemical labelling and disposal rules seem to be designed for

larger entities. Others reported that the recent conflict-of-interest regulations may require some universities to establish a new office or hire additional staff dedicated to handling anticipated new paperwork. (See table 3 in the enclosure for a listing of the regulatory areas reported as costly and burdensome by researchers.)

Regardless of the type of research being performed, staff time devoted to compliance was typically reported by administrators and researchers as the greatest cost and burden. Beginning with the initial grant application process and continuing throughout the life of the grant, time devoted to compliance is a pervasive concern of administrators and researchers. For example, the documentation requirements involved in the care of laboratory animals was frequently cited as expensive and time-consuming, while adding no value to animal care or research results. In fewer instances, officials expressed concern with the costs and burdens of having to remodel facilities, purchase specific equipment, or obtain certain services to meet regulations and requirements.

COST DATA NOT READILY AVAILABLE
AND MAY BE OF LIMITED USE

We did not estimate the costs of regulatory compliance because the needed data are not readily available. Neither the academic institutions we visited nor the organizations representing the research community maintain systems that can differentiate the costs of regulatory compliance. Because many of an institution's functional areas, may be involved in compliance activities, its ability to establish costs becomes more difficult.

While researchers lacked documentation of staff time devoted to regulatory compliance activities, it was the most frequently cited cost. Although the scientists and administrators at the universities we visited were sometimes able to provide us with an approximation of the percentage of time that they and their staff devote to compliance activities; estimates of such costs may be unreliable because salary and benefit costs would not necessarily be saved if the regulatory requirements were eliminated.

A further difficulty in estimating the costs of compliance is the challenge of determining what costs

would have been incurred if the regulations were not in place. Most of the officials that we spoke with told us that prudent management, the needs of good science, or general safety would compel them to take actions for most regulated activities, even without regulations. For example, while some officials were concerned with the costs of protecting human subjects, they also told us that procedures must be in place to ensure their protection. Therefore, the costs of complying with regulations for the protection of human subjects are the institution's current costs less the cost of what they would do to protect human subjects in any case. Scientists and administrators suggested that some of the same steps included in regulations would be followed, even in the regulation's absence. In addition, several researchers and administrators noted areas where they currently exceed regulatory requirements or where they previously had procedures in place that are now required by regulation.

Finally, the unique situations facing each institution raise questions about the ability to generalize from the experiences of individual institutions. For example, some officials told us that states and localities impose their own regulations that are more stringent than federal regulations in some instances. In such situations, the elimination of federal regulations would not reduce the burden or costs. Other officials told us that because operational costs may vary by institution, implementation of similar regulatory requirements may result in disparate costs in different locations.

AGENCY COMMENTS

NIH officials reviewed a draft of this report and consider it a balanced presentation of the regulatory compliance issues affecting the agency's grantees. They share the concern expressed by researchers and administrators that compliance activities require substantial time and resource commitments. Under the National Performance Review, NIH is examining and redesigning its grant administration policies and practices. The NIH officials stressed that the goal of their reinvention efforts is to encourage optimal use of resources while advancing science, promoting integrity, reducing administrative burdens, and facilitating compliance. The NIH officials also offered several technical comments that we have incorporated as appropriate.

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We are sending copies of this letter to the Director of NIH. We will make copies available to others upon request. Major contributors include Paul Alcocer, Geraldine Redican-Bigott, Angela Pun, and Frederick Schmidt. Please call me at (202) 512-7123 if you or your staff have any questions concerning this correspondence.



Sarah F. Jaggard
Director
Health Financing
and Public Health Issues

Enclosure

Table 1: Organizations Contacted

American Physiological Society
American Society for Microbiology
Association of American Medical Colleges
Association of American Universities
Baylor College of Medicine
Congressional Budget Office
Congressional Research Service
Council on Governmental Relations
Department of Health and Human Services
Executive Office of the President
 Office of Science and Technology Policy
Federation of American Societies for Experimental Biology
Massachusetts General Hospital
National Academy of Sciences
 Federal Demonstration Project
National Academy of Sciences
 National Research Council
National Association for Biomedical Research
National Institutes of Health
Northwestern University
Office of Technology Assessment
The University of Chicago
The University of Illinois at Chicago

Table 2: Excerpt from the Council on Governmental Relations' Inventory of Regulations, February 12, 1996^a

