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Demystifying the Academic Research Enterprise

Becoming a Successful Scholar in a Complex and Competitive Environment

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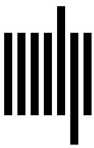

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Better Safe than Sorry: Research Compliance

Chapter Overview and Learning Objectives

Analogous to the rules, policies, and laws governing our everyday lives, various laws, guidelines, and policies govern research and creative activity in a broad subject area known as research compliance. Because severe consequences can occur when research and creative activity are conducted inappropriately, research compliance rules and regulations exist to maintain the integrity of work as well as stakeholder trust in researchers. Failure to adhere to such rules and regulations can result in stiff penalties to the researcher, damage to one's reputation, and of course harm resulting from the research itself and to the research enterprise more broadly.

This chapter highlights various categories of research compliance and the history, importance and enforcement of each. It also discusses the roles played by researchers in understanding and complying with rules and regulations, and participating in the development and modification of compliance requirements. After reading this chapter, you should

- Understand the history and importance of research compliance and your roles in both ensuring compliance in your own research and participating in the broader creation of compliance rules and regulations;
- Be able to describe the key categories of research compliance and the most important elements within them;
- Know how research compliance rules and regulations are enforced and the consequences for violating them; and
- Understand efforts now underway to streamline and reduce the burden associated with unnecessary or ineffective research compliance rules and regulations.

10.1 History and Purpose of Research Compliance

In chapter 9, we addressed the importance of ethical conduct of research and discussed the exceptionally harmful consequences to researchers, their institutions, and the research enterprise more broadly that arise when research results are fabricated, falsified, or plagiarized. We also discussed how other deviations from accepted practice can be equally damaging, and the keen responsibility you have, as a researcher, for making decisions and conducting yourself in an ethically responsible manner.

Actually, ethical conduct is part of a broader topic known as research compliance, which encompasses an extremely complex and diverse set of laws, rules, regulations, and policies governing research and creative activity. In this sense, research compliance is not unlike other rules we encounter in our daily lives—such as automobile speed limits, procedures for filing our taxes, and keeping our dogs on leashes. Ultimately, these and other forms of compliance, just like research compliance, are designed to achieve one principal goal: to drive human behavior in desired directions, usually via the imposition of stiff penalties, to ensure that we act with the highest standards of ethics, integrity, safety, and security.

In the context of research, the penalties (section 10.4) must be stiff because so much is at stake. For example, human subjects involved in clinical trials of experimental drugs; the use of biological agents in understanding and curing diseases; the development of materials and devices having dual use in both civilian and military applications, which therefore could harm national security if not adequately protected; and the expenditure of billions of taxpayer dollars each year to fund most of the fundamental or discovery research conducted in the US (chapter 2).

Although research compliance as we know it today emerged only over the past eighty years or so, the Hippocratic Oath, dating from the fifth to the third centuries BC, perhaps is the first known example in which ethical conduct was formalized—in that case for the healing arts. Perhaps not surprisingly, human subjects were the focus of research compliance in its early modern years.

For example, the Federal Food, Drug, and Cosmetic Act, passed into law in 1938, required drugs to be shown safe prior to marketing, which resulted in the need for testing using human subjects. Not long before, a fifty-year study, started in 1932 and known as the Tuskegee Syphilis Study (Gray 1998), was sponsored by the US Department of Health to evaluate the impacts of syphilis on African American males. Unfortunately, the subjects of the study were not told of their disease, nor were they offered penicillin, which was a proven cure.

Many subjects died, and this atrocity led to the National Research Act in 1974, which focused on the protection of human subjects in biomedical research.

Ironically, it was World War II that contributed substantially toward an effective research compliance framework owing to an American military tribunal, convened in late 1946, that brought criminal charges against twenty-three German physicians and others for conducting experiments on concentration camp prisoners without their consent. Many prisoners died or were permanently disabled, and in 1948, the Nuremburg Code (e.g., Shuster 1997) was created as a result. Among its ten stipulations, the Code states, first and foremost, that "The voluntary consent of the human subject is absolutely essential." It goes on to state that benefits of the research must outweigh the risks; that experiments must be scientifically necessary and conducted by qualified personnel; that animal studies should precede experiments involving humans; and that, during the course of the experiment, the human subject, or the scientist in charge, must be free to bring it to an end. These same issues were addressed in the 1964 Declaration of Helsinki, in which the World Medical Association provided guidance for human subjects research. The Declaration has since been revised many times and serves as the foundation for good clinical practice.

A watershed report, which set the course for modern research compliance involving human subjects, was the Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (US Department of Health, Education and Welfare 1979). It laid out the following three fundamental ethical principles: Respect for persons. Beneficence. And Justice. From this report, and subsequent reports and discussions, came in 1981 the "Common Rule" (and subsequent modifications) governing research involving human subjects, discussed in the next section. Numerous other laws and policies subsequently have been enacted, and lists can be found in the references (e.g., Resnik 2015; Resnik n.d.).

10.2 The Universe of Research Compliance

Although research involving human subjects dominated the compliance landscape for several decades and continues to be vitally important today, other types of research compliance began to emerge following World War II, owing in large part to dramatic increases in federal government funding for nonmedical fundamental research. Today, research compliance can be divided into seven broad categories.

The first category of research compliance involves the *use of human and animal subjects*. With regard to humans, the most well-known example concerns

clinical trials of experimental medical therapies, devices, or other interventions as a means for demonstrating their effectiveness and safety. These steps are part of the process needed to gain government approval for actual use. Such trials are carefully designed and monitored and consist of five phases, ranging from testing on small populations using limited doses, in the case of drugs, to tests involving several thousand subjects just prior to commercialization. Any research study involving human subjects is required to develop a set of protocols, or specific rules and steps by which the work will be conducted, and submit them for approval to what is known as an Institutional Review Board (IRB).

