Federal, state, and local laws and regulations entail significant costs for universities engaged in federally sponsored research. While the laws and regulations are enacted for worthwhile purposes, they bring about real costs. Universities must design and maintain their facilities to comply with these requirements, and they must create mechanisms to ensure and certify compliance. The costs are substantial in both facilities and administration. The imposition of a cap on administrative costs that can be included in F&A rate negotiations means that universities must bear all administrative costs over the cap. One option for reducing administrative costs would include reducing some of the administrative requirements generated by these laws and regulations. The potential savings could benefit both the universities and the government.

THE SPECTRUM OF LAWS AND REGULATIONS AFFECTING RESEARCH UNIVERSITIES

Facilities and administrative costs at colleges and universities are governed by the principles in Circular A-21. Circular A-21 specifies which costs are allowable for purposes of negotiating F&A reimbursement rates. But many other laws and regulations—at the federal, state, and local level—affect costs for facilities and administration. These laws and regulations support a number of objectives, including the desire to protect the health and safety of humans and animals and to promote good stewardship for federal research funding. In response, research universities have created administrative departments and panels to monitor compliance efforts in many areas of their operations: hazardous waste storage and disposal, occupational safety and health, animal care, and human subjects protection. The cost of compliance includes inventories; certification programs; training programs for faculty, staff, and students; and legal expenses. These laws and regulations can also incur facilities costs. Facil-
ities must be constructed, renovated, and operated in accordance with federal, state, and local laws.

The nature of these laws and regulations has changed markedly over time. In the past, it was often presumed that laboratory scientists were in the best position to understand and manage the risks of the chemicals and biological agents they used. Other areas of concern were also monitored at the laboratory or facility level. But over time, increasingly sophisticated regulations have required new specialized personnel. One university explained:

[While many of these standards began as ancillary requirements that could be supervised by facilities employees, they have rapidly grown into jobs requiring specialists to manage the complex and sometimes bureaucratic laws and regulations that they represent. (Goldman, 1999.)

The costs of these compliance efforts directly affect the components of F&A rates. Costs for compliance affect both facilities and administrative components. Administrative costs generally are recurring costs to staff oversight committees. Facilities costs may be onetime costs involved in construction of new facilities or major renovations of older facilities, but they may also be ongoing in character. We have seen no systematic data on the costs of these requirements. We obtained some detailed information from one public university whose research base was slightly above the average for the COGR survey institutions. Although we are not sure how this information would generalize, the university maintains a wide range of research programs and does not appear to represent an extreme case. The university reported that compliance with facilities requirements necessitates so many improvement projects for existing facilities that it is infeasible to undertake them all at once. This university has committed $1.2 million per year, indefinitely, for facilities improvements to enhance compliance with hazardous waste, occupational safety, animal care, and other facilities regulations (Goldman, 1999). This annual expenditure represents roughly 2 percent of the university’s MTDC base (which would correspond to two percentage points of the university’s F&A rate). This is only a partial estimate of the costs of compliance. This estimate does not include the costs of compliance associated with major building renewal or new construction projects that the university undertakes. Neither does it include the costs of administrative oversight each year to track compliance, train people, and make reports. The additional costs as part of facilities construction, operation, and administration would increase this estimate of compliance costs substantially.

As stated above, the university’s experience is difficult to generalize, but the range and complexity of requirements discussed in the following sections point toward a significant influence on both facilities and administrative costs.
HAZARDOUS WASTE DISPOSAL AND LABELING

Prior to the 1980s, research scientists working with various chemicals were presumed to know how to handle and dispose of them. The 1980s marked an evolution in how to handle, store, use, and dispose of hazardous materials. Over the past 19 years, safety information, standard procedures, regulations, and laws have been developed addressing the acquisition, storage, and use of hazardous chemicals.