Regulation	Requirement
Drug-Free Workplace (P.L. 100-690)	Development of drug-free workplace policy
Drug-Free Work Force (DOD only) (DFARS 223.570)	Requirements of drug-free workplace plus supervisory training and random drug testing
Drug-Free Schools and Campuses Act (P.L. 101-226)	Annual distribution in writing to each employee and student describing standards of conduct, legal sanctions, health risks and counseling, treatment and rehabilitation with respect to use of illicit drugs and abuse of alcohol
Lobbying (Byrd Amendment) (P.L. 101-121)	Requires disclosure of lobbying activities regardless of source of funds; prohibits lobbying with Federal funds
Lobbying Disclosure Act of 1995 (P.L. 104-65)	Requires registration of institutions who employ individuals who make at least two lobbying contacts each 6 months, devote 20% time to lobbying activities, and incur expenses for lobbying of \$20,000 or more in each six month period

^aWe did not edit or verify the information in this table. The Council on Governmental Relations, an organization of research universities, developed this list because of concern that principal scientists are required to spend increasing amounts of time on administrative functions, thereby diverting dollars from direct research to cover some unnecessary regulatory burdens. This inventory also provides a description of the burden imposed by each regulation. It recommends revisions to 70 percent of the listed regulations, while proposing no change to the remaining 30 percent. Many of the recommended revisions entail simplifying certification requirements.

Davis-Bacon Act (P.L. 86-624 & 88-349)	Payment of not less than minimum wages to laborers and mechanics; wages paid at least once a week
Walsh-Healey Public Contracts Act (41 USC 35)	Imposition of fair social employment standards on government contractors
Service Contracts Act (41 USC 351)	Requires minimum wages and fringe benefits, safe and sanitary working conditions, notification to employees of the minimum allowable compensation, and equivalent federal employee classifications and wage rates
Contract Work Hours and Safety Standards Act of 1962 (40 USC 327-333)	Prescribes protection to laborers and mechanics employed on government contracts and prescribes forty-hour work week with paid overtime at a rate of not less than one and one-half times the rate of basic pay
Misconduct in Science (FR 5/14/89 & FR 8/8/89)	Development of institutional procedures to respond to allegations of misconduct
Procurement Integrity (41 USC 423)	Prohibition of certain activities by competing contractors, government procurement officials, and other individuals during the conduct of a federal agency procurement process
Debarment and Suspension (EO 12549)	Provides sanctions to individuals or entities for fraudulent or improper use of federal funds
Covenant Against Contingent Fees (FAR 52.203-4)	Requires that no individual or firm can be paid a contingent fee to secure government contracts

Anti-Kickback Act of 1986 (FAR 52.203-7)	Prohibits payment to subcontractors by prime contractors when such payments were made for the purpose of improperly obtaining or rewarding favorable treatment in connection with either a prime contract or subcontract relating to a prime contract
Buy America Act (41 USC 10)	Requires each end product to be substantially mined, produced or manufactured in the US
Fly America Act (FAR 52.247-63)	Requires that US flag carriers be used for personal transportation and property when US funds used; very few exceptions
Competition in Contracting (10 USC 2304; 41 USC 253)	Requires full and open competition for US government procurements
Export Administration Act and Arms Export Control Act (50 USC 2401-2420; 22 USC 2778)	Under certain conditions, provides for restriction on export of technology, including scientific and technical data
Insurance - Immunity From Tort Liability (FAR 28.301)	Contractors receiving cost-reimbursement r&d contracts must provide liability from injuries to third parties
Prompt Payment (P.L. 97-177)	Provides for payment of interest to contractors due to late payment by the government of invoices
Certificate of Current Cost and Pricing Data (FAR 15.801-1)	Provides that cost and pricing data submitted is accurate and current
Non-Delinquency of Federal Debt (OMB A-129)	Requires that federal agencies take appropriate steps to insure that those receiving federal financial assistance are not delinquent on loans or other accounts to the federal government