An IRB is a committee, consisting of peer experts, that reviews proposed research methods to ensure they are ethical. It also approves and monitors all activities associated with research involving human subjects. In the US, IRBs are governed by federal law and are regulated by the Office for Human Research Protections (http://hhs.gov/ohrp/index.html) within DHHS (http://hhs.gov). At academic institutions, IRBs usually are coordinated out of the office of the senior research officer (section 1.6), such as the vice president or vice chancellor for research.

The foundation for IRBs is the Common Rule (Office of Human Research Protections n.d.). It establishes the ethical principles for research involving human subjects and consists of three requirements: First, assuring that research institutions comply; second, obtaining and documenting informed consent; and third, guidelines for IRBs. Most federal research funding agencies have signed onto the Common Rule, and most academic institutions conducting research involving human subjects enforce it even when the research being performed is funded internally or by a nonfederal source. Note that private companies, nonprofit research institutions, and even Native American tribes have IRBs if they conduct research involving human subjects.

It is important to recognize that research involving human subjects is not confined to the medical arena, but extends to areas such as history, sociology, political science, psychology, art, anthropology, language, and other disciplines. In such cases, human subjects can be involved via participation in surveys, focus groups, interviews, or even as subjects being observed in particular settings, such as students in a classroom. The Common Rule provides a variety of protections for certain populations such as prisoners, pregnant women, and children, to ensure informed consent is obtained. This is to avoid the sorts of abuses that occurred in the early and middle part of the twentieth century, as described in the preceding section.

Turning now to the use of animals in research, the associated protocols are not governed by the IRB and the Common Rule, but rather by a parallel

construct known as the Institutional Animal Care and Use Committee (IACUC). Here, the word "animal" has broad meaning, ranging from fish, frogs, rats, and mice to chimpanzees, baboons, cats, and dogs. As is the case for IRBs, any institution, public or private, that conducts research involving animals must have an IACUC. Policies for the IACUC, which were formally established in 1986, are developed by NIH's Office of Laboratory Animal Welfare (http://olaw.nih.gov/home.htm). The IACUC itself comprises no less than five individuals appointed by the chief executive of the institution, with all members being able to judge whether rules are being followed. Some are expert researchers, but at least one must be a nonscientist. Additionally, law requires that a veterinarian, who has experience conducting research with animals, serve on the IACUC.

Rules governing the use of animals in research are quite specific and emphasize solid experiment design, avoiding discomfort and distress to the animal, provision of care and appropriate living conditions, and so on. Every few years, the National Research Council issues a guide regarding the use of animals in research (see National Research Council 2011). It is important to note that some individuals and organizations are adamantly opposed, on ethical grounds, to the use of any type of animal in any type of research. One study indicates a statistically significant increase, over a fifteen-year period, in the use of vertebrate animals—principally mice—in research funded by NIH (Goodman et al. 2015). Yet, overall trends are difficult to assess owing to the complexity of issues involved.

The second category of research compliance involves the *research environment* itself, particularly safety in laboratories, studios, and field sites. Many academic institutions have an Environmental Health and Safety Office (EHSO), which collaborates across numerous organizations to ensure a safe and healthy work environment for the campus as a whole, including research but also education, recreation, and other activities. Of particular importance in this context is safety in laboratories that support the use of hazardous chemicals, dangerous gases, or devices that pose a significant threat to life and property if not used in the manner intended.

Given the wide variation of characteristics among facilities, the EHSO works with researchers to develop specific protocols for training, facility access, use and storage of materials, and facility organization and management. The value of such protocols was highlighted in a report (Association for Public & Landgrant Universities 2016) that emphasizes the importance of a culture of safety in academic research laboratories. It provides a fascinating overview of accidents that motivate the need for continuous improvement of laboratory safety, as well as tools and resources available for ensuring a safe environment.

The third broad category of research compliance concerns *materials used in research*, including but not limited to radioactive isotopes, select biological agents such as highly virulent strains of bacteria, and other toxins that might pose a severe threat to public health and safety, or to animals and plants or their products. The use of radioactive materials typically is governed by a campus radiation safety office or committee based upon an array of federal rules and regulations. The use of biological agents is governed by an Institutional Biosafety Committee (IBC). Similar to the IRB and the IACUC, the IBC comprises research experts who review and approve all research activities and protocols involving items such as recombinant DNA, synthetic nucleic acid molecules, microorganisms, viruses, and biological toxins. They also sometimes review research involving bloodborne pathogens, stem cells, dual use activities, and nanotechnology. IBCs are overseen by the National Institutes of Health Office of Biotechnology Activities, and as for IACUCs, IBCs consist of at least five individuals with appropriate expertise, two of whom are not affiliated with the home institution.

The fourth broad category of research compliance involves *research grant proposals, contracts, and other instruments related to funding*, including their associated terms and conditions. Although, as mentioned in previous chapters, individual researchers have a personal obligation to understand their roles and responsibilities associated with the receipt of grants and contracts, the breadth and complexity of laws, policies and rules involved has led to the creation of entire offices (section 1.6) devoted to such matters, especially at research universities. They deal with rules that include but are not limited to grant and contract provisions, reporting of results, cost accounting, lobbying certification, audits, and many others.

OMB, which is the largest executive branch organization, has so-called circulars that contain key rules and regulations governing these and other topics. Consult the office of sponsored programs or the grants and contracts office of your institution for assistance in all matters related to this dimension of compliance. If your institution has no such office, speak with your advisor or research supervisor to determine how your needs can be met. As noted previously, in many cases, underresourced institutions sometimes partner with nearby larger institutions on matters of compliance using a shared-services model that is quite effective.