Although we did not find precise estimates, research universities appear to produce a very small amount of the nation’s hazardous waste. But research institutions must follow federal, state, and local guidelines just as industrial firms do. Industrial operations, though, often produce large quantities of a few waste products as a result of a specific manufacturing process. In contrast to the industrial firms, research universities produce “hundreds—or even thousands—of different waste products, some in quantities as small as a gram.” (Andrews, 1991.)

There are many federal laws and regulations concerning how, when, and where to store and dispose of hazardous materials. Research universities must comply with federal laws, including the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, also known as “Superfund”), Clean Air Act, Clean Water Act, Toxic Substances Control Act (TSCA) and the Hazardous Materials Transportation Act (HMTA).2

States may further regulate hazardous materials. In California, Proposition 65 requires informing the public of environmental exposures to chemicals above specific risk levels. This law requires the posting of warning signs in or near areas that contain any of the cancer-causing agents or reproductive toxins known to the state to cause cancer or reproductive harm. As of 1999, the state had listed 660 substances as subject to this act. Businesses, including higher education institutions, must notify employees and the public if they may be exposed to one or more of these substances, unless the business chooses to evaluate the specific risk posed and demonstrate that it is below legally specified thresholds.

California also regulates acutely hazardous materials (AHM) with local implementation subject to limited oversight by the state’s Office of Emergency Services. When the maximum quantity of AHM in one of its buildings exceeds

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1Andrews (1991) claims that the fraction of hazardous wastes produced by academic laboratories is “probably less than 1 percent” of the national total.
specified threshold quantities, a university, like other businesses, must register as an AHM handler.

The local government could require the university to prepare a Risk Management and Prevention Program (RMPP) for one or more on-site acutely hazardous materials. If required by the local government, the RMPP would specify risk-reducing changes in equipment, operations, and maintenance. The RMPP involves engineering and operational reviews of the AHM-handling system, evaluations of the off-site consequences of likely AHM accidents, and the implementation of on-site improvements to reduce the likelihood and severity of any AHM accidents. Release of AHM must be reported to local administering agencies. In addition, the federal Environmental Protection Agency has established for each AHM a reportable quantity under Superfund, such that any unauthorized release of an amount exceeding the reportable quantity also triggers immediate reporting requirements.

Local ordinances may require universities to comply with a variety of standards, such as those listed here.

- Permits for facilities that store hazardous materials. A research university must submit a plan for monitoring stored materials to detect releases; for posting emergency procedures where hazardous materials are stored; for regular testing and inspection; and for regular maintenance, repair, and replacement of storage facilities and emergency equipment.
- Inventory statements. Universities must submit an inventory statement (hazardous materials inventory statement) as part of the hazardous materials management plans for each building containing such materials. Failure to submit an adequate inventory exposes the university and individual researchers to criminal and civil penalties.
- Toxic gas regulations. An ordinance may require seismic protection, security, leak testing, separation of incompatibles, protective plugs, emergency drills, fire extinguishing systems, and annual maintenance applied to all regulated gases. Specific control mechanisms and procedures for different classes of gases may also be required.

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3The statement list must contain general chemical names; common trade names; major constituents for mixtures; manufacturers; United Nations or North America shipping numbers, if available; aggregate quantity ranges; and carcinogen identification forms. The inventory is a public record.
To take one example, as a result of state and federal environmental regulations, local authorities have increased requirements for the enforcement of lower mercury discharge. To avoid abatement orders from local authorities, universities must increase mercury discharge-monitoring and prevention measures for such research fields as dentistry, chemistry, and pharmacy.

To ensure compliance with federal, state, and local environmental laws and regulations, universities establish environmental health and safety departments. These departments develop the university’s hazardous materials management plan. Regulations require the plan to contain a detailed floorplan that shows all hazardous materials, including wastes, the hazard class, and the quantity range for each class aggregated within each storage facility. The plan must also include a description of the methods used to ensure separation and protection of stored hazardous materials from factors that may cause fire or explosion, monitoring methods, emergency procedures, maintenance schedules, and record-keeping forms.