Certificate of Technical Data Conformity (DFARS 252.227-7036)	Requires that technical data delivered under a DOD contract is complete, accurate, and in compliance with requirements
Certification of Accuracy of Indirect Costs (FAR 52.242-4)	Requirement that all contractors certify under penalty of perjury that all indirect costs are allowable and properly allocated
Student Unrest	Requirement annually in HHS appropriation act that no payment can be made to individuals involved in campus unrest after August 1, 1969
Acknowledgement of Federal Grant Support (DHHS only)	Requirement on any statements or other documents funded in whole or in part with federal money, that percentage of total costs, dollar amount of federal funds, and total costs of project be clearly stated
The Coordinated Review Process (EO 12372)	Mandates state-level review of certain federal programs after rescission of OMB A-95. Purpose of review stated as coordination of development and support money
Resource Conservation and Recovery Act (RCRA), reauthorized in 1984 for hazardous and solid wastes (40 CFR 260-265, 270)	Brought small quantity hazardous waste generators, including colleges and universities, into the regulated community
Underground Storage Tanks (40 CFR 280)	Requires underground storage tanks to meet standards relating to corrosion protection and the prevention of spills and overflow, and requires new systems to be equipped with leak detection devices

<p>Toxic Substance Control Act (40 CFR 761)</p>	<p>Regulates polychlorinated biphenyls used in electrical transformers. Educational institutions must comply with EPA regulations concerning use, service, storage, and disposal of transformers containing PCBs</p>
<p>Right to Know regulations (Hazard Communication Standard), 1987 (29 CFR 1910.1200)</p>	<p>Requires employers to provide employees with certain information regarding chemical identity, safety, and related health effects of materials with which they come into contact while on the job</p>
<p>Historic Preservation (Section 106 of National Historic Preservation Act of 1966)</p>	<p>Activities which involve construction, acquisition, or modification of any items on registry require coordination between awarding agency and recipient institution</p>
<p>Civil Rights Act of 1964 (P.L. 88-352), codified at 42 USC 20000D et seq.</p>	<p>Bars recipients of federal funds from excluding persons because of race, sex, color, or national origin</p>
<p>Employment of the Handicapped - Rehabilitation Act of 1973 (20 USC 793; 29 USC 794; FAR 22.14)</p>	<p>As a condition of award, institution must execute either with each award or have on file with agency an assurance that federally funded activities will be made available and accessible to handicapped persons and that there will be no discrimination based on handicap</p>
<p>Americans With Disabilities Act, 1990 (P.L. 101-336)</p>	<p>Extends protection as in Civil Rights Act of 1964 to individuals with disabilities</p>
<p>Sex Discrimination (Title IX, 1972) (P.L. 92-318, codified at 20 USC 1681-1686)</p>	<p>Prohibits exclusion of individual on basis of sex from any education program or activities receiving federal support</p>

<p>Age Discrimination (P.L. 94-135, codified at 42 USC 610 et seq.)</p>	<p>Prohibits unreasonable discrimination on the basis of age in any program or activity receiving federal assistance. In actuality, adds age to the Civil Rights Act of 1964.</p>
<p>Equal Employment (EO 11246; FAR 52.222-26)</p>	<p>Requires equal opportunity without regard to race, sex, color, religion, or nationality to persons employed or seeking employment</p>
<p>Affirmative Action for Special Disabled and Vietnam Era Veterans (38 USC 2012; 41 CFR parts 60-250 and 61-250; FAR 52.222-28)</p>	<p>Employers are to list all suitable employment opportunities with local employment service office and take affirmative action to employ and advance qualified special disabled veterans and veterans of the Vietnam Era without discrimination based upon disability or veteran's status.</p>
<p>Utilization of Women-Owned Small Businesses (15 USC 631-647, EO 12138, FAR 52.219-13)</p>	<p>Directs agencies to take appropriate action to facilitate, preserve, and strengthen women's business enterprise</p>
<p>Utilization of Labor Surplus Area Concerns (44 CFR 331; 20 CFR 654, Subpart A; 15 USC 644 (d), (e), (f); FAR 52.220-3)</p>	<p>Assures appropriate contracts will be awarded to eligible Labor Surplus Area concerns</p>
<p>Utilization of Small and Small Disadvantaged Business Concerns (15 USC 631-647, 13 CFR 125.4(g)(7), P.L. 95-507, FAR 52.219-8 and 9)</p>	<p>Provides maximum practical opportunities to small and small disadvantaged businesses to participate in contract performance</p>
<p>Confidentiality of Patient Records (P.L. 92-255, Section 408, 21 USC 1175, P.L. 91-616, Sect. 333; 42 USC 4582; 42 CFR 2)</p>	<p>Protects persons with substance abuse problems who seek treatment</p>