The fifth broad category of research compliance concerns the *reporting* and/or public posting of information and data related to a research project, including progress and final reports, information about project participants, use of funding, and data used in publications. Most of the guidance is contained in the terms and conditions of grant and contract awards and varies by agency or

funding source. However, I want to highlight one point in particular, which is discussed further in section 11.2, that is having a transformative impact on research and creative activity. Namely, a 2013 policy (updated in 2022) from OSTP requiring that publications resulting from most federally funded research be made available free of charge, in a publicly accessible online repository (Office of Science and Technology Policy 2013, 2022). The same is true of all data used in a given publication. Open access publishing (section 11.2) and OSTP guidance on public access are very effective means of ensuring that scholars and the general public have ready access to publications resulting from taxpayer- or philanthropically funded research and creative activity.

The sixth general category of research compliance concerns *conflicts of interest and commitment*. In general, a conflict of interest (COI) exists if one cannot be impartial or objective in carrying out a specific task, such as making decisions, owing to personal benefits they may derive in doing so. Additionally, a COI can exist owing to inherent incompatibility between the role of one individual and that of another person or persons, say by virtue of their position or relationship. Conflicts of interest can be both real and perceived.

As an example of the former, suppose a researcher is working to create a cure for diabetes and the research is being funded by a company in which the researcher owns stock. In this case, the researcher would stand to benefit personally by finding the cure and thus a financial COI exists. Likewise, if the researcher did not personally own stock in the company, but rather her husband was employed by the company as the individual who determines which research the company funds, a familial COI would exist. Both of these examples are real COIs.

In some cases, a COI does not formally exist, though the appearance of one does. Such would be the case if the husband noted above simply worked in the company funding his wife's research but had no formal role over the funding decision.

The existence of conflicts of interest does not necessarily preclude the associated activity from proceeding, and in many cases, conflicts can be managed. In the aforementioned example, the husband making the corporate funding decision could recuse himself from all activities in which his wife was involved, with another individual in the company serving in his place. The use of such a "substitute" individual, usually having a positional rank higher than the one conflicted, is standard practice for managing conflicts of interest. Yet, in some cases, management is impossible and the conflict needs to be eliminated.

Conflicts of interest also can occur at the institutional level. For example, a university receiving a large donation from a private company for a new building would be in a potentially conflicted position if it also accepted money from

the same company to conduct research on a topic for which the company could receive a financial windfall, or which might involve changing federal regulations that would be disadvantageous to the company. Because of these and many other situations, federal research funding agencies, private foundations, and even journals have strict policies whereby researchers and institutions are required to publicly disclose financial and other information to ensure integrity of the research enterprise.

Conflicts of commitment involve dedicating time to organizations or activities in ways that interfere or are inconsistent with one's primary employer and stated duties. Examples include a professor who spends more time consulting for a private company than her academic institution allows, a researcher who is affiliated with and is compensated by either domestic or foreign institutions without disclosing such information as required on grant applications, and a faculty member who commits more time to federally funded projects than they have available.

The final category of research compliance involves the *protection of sensitive information, processes, devices, activities, or other things* that might pose a threat to personal, economic, or national security if disclosed. The most familiar and extreme example is classified information, which contains multiple levels of security and operates with very clear and strict rules regarding access and handling.

A more recent innovation in security and access is export controls, which started in the late 1970s and involves, quoting from the federal government (US Department of State n.d.), "the control of exports of sensitive equipment, software and technology as a means to promote national security interest and foreign policy objectives." Three federal agencies are involved in the current export control system: the Department of State, the Department of Commerce, and the US Treasury.

Exports can be either real, which means material actually leaving the US, or deemed, which means something is deemed to have been exported if it is viewed or accessed by an unauthorized individual while in the US. In contrast to rules for classified research, rules regarding export controls have long been in a state of flux and are in many cases ambiguous. One important consideration for academic research institutions is an exemption from export controls for research that is determined to be fundamental or curiosity driven. However, an increasingly large body of fundamental research is deemed to be of dual use; that is, applicable to both civilian and military applications, and thus subject to export control restrictions. An interesting dilemma exists when research that was originally fundamental in character (and thus open according to export control rules) progresses to the point where it becomes dual use

or even needs to be classified. Such is the complexity of today's research enterprise in an increasingly challenging global context.

Other types of sensitive information exist and must be protected via appropriate measures, such as Controlled Unclassified Information (CUI). Overseen by the National Archives and Records Administration, this control formally began in 2010 and is still evolving. CUI is government-owned information that is of a sensitive nature and which, if disclosed, could have negative consequences. Examples of CUI include personally identifiable information (e.g., social security numbers), confidential employment records, federal agency information about principal investigators, and proprietary business information provided to the federal government, say in a grant proposal application.

Perhaps the most important example of managing sensitive data, outside national security and related issues, is that associated with research involving human subjects. When humans are involved in clinical trials and certain other types of studies, they provide what is known as personalized health information (PHI). This might include a good deal of their medical history as well as other information, and obviously such information must be protected. Certain strategies exist for deidentifying PHI data, such as removing names, addresses, and birth dates. However, in situations where the number of research subjects is small, specific individuals are more easily identified. Special measures are employed in such cases. Key data privacy and security provisions for safeguarding medical information in the US are governed by the Health Insurance Portability and Accountability Act of 1996, otherwise known as HIPAA.

10.3 Research Security: A Balancing Act between Promotion and Protection

An increasingly significant challenge facing America's research enterprise involves striking an appropriate balance between two goals that often are viewed as competing with one another but which, as described below, I view as complementary: protecting America's research assets against malign foreign government interference and promoting the openness of America's research enterprise—as both a domestic and international endeavor—which is so critical for scholarly work to flourish.