In addition to the environmental health and safety departments, universities generally form oversight panels that report to the president through a university official, such as the provost or dean of research. These administrative panels monitor the university’s research activities by reviewing proposals that may involve hazardous materials, including chemical, biological, and radiological agents. The university official responsible for oversight of university research will frequently undertake to produce a research policy handbook describing the responsibilities of principal investigators and their staffs to be in compliance with federal, state, and local laws and regulations.

Specialist environmental managers are needed for local and EPA permitting, preparation and revision of hazardous materials plans, abatement of hazards, and developing processes that will keep the institution and its personnel current with environmental regulations.

The universities’ response to federal, state, and local regulation entails significant costs. When building new facilities and renovating old ones, the cost of construction includes satisfying environmental standards based on law and regulation and obtaining the proper permits from local authorities. Operations and maintenance costs include ongoing utility costs for required ventilation, personnel and materials to maintain storage tanks, and complying with abatement plans. Administrative costs include staffing for the environmental health and safety department, maintaining databases of materials on campus, production of handbooks for researchers, and training.
OCCUPATIONAL HEALTH AND SAFETY

The federal Occupational Safety and Health Administration requires following OSHA Laboratory Standards and protecting workers against potential exposures to HIV, hepatitis B virus, and other bloodborne agents by maintaining and mandating the establishment of a written Exposure Control Plan. The Exposure Control Plan requires that the university

- identify the tasks and procedures where occupational exposure to bloodborne pathogens is likely to occur; and
- specify a schedule for implementing record-keeping; housekeeping; communicating hazard information; following Universal Precautions; implementing engineering and work practice controls; ensuring medical follow-up for workers who have an exposure incident; and providing training, personal protections equipment, and hepatitis B vaccinations, including a training course prior to vaccination.

The OSHA Laboratory Standard is tailored for individual laboratories and exempts research and clinical labs from state requirements intended for industrial environments. A “laboratory scale” chemical is defined as one that is not part of a production process and can be manipulated by one person. The university is required to generate a comprehensive Chemical Hygiene Plan that protects workers’ (including students’) health around chemical hazards. The plan includes control measures, equipment performance measures, and the implementation of written standard operating procedures.

State Occupational Safety and Health laws may further regulate carcinogens and their use. State OSHA laws may designate areas where the use of certain carcinogens is permitted and require that any spills, leaks, and possible exposures be reported to the university’s department of environmental health and safety immediately. The university’s department of environmental health and safety may in turn be required to report the exposures to the state within 24 hours. Failure to report in the appropriate time frame could lead to a serious citation and fine by the state. Federal and state OSHA regulations mandate training, the use of personal protective equipment, standard operating procedures, labeling, emergency measures, and posting.

To maintain compliance with occupational health and safety standards, universities incur costs to bring facilities up to standard and for administrative organizations to document and monitor compliance.
ANIMAL CARE

Research universities are required to comply with three major federal laws and regulations when working with animals: the Animal Welfare Act (AWA), the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the National Academy of Sciences Guide for the Care and Use of Laboratory Animals.4

Originally enacted in 1966, the legislative intent of the Animal Welfare Act (AWA) was to ensure that pets or animals in research facilities or for exhibition purposes are provided humane care and treatment and ensure the humane treatment of animals during transportation in commerce.5

The AWA establishes the minimum requirements for the care of animals, including their housing, feeding, shelter, and exercise (AWA, Section 13(a)(2)(A)). Research universities are required to meet these standards:

- Show upon inspection, and to report at least annually, that the provisions of this Act are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during the actual research or experimentation (AWA, Section 13(a)(7)(A)).

- Establish at least one Institutional Animal Care and Use Committee (IACUC or other similarly named committee) consisting of three members to inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection the practices involving pain and the condition of the animals to ensure compliance (AWA, Section 13(b)(1)).

- Provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment in such facility (AWA, Section 13(d)).