<p>Clean Air Act and Clean Water Act (42 USC 7401; 33 USC 1251 et seq.; EO 11738; 40 CFR, Part 15)</p>	<p>Prohibits use of facilities listed by the EPA as violators of these acts to be used for performance of government contracts</p>
<p>Hazardous Materials (40 USC 327-330; 29 CFR, Part 5; FAR, Subpart 23.3)</p>	<p>Institutions must notify employees of hazards in the workplace describing hazard, symptoms, and precautions</p>
<p>Human Subjects Compliance (P.L. 93-348, Implemented by 45 CFR 46. Final rules 56 FR 28004)</p>	<p>Sets forth common federal policy for the protection of human subjects. Applies to each federal agency supporting research involving human subjects.</p>
<p>Use of Animals in Research (Animal Welfare Act) (P.L. 89-544 as amended by P.L. 91-579, 94-279, 99-198; 7 USC 2131 et seq; CFR, Title 9, Subchapter A, parts 1-4; NIH Guide 85-23)</p>	<p>Sets forth policy to ensure that animals used in research, for exhibition or as pets receive humane care and treatment. Provides for regulation of transport, purchase, sale, housing, care, handling and treatment of animals</p>
<p>Marine Mammal Act (P.L. 92-522)</p>	<p>Organizations wishing to use marine mammals in research must apply for and receive a permit specifying the number and kind of animals to be used and the period of time for which the permit is requested</p>
<p>Research Involving Recombinant DNA Molecules No statutory authority, guidelines issued by NIH May 7, 1986 et seq.</p>	<p>Specifies practices for constructing and handling recombinant DNA molecules, organisms, and viruses containing recombinant DNA molecules</p>
<p>Bloodborne Pathogens (29 USC 655)</p>	<p>Requires training, controls, protective equipment, vaccinations, recordkeeping, etc. for personnel handling potentially infectious materials</p>

Rights to Inventions Made by Non-Profit Organizations and Small Business Firms (37 CFR Part 401)	Vests title to patentable ideas conceived or developed under federal sponsorship in nonprofit organization or small business subject to certain conditions
Conflict of Interest (NSF, 59 FR 35820) (PHS, 59 FR 35809)	Requires disclosure by principal investigators of certain financial interests; institutional review, management, reduction, or elimination of potential financial conflicts that might threaten the objectivity of the research
Workplace Substance Abuse Programs (DOE, 10 CFR 707)	Requires drug testing, training, education, employee assistance programs for contractor employee at certain DOE nuclear test sites
Small Business Set-Asides (FAR, Part 18-19)	Federal contractor and subcontractors may, under certain contracts in excess of \$100,000, be required to set aside a portion of funds for procurements for small and other disadvantaged businesses
Military Recruiting (P.L. 103-337)	Any segment of an institution receiving DOD funds must allow campus entry, access to students, and directory information for military recruiting purposes
Cost Accounting Standards (59 FR 55756)	Institutions receiving negotiated contracts in excess of \$500,000 must adhere to four CAS standards, submit disclosures, and comply with other requirements when making accounting changes
OMB Circular A-21 (Cost Principles)	Prescribes principles for allowability of costs in agreements between colleges and universities and the federal government

OMB Circular A-110 (Uniform Administrative Requirements)	Sets forth uniform administrative requirements for grants and contracts awarded to institutions of higher education
OMB Circular A-133 (Audit Requirements for Universities and other Nonprofits)	Sets forth audit standards for colleges and universities
OMB Circular A-128 (Audit Requirements for State and Local Governments)	Sets forth audit standards for state and local governments (which at the state's designation may include colleges and universities)

Table 3: Areas of Regulation Reported by Researchers and Administrators as Burdensome or Costly

Environmental protection regulations relating to the handling and disposal of hazardous waste (including radioactive isotopes) and emissions from laboratories
Worker protection regulations regarding labeling laboratory chemicals, providing certain types of safety equipment, maintaining serum samples, and training staff
Human subject protection rules relating to periodic reviewing of clinical trial proposals and subsequent documentation and informed consent procedures
Animal care regulations relating to the care, protection, and use of animals in biomedical research
Cost accounting standards applying to recipients of federal research funds
Conflict-of-interest regulations involving disclosure of information by researchers receiving federal research money
Permitting requirements relating to importing, exporting, and transporting of biological samples
Construction and renovation requirements resulting from the Americans with Disabilities Act

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