Apart from the categories of restricted research and data described in section 10.2, the American research enterprise has been very open since the end of World War II. Specifically, guided by National Security Decision Directive (NSDD)-189 (National Archives and Records Administration n.d.), issued in 1985, fundamental research remains unrestricted to the extent possible. Additionally, individuals from other nations who come to study and conduct research at US colleges and universities generally have unrestricted access to

libraries, collaborators, support staff, facilities, data, equipment, and instruments. This also is true for many government laboratories and facilities. Unfortunately, reciprocity is not provided by certain other countries to American researchers studying abroad, and in some cases, the restrictions imposed are severe. Even worse, the presence of malign foreign government interference has been documented at many US universities, large and small, thus representing a serious and systemic threat to America's research enterprise and indeed, that of the world. More importantly, the theft by some foreign governments of America's research ideas, plans, outcomes, and intellectual property is well documented (e.g., National Research Council 2009; Hannas et al. 2013; Federal Bureau of Investigation 2019; Stark and Tiffert 2021) and has profound implications for America's economic and national security.

For these and other reasons, the issue of research security has become a topic of great interest within all three branches of the federal government, as well as in academia and private industry. Not surprisingly, research security and research integrity often are mentioned together in policy and practice. Although they overlap to some extent, they are different. Specifically, the National Science and Technology Council (2022a) defines research integrity as "The use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results with particular attention to adherence to rules, regulations and guidelines; and following commonly accepted professional norms." It defines research security as "Safeguarding the research enterprise against the misappropriation of research and development to the detriment of national or economic security, related violations of research integrity, and foreign government interference."

During the past several years, numerous reports have been written about existential threats to US research (see references above), as well as the dangers of restricting academic research in any manner. Moreover, given that some foreign governments pose a greater threat than others, issues concerning possible racial and ethnic profiling have been raised, leading to concerns that some categories of foreign nationals currently in the US are being persecuted as well as targeted inappropriately by federal officials for presumed illegal activity. And of course, this notion has a chilling effect for those looking to come to the US to pursue their education and research interests.

These and many other issues in the research security domain are difficult indeed, requiring careful analysis of data, open dialog among all stakeholders, and thoughtful policy. I was on the front lines of research security during my time as director at OSTP and can speak to the challenges directly.

Specifically, while at OSTP, I had the privilege of taking part in the research security policy effort within the Executive Office of the President,

where we created the Joint Committee on the Research Environment (JCORE) within the NSTC. With membership drawn from all federal agencies that fund research or have research policy responsibilities, JCORE collaborated with academia, private industry, nonprofit organizations, and the National Security Council (NSC) to develop two important documents, both issued in 2021.

The first is National Security Presidential Memorandum 33 (NSPM-33) (White House 2021) on securing America's research assets. It emphasizes, among many things, the disclosure of activities and affiliations by researchers that might compromise personal and research integrity and thus imperil personal or national/economic security. Basically, the policy simply seeks to ensure that everyone involved in American research—irrespective of discipline, organization, or country of origin—plays by the rules. In this regard, JCORE took a "behavior-based" approach to research security, for as noted previously, research compliance is the personal responsibility of every researcher. The NSTC issued a follow-on document (National Science and Technology Council 2022a) regarding federal agency implementation of NSPM-33, and work continues.

The second document is an NSTC report (National Science and Technology Council 2021), developed in close collaboration with the academic community, which offers recommendations "research organizations (e.g., academic institutions, private companies, independent research institutes) can take to better protect the security and integrity of America's research enterprise." One of the most important aspects of the document is that it lays out a set of foundational principles and values for research, which it notes are consistent with American values:

- Openness and transparency enable productive collaboration and help ensure appropriate disclosure of potential conflicts of interest and conflicts of commitment.
- Accountability and honesty help acknowledge errors and correct behaviors that can hamper progress.
- Impartiality and objectivity protect against improper influence and distortion of scientific knowledge.
- Respect helps create an environment where all can be heard and contribute.
- Freedom of inquiry allows individual curiosity to guide scientific discovery.
- Reciprocity ensures that scientists and institutions exchange materials, knowledge, data, access to facilities and natural sites, and training in a way that benefits all collaborating partners.

- Merit-based competition helps ensure a level playing field where the best ideas and innovations can advance.

I mentioned previously that I view openness of America's research enterprise and the protection of its assets to be complementary. The research values listed above are the reason why. The performance of research, as noted in chapters 4 and 9, is founded upon integrity, openness, accountability, trust, and respect. Research simply cannot exist without them. Fortunately, and not surprisingly, these same research values comport with our American values—namely, the freedom to discover and create; the freedom to respectfully debate, challenge, and speak freely; the freedom to share; a free-market system to transition research outcomes into practice for the benefit of humanity; and the freedom to pursue our own pathways and dreams while adhering to policies and laws.

Some individuals coming to study and perform research in America did not learn these values in their home country, at least not in the manner we interpret and apply them. Consequently, research security affords an opportunity for those of us in America to lead with our values. That is, to ensure that individuals coming to America understand these values as scholars, know how to put them into practice, are aware of the consequences of failing to uphold the values, and know where to turn if they have questions. Values determine decisions and decisions determine direction. Research security is not about country of origin, ethnicity, race, or any other attribute. It is about playing by the rules, period.

When I was at the White House working with JCORE and meeting with hundreds of researchers across America, not a single one—not one—told me they wanted someone in their studio, laboratory, or group who knowingly breaks the rules. Research security—which importantly represents a *working partnership* among academic and other research institutions, funding organizations, the intelligence community, and law enforcement—is about behavior, and also about leading with our American values. In doing so, the research enterprise remains open and accountable, welcoming to all, and mindful of the risks we face in today's world. Failure on our part to take a balanced approach to research security could result in notably negative consequences, ranging from limiting foreign collaborations to halting completely the immigration of foreign nationals who seek to study and perform research at US colleges and universities. In those cases, everyone loses.

10.4 Creation and Enforcement of Research Rules and Regulations

As is the case with laws and policies governing our everyday lives, it is important to understand and to actively participate in the processes by which research

compliance rules and regulations are created and enforced. In fact, active involvement by the research community is essential because we, as researchers, are the experts in knowing how rules and regulations are likely to impact the research enterprise. Thus, we are best suited to helping others determine whether the rules and regulations will in fact meet their intended purpose.