The Office for Protection from Research Risks of the DHHS develops, implements, and oversees compliance with the Policy on Humane Care and Use of Laboratory Animals. For any research university participating in the sponsored projects of the DHHS Public Health Service (PHS), documentation must be provided of compliance with the Policy on Humane Care and Use of Laboratory Animals through a Letter of Assurance. The essential elements of this letter must describe the following:

- The institutional program for care and use of animals, including information about the research university’s Institutional Animal Care and Use Committee; the employee health program for those in frequent contact with the research animals; and the gross square footage, average daily census, and annual use of each animal facility.

- The research university’s institutional status as either accredited by the American Association for the Accreditation of Laboratory Animal Care or nonaccredited. If an institution is not accredited it must establish a plan, including specific guidelines for correcting any departures from the recommendations in the National Academy of Science’s *Guide for the Care and Use of Laboratory Animals*.

- The Institutional Animal Care and Use Committee. In contrast to the AWA, the PHS policy requires a minimum of five members.

The *Guide for the Care and Use of Laboratory Animals* provides guidelines to research universities on animal care programs and facilities. The NIH and most federal funding agencies require its use in determining the appropriate standards for animal care.

USDA’s legislative mandate on animal care and use is somewhat broader than DHHS’s, covering exhibitors and dealers in addition to research use. Regulatory approaches also differ. For example, USDA regulates specifically covered species whereas the DHHS policy applies to animal research conducted at facilities receiving DHHS funding. The two departments cooperate on the regulation of animal care and use.

Research universities must either maintain or modernize their facilities to be in compliance with these standards. Modernization of facilities can entail significant expense in construction. One social science laboratory alone reported that the cost of remodeling animal quarters was more than $3.5 million. In addition to construction costs, specific environmental controls and backup systems must be maintained, including virus-isolation mechanisms. Research universi-
ties report that the operations and maintenance costs, such as ventilation, are significant to comply with animal welfare regulations.

Universities thus incur administrative costs for the review panels required by laws and regulations, as well as facilities costs to build, renovate, and operate facilities in compliance.

HUMAN SUBJECTS

Congress has authorized the DHHS to regulate the protection of human subjects when they are part of a research project. Specifically, the law applies to any entity that receives federal funding for projects in behavioral or biomedical research on human beings. The law requires such entities to establish an institutional review board to review all research in these areas with the institution. It is the responsibility of DHHS to promulgate standards for review, composition of the review boards, and support of the review boards by the institution. The standards are based on ethical research policies developed at each institution based on the federal regulations. Individual researchers, the institutional review board, and the senior university administrators all play a role in ensuring compliance with public policy and research ethics.

The institutional review board must consist of at least five members, typically faculty but including at least one member of the community who is unaffiliated with the institution. The board, which is often larger than the minimum, must represent a range of professions and perspectives. The members cannot all come from the same field.

The regulations require review boards to maintain records of their evaluations of each research proposal. The regulations also set standards for the informed consent of research subjects and establish guidelines for projects that do not require a full review. Even in those cases, the review board must still maintain records for all projects concerned with human subjects.

In the regulations, special requirements for scrutiny apply to potentially vulnerable populations, including fetuses, pregnant women, human ova, prisoners, children, and the cognitively impaired. In particular, the review board must give consideration to whether its members are adequately knowledgeable about the specific vulnerable population. If not, they may seek outside expert advice to aid the board. For Department of Education research that concerns either handicapped children or mentally disabled people, the review board must have a person primarily concerned with the welfare of the relevant subject

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population. In all cases where research involves subjects from a potentially vulnerable population, there are specific standards required of researchers for each category of vulnerable population. In some cases, the review board may need to authorize regular monitoring of the research to guard against unanticipated risks to the subjects.