You probably won't be surprised to hear that multiple processes and organizations are involved in creating and enforcing research compliance regulations at multiple levels—ranging from research institutions themselves to individual states to the federal government, not to mention private corporations and nonprofit foundations. It is lot to keep track of, and as described in the final section of this chapter, efforts are underway to streamline and harmonize compliance requirements, and to eliminate those which are known to be ineffective, so as to reduce unnecessary administrative work and maximize researcher productivity.

Consider first how compliance requirements are created. Quite often, the need for a new rule or regulation comes about by virtue of a negative consequence. For example, an accident in a research laboratory, fraud uncovered during an audit, the theft of intellectual property, or—as was the case in the Tuskegee Syphilis Study described previously—the eventual realization that research subjects were being severely mistreated.

Rules and regulations also come about when a need is recognized and is deemed to be in the public interest, such as providing free and open access to data used in government-funded publications, the public posting of researcher COI information, and the submission to funding agencies of research progress reports to ensure full accountability and transparency of how taxpayer dollars are used.

Congress frequently promulgates research compliance rules and regulations, as was the case in the 2007 America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act, where responsible conduct of research (chapter 9) training was mandated for all students and postdoctoral researchers funded by NSF grants. Likewise, OSTP creates research compliance rules, though it is not formally a directive agency. Such was the case with the aforementioned public access policy for publications and data created with federal funding.

Individual grant funding agencies also have their own array of compliance policies, such as NSF which, in contrast to other agencies, prohibits those seeking funding from making their proposals more attractive by providing cost sharing (section 6.2) or matching support (a few exceptions exist). OMB has broad responsibility for establishing and enforcing financial accounting, auditing, and related research compliance rules and regulations. Its Office of

Information and Regulatory Affairs (OIRA; http://whitehouse.gov/omb/information-regulatory-affairs) is where much of that work takes place. In the case of human health research compliance, the Office of Research Integrity (ORI) oversees and directs activities on behalf of the Secretary of Health and Human Services, with the exception of the regulatory research integrity activities of the Food and Drug Administration (http://fda.gov).

When a new rule or regulation, or a change to an existing rule or regulation, is being considered by an agency of the US government, the law requires that an NPRM be placed in the Federal Register (http://federalregister.gov) to solicit public input. Information gathered is used to develop the actual policy, which sometimes is issued as an interim rule or interim guidance until the final version is completed. In the case of academic research compliance, comments to Federal Register notices frequently are provided by academic institutions themselves, or by consortia that represent the interests of a collection of institutions.

One such organization, which is extremely effective in this role, is COGR (http://cogr.edu). As a national, nonprofit consortium of research universities, affiliated medical centers, and independent research institutes, COGR is an important partner with the federal government that helps ensure research compliance is appropriately conceived and structured, effectively implemented, and that it meets the intended purpose with known impacts. COGR often partners with professional associations to work on behalf of the broader academic research enterprise, especially the Association of Public and Land-grant Universities (APLU), the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC; http://aamc.org), and the American Council on Education (ACE; http://acenet.edu).

With regard to enforcement of research compliance rules and regulations, the mechanisms are as varied as the rules themselves. At the institutional level, most research colleges and universities have senior research officers, such as a vice president or vice chancellor for research, who help coordinate research compliance activities (section 1.6). They often are aided by other offices, such as those of legal counsel and the provost, and are a wonderful resource for both learning about compliance as well as making sure you indeed are following the rules. If your institution does not have a senior research officer, consult your advisor or research supervisor to learn how compliance is managed and the resources available to you.

Clear processes exist for dealing with possible rule violations, and sometimes violations are uncovered through audits conducted periodically by federal agencies or institutions themselves. In some cases, such as research involving human and animal subjects, institutions go through a periodic accreditation process to ensure all required administrative and other structures are

in place. Accrediting organizations include AAHRPP, which stands for Association for the Accreditation of Human Research Protection Programs (http://aahrpp.org), and AAALAC, which stands for Association for Assessment and Accreditation of Laboratory Animal Care International (http://aaalac.org). At the federal level, inspectors general (IGs) serve in agencies as an independent mechanism to determine whether the agency is following all required rules, laws, and procedures. In some cases, IG offices become involved in research misconduct cases, and in severe cases they work with law enforcement on prosecution.

Although the research compliance landscape is highly complex, a variety of excellent resources exists to ensure your understanding of and ability to follow the rules, as described in the next section.

10.5 Your Role in Understanding and Meeting Compliance Rules and Regulations

As mentioned many times throughout this book, you, as the researcher, ultimately are responsible for knowing about, understanding, and following all rules, procedures, and processes associated with the performance of research and creative activity. Fortunately, a wide array of resources exists to assist you in this rather daunting task, and the institution where you are performing research, such as a research university or even a private company, has in many cases a legal responsibility to make resources available to you.

One of the most effective ways to become familiar with research compliance rules and regulations is to attend workshops and seminars. They are offered not only by research institutions themselves, usually through the senior research officer and involving experienced faculty and administrators, but also by private companies that specialize in researcher training. The workshop format provides an opportunity for you to interact with others as you learn together, and to work through sample scenarios that will be of practical use in your own research. You can learn more by visiting the research website of your institution, or by searching the web for research compliance workshops and seminars, many of which are free.

Not surprisingly, a variety of online training options also exist, one of the most well-known of which is the Collaborative Institutional Training Initiative (CITI; http://citiprogram.org). Founded in 2000, CITI is "dedicated to promoting the public's trust in the research enterprise by providing high quality, peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual

learners." Many institutions use CITI-based training as an eligibility requirement for IRB-based and other forms of research, and topics offered by CITI include animal care and use, COI, good laboratory practice, responsible conduct of research, and biosafety and biosecurity. If your institution has a membership in CITI, the training likely is free to you. If it does not, consult your advisor or research supervisor regarding options for obtaining such training.

Despite this wide array of resources and after years of practical experience, you still may find yourself in a situation of having failed to comply with research rules and regulations. What then? The consequences depend upon the situation, of course, so here are a few examples.

If you fail to complete a progress report to a federal agency funding your work, the agency may withhold additional funding or not allow you to submit another proposal until you are current with all pending reports. If you fail to disclose a financial or organizational conflict of interest or commitment to a federal agency funding your research, the agency may terminate your research grant and perhaps require that your institution return all funds expended. If you are not properly trained in the use of laboratory equipment or the handling of toxic materials, you may cause injury to yourself or others. If you violate protocols for experiments involving human subjects, your research may be suspended or terminated and, if the violation was egregious, you may not be allowed to perform research again for up to several years. If you allow unauthorized individuals to access materials, data, or equipment that is subject to an export control restriction, you may be prosecuted, and even jailed, if the violation is deemed to be sufficiently severe.

These are not extreme examples, though only the more extreme ones tend to appear in the media. All inspectors general are required to submit semiannual reports to Congress, and in them you can find a variety of examples in which research compliance rules and regulations were violated. The bottom line for you as researcher is this: be aware of the rules, understand the rules, and follow the rules. When in doubt, ask. Never forget that the goal of research compliance is to drive human behavior in desired directions, not destroy careers or cause harm to the research enterprise.

10.6 Recent Reforms: Ensuring Effective Compliance without Undue Burden

I hope it is clear from the preceding sections of this chapter that research compliance is an extremely important element of our Nation's research enterprise—important to those funding the research, performing the research, and using outcomes from the research. Compliance rules and regulations ensure that research and creative activity are performed with safety, integrity, sensitivity,

transparency, and accountability. All of these attributes are foundational to maintaining the trust and confidence placed by taxpayers and others in our research enterprise, and thus in ensuring that the US maintains its role as a world leader in research and innovation.

Yet, compliance has another dimension to it. During the past thirty years or so, research compliance has grown dramatically in scope and complexity. This is due in part to the increasingly complicated nature of research itself, but also as a result of increasingly limited federal research budgets and heightened national security, which has led to increased scrutiny and restrictions on broad classes of activities.

Since 1991, as shown in figure 10.1, the number of new research compliance regulations impacting US universities has increased dramatically. Ironically, that same year, the percentage of funding available to universities from research grants and contracts to support such compliance was capped (i.e., the administrative or A component of the F&A rate, described in section 6.2, was capped at 26 percent). As a result, compliance costs have been shifted to other sources, including tuition.

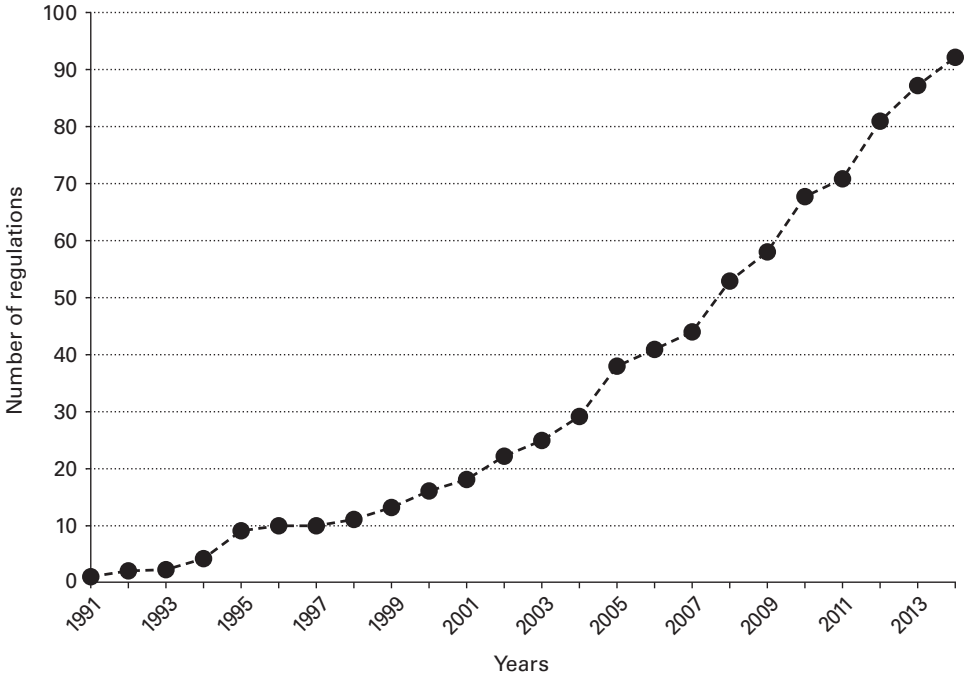

Figure 10.1
Cumulative number of federal regulatory changes, applicable to research institutions, in the US from 1991 to 2014. *Source*: National Academies of Science, Engineering and Medicine (2016).

Another important indicator of how research compliance regulations have increased is a national survey, first conducted in 2005, by the Federal Demonstration Partnership (FDP). It showed that, for research projects funded by the federal government, university principal investigators spent 42 percent of their time *not* performing research, but rather working on research compliance and proposal preparation activities (Rockwell 2009). Remarkably, when the survey was given seven years later, in 2012, this same figure of 42 percent was obtained (Federal Demonstration Project 2014). And even more remarkably, when the survey was given yet again in 2018, the workload had risen to slightly over 44 percent (Schneider 2020).