A number of expenses are associated with compliance with human subject regulations. These are usually categorized as allowable administrative costs. Universities are required to provide space and support staff for meetings and record-keeping of the boards. There may be costs for the members of the boards, as well. Because a large university can generate many research proposals requiring human subjects review, some universities indicate that they fund substantial release time for faculty who chair or serve on these review boards. This release time may be classified as an administrative expense. If the review board determines that it needs outside evaluations of research proposals, or ongoing monitoring of projects with vulnerable populations, the university may incur additional expenses for these services.

FOIA DISCLOSURE OF RESEARCH DATA

Pursuant to the requirements of Public Law 105-277 (The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999) OMB has implemented requirements for research institutions to release data that are developed with federal research grants through the Freedom of Information Act (FOIA). These regulations were added to OMB Circular A-110 on September 30, 1999. The requirement applies to research data that are used by a federal agency “in developing an agency action that has the force and effect of law.”

The circular authorizes agencies to collect “a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients.” Because this is a new requirement, there may be some unanticipated effects. If the fees do not cover the costs of determining which data can be released and in what form, the universities may bear some of these costs. In addition, universities may have to establish additional administrative offices to receive and coordinate FOIA requests. If these unreimbursed costs prove to be substantial in practice, they would tend to increase expenditures for administration.

COST ACCOUNTING STANDARDS

All universities are required to comply with the four Cost Accounting Standards (CAS) for educational institutions, as set forth in OMB Circular A-21. In addition, all universities that receive aggregate sponsored agreements totaling $25 million or more during their most recently completed fiscal year are required to file a Disclosure Statement, Form DS-2. The purpose of the DS-2 is to document the institution’s specific set of cost accounting practices in enough detail to document that its procedures meet the requirements of the CAS.

The four cost accounting standards for universities require that universities implement accounting procedures that ensure (1) consistency in estimating and reporting costs across departments, programs, and functions; (2) consistency in allocating costs to direct or indirect pools; (3) identifying unallowable costs; and (4) using the same fiscal year for all programs and functions within the institution. Many universities have used somewhat different methods to account for costs in different areas of the university and therefore have accounting systems that do not always conform to the new CAS requirement. Changing complex accounting systems and methods of accounting as required for compliance with CAS entails significant onetime costs.

A recent survey of 18 major research universities by COGR reported that the average university in this group spent $200,000 to prepare its initial DS-2 disclosure statement, frequently involving outside consultants. Depending on the size of the university’s MTDC base, this would represent between approximately 0.5 and 1.0 percent of MTDC, or 0.5 to 1.0 percentage points of the F&A rate during the first year.

Ordinarily, the costs of changing accounting methods and systems and preparing required disclosure statements are allowable administrative costs. However, the CAS Disclosure Statement requirement applies to the largest universities. Because larger universities are more likely to have higher negotiated rates for administration, many universities subject to the disclosure statement are already limited by the 26 percent administrative cap and hence cannot increase recovery to recoup these costs. Ongoing costs are likely to be much lower, because most of the costs are a result of initial changes and filings.

To summarize, the requirements of CAS are causing large universities to revamp their accounting systems and procedures. If it were not for the administrative cap, these changes would result in one-year increases in administrative rates of between 0.5 and 1.0 percent. As a result of the caps, it appears that most of these costs will be borne entirely by the universities. We expect that these costs are primarily onetime and ongoing costs should be much smaller.
CERTIFICATIONS AND ASSURANCES

To comply with federal requirements concerning health and safety, the environment, animal care, human subjects, and fiscal accountability, universities undertake the measures described in the preceding sections. In addition, universities are required to adhere to other major federal policies. Two of these requirements are that universities uphold federal nondiscrimination policies and maintain a drug-free workplace in accordance with relevant laws. For all of these areas of law and regulation, universities must provide certifications and assurances that they are in compliance.9

Certifications and assurances are administrative activities. The university’s sponsored programs office coordinates the preparation of the required certifications and assurances, some of which can be submitted one time to cover a whole year. Others must be submitted with each award application. The costs of preparing these documents and packaging them with each application are part of the administration component in F&A rates. There may be opportunities to consolidate the processing of certifications and assurances, because these requirements generally are implemented institutionwide, rather than as part of each grant or contract proposal. Consolidation would reduce administrative costs for both universities and the federal government. In addition, reductions in these requirements might be passed through in lower proposed administrative rates.