Looking more closely at the workload data (figure 10.2), one can see a number of the compliance topics discussed in this chapter. For example, COI; IRB; chemical safety; HIPAA and IACUC; export controls; and select agents. In some cases, the workload is substantial (figure 10.3), and thus an obvious question to ask is: What is the *appropriate* workload? No one really knows, but 42

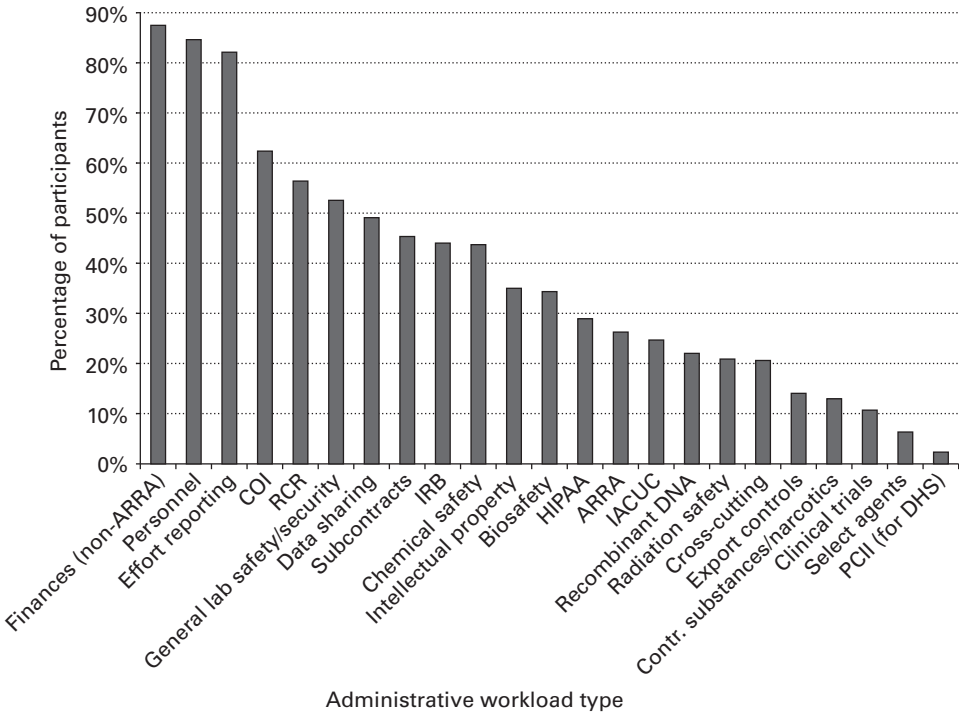

Figure 10.2
Prevalence of twenty-three administrative responsibilities associated with federally funded research, among principal investigators in American universities, from the 2012 Federal Demonstration Partnership Survey. *Source*: Federal Demonstration Partnership (2014).

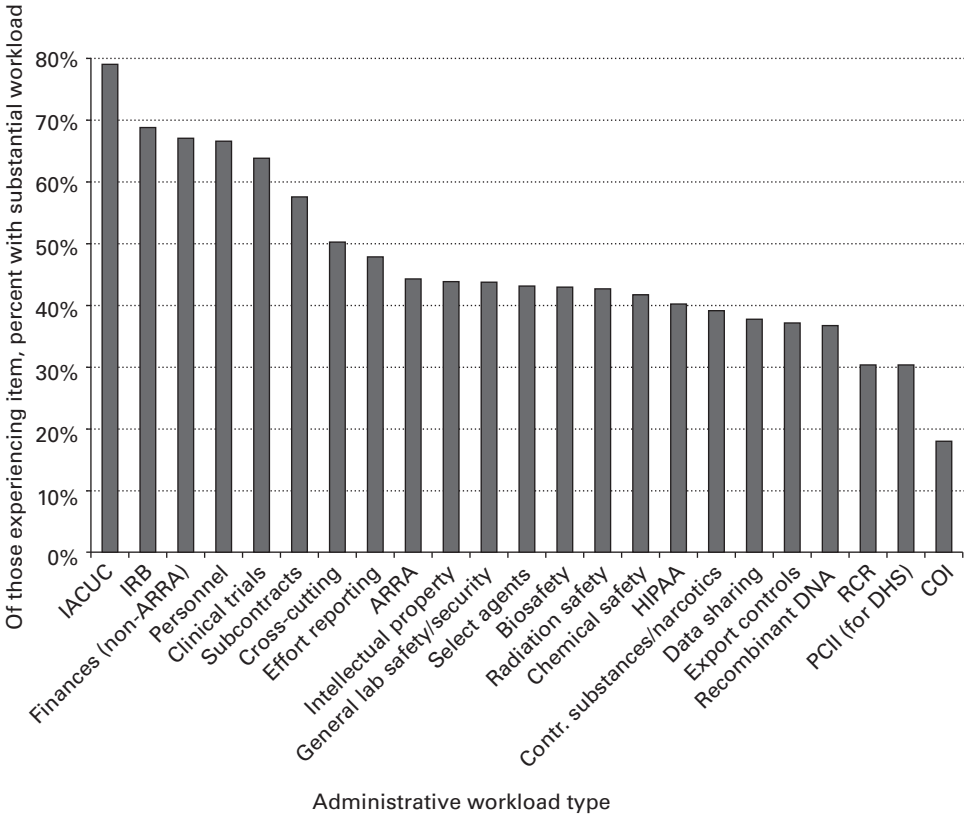

Figure 10.3
For participants in the 2012 Federal Demonstration Partnership Survey of university principal investigators who experience a given type of workload, the percentage reporting substantial (some to very much) time taken by that responsibility. *Source*: Federal Demonstration Partnership (2014).

percent is, on its face, probably far too large. Is 20 percent right? 25 percent? Instead of trying to answer that question, let me turn to a final point.