STATUTORY LIMITS ON F&A REIMBURSEMENT

Certain agencies and programs do not reimburse universities for the full cost of projects, including direct costs and the negotiated F&A rates. The NSF requires grantees to share at least 1 percent of project cost, including direct and F&A costs. In practice, cost-sharing has been higher than the minimum in some NSF programs. NSF grants typically do not include support for faculty effort during the academic year, meaning that the university must bear those costs (including the corresponding share of F&A costs) from other sources. Other agencies also have cost-sharing policies that apply to direct project costs. For example, NIH has a legislatively imposed salary cap for research grant participants, currently $136,700 per year. If any participant in a research project earns a salary higher than the cap, the institution must pay all costs over the cap, including the corresponding share of F&A costs.

Statutory limits also specifically apply to F&A costs in three agencies. These limits apply to all USDA competitive research grants, NIH grants for predoctoral

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9See NSTC (1999), Chapter 5.
and postdoctoral training, and certain Department of Education grants. As discussed in Chapter Two, agricultural extension programs are generally characterized as the federal share paying only for direct costs and the state share paying for all F&A costs as well as some direct costs.

NIH awards under the National Research Service Act of 1974 provide institutional grants for predoctoral and postdoctoral training, as well as individual grants. Under DHHS policy, institutional grants are limited to an F&A cost reimbursement of 8 percent of MTDC. Individual grants include a fixed allowance paid to the fellow’s institution rather than F&A reimbursement. The allowance covers such expenses for the individual fellow as research supplies, equipment, travel to scientific meetings, and health insurance. If those allowed expenses do not exhaust the 8 percent of MTDC for the grant, any remainder may be applied to the institution’s administrative costs.

NIH grants for career support to faculty—as opposed to project funding—also come with an 8 percent F&A cost reimbursement limit. Other agencies that award institutional training grants, including USDA and the Department of Education, follow the same 8 percent F&A cost reimbursement formula.

USDA operates under several congressional limitations on F&A reimbursement. The National Research Initiative specifies that no more than 19 percent of an award can be used for F&A costs. The appropriating language, however, further reduces that to 14 percent of an award. Certain programs maintain the 19 percent level. Two USDA programs allow recipients to claim their full negotiated rate: some SBIR awards to small businesses and higher education awards to tribal colleges. USDA believes that small businesses would find it too difficult to participate in its grant programs if they could not recover their full indirect costs. Universities, on the other hand, are presumed able to share F&A costs from other sources.

USDA calculates reimbursement using a college’s or university’s negotiated F&A rate against the MTDC for a project. If that amount is below 14 percent of the total project cost (or 19 percent in certain programs), then the award is made for the lower amount of F&A costs.

The largest part of USDA’s awards are formula funding for research and extension that require matching by states or institutions and are construed to contain no reimbursement for F&A costs. For these awards, the recipient institution or its state must share at least half of the total costs, including absorbing all facilities and administrative costs.

In Chapter Two, we estimated that between $0.7 and $1.5 billion of the negotiated F&A reimbursement rates are not actually reimbursed to universities each year. In addition, universities must support costs for personnel who do not
charge their time directly to projects, such as faculty time during the academic year and the costs of researchers for salaries above the NIH salary cap. The costs not borne by federal agencies must be borne by others. In the case of state-supported universities, many of these costs are likely to be borne by state appropriations, which cover faculty salaries, building operations, and maintenance. At private universities, the situation is more ambiguous. Private universities receive funds from students and their families for tuition and from private donors for many purposes. We conclude that some funds from these sources cover unreimbursed costs of faculty time in research and F&A costs not provided by research sponsors, including the federal government, industry, and foundations.