In light of the dramatic and sustained increase in compliance regulations and associated costs, efforts have been underway for many years to reform the research compliance framework. Leading the way are professional research societies, university associations, and organizations representing independent research institutes. Recognizing the value of compliance in research, as noted previously, emphasis in these efforts has been placed on the following key actions (Smith et al. 2011): "Eliminate outright or exempt universities from the regulation; Harmonize the regulation across agencies to avoid duplication and redundancy; Tier the regulation to levels of risk rather than assuming that one

size fits all; Refocus the regulation on performance-based goals rather than on process; Adjust the regulation to better fit the academic research environment."

Numerous reports have been written along these lines (e.g., Leshner 2008; National Academies of Science, Engineering and Medicine 2016; Association of American Universities n.d.). I was privileged to work on one in particular (National Science Board 2014), which examined researcher administrative workload on federally funded grants and framed its several recommendations for NSF, as well as other federal agencies, around the following four actions: Focus on the science, eliminate or modify ineffective regulations, harmonize and streamline requirements, and increase university efficiency and effectiveness.

Additionally, Congress has taken important steps toward reducing what generally is known as research-related regulatory burden, most recently in the 21st Century Cures Act. However, a great deal more work remains in order to bring the administrative workload to a level that achieves the intended purpose of compliance without crushing researchers under a mountain of administrative work.

In the end, it is important to note that research compliance is important and generally is viewed by researchers as necessary and valuable. It also is important to recognize that compliance regulations need to be thoughtfully conceived, appropriately structured and implemented, shown to be achieving the intended purpose, and funded in ways consistent with the social compact upon which our research enterprise so critically depends.

Assess Your Comprehension

1. Define research compliance.
2. Describe how research compliance has evolved over the past several decades.
3. What is the Nuremburg Code and why is it important?
4. List the principal categories of research compliance.
5. What is an Institutional Review Board (IRB) and what roles does it play in research?
6. What is the Common Rule and how is it applied?
7. What is an Institutional Animal Care and Use Committee (IACUC) and what roles does it play in research?
8. What is the role of an Environmental Health and Safety Office (EHSO) in supporting research and creative activity?

9. What types of materials might pose a threat to researchers if not used and stored properly?
10. What is an Institutional Biosafety Committee (IBC) and what roles does it play in research and creative activity?
11. What are "terms and conditions" of grants and contracts and what roles do principal investigators have in ensuring they are met?
12. What is a conflict of interest and why is it important?
13. How do real and perceived conflicts of interest differ from one another?
14. What mechanisms exist to address conflicts of interest?
15. What is an institutional conflict of interest, and how does it differ from an individual conflict of interest?
16. What are export controls and how are they applied in research and creative activity?
17. What is a deemed export?
18. What is personalized health information (PHI)?
19. Why is it important for researchers to disclose affiliations and other required information to organizations to which they are applying for funding?
20. What is National Security Decision Directive 189 (NSDD-189) and what are its principal elements?
21. What is National Security Presidential Memorandum 33 (NSPM-33) and what are its principal elements?
22. How does NSPM-33 differ from NSDD-189?
23. What factors or events stimulate the creation of research compliance rules and regulations?
24. List organizations in the research enterprise that have and enforce compliance rules and regulations.
25. What is the Federal Register, and how is it used in the compliance process?
26. What mechanisms exist for you, as a researcher, to learn about compliance rules and regulations?
27. What mechanisms exist to address violations of compliance rules and regulations?
28. List the penalties that may arise if you fail to comply with compliance rules and regulations.
29. What percentage of time, on average, is spent by university principal investigators in America on compliance activities associated with federally funded research?

30. What administrative compliance rules and regulations tend to dominate the time of federally funded principal investigators in America?
31. What key principles and values underpin America's research enterprise?
32. Describe the importance of research security and balancing the openness of the research enterprise with protecting its assets.
33. Why is streamlining compliance rules and regulations important to the research enterprise?
34. How can you, as a researcher, participate in developing or changing compliance rules and regulations?

Exercises to Deepen Your Understanding

Exercise 1: It is likely you have seen one or more media reports describing unethical behavior or other inappropriate conduct in the context of academic, government, or industry research. As you have learned, however, these situations sometimes happen to those having no ill intent. For this exercise, find and summarize a recent news article or set of articles concerning violation of research compliance rules and regulations (e.g., conflict of interest, inappropriate protocols in human/animal subjects, etc.). Discuss what resources the researcher(s) could and should have drawn upon to avoid the associated negative consequences. Additionally, discuss any factors that may have led the researcher(s) to make their decisions.

Exercise 2: Select a research topic of interest that involves the use of human subjects. As noted in this chapter, such studies range from the testing of medicinal therapies to focus groups on key topics of national concern to individual interviews to the observation of children in the classroom. Using information found at https://files.eric.ed.gov/fulltext/EJ1136504.pdf, create a framework for an Institutional Review Board (IRB) protocol. In performing this exercise, briefly describe what surprised you about the process, and what you found to be particularly useful.

Exercise 3: Identify those compliance topics in this chapter that apply to your own research and describe training you have taken relative to them, as well as actions you are now taking to ensure that you follow all appropriate rules and regulations. How much time do you spend on compliance-related activities relative to the research you actually perform, and do you undergo periodic assessment or review to ensure you remain compliant? Note that compliance can include—for students, postdoctoral and staff researchers—submitting to their supervisor or institution periodic reports on research progress.

Exercise 4: Research compliance is an extremely important and valuable element of the research enterprise. However, some compliance requirements are either ill-suited for application to academic institutions, are not appropriately structured to achieve their goals, or simply are out of date. This has led, as noted in this chapter, to significant efforts to reform the compliance framework. Using information in this chapter, supplementary information provided, and references found on your own, identify a particular compliance rule that is viewed as problematic and describe why this view exists. Also, discuss alternatives being considered and make recommendations as to how you would modify the rule or perhaps replace it with something more effective.

Exercise 5: Interview your institution's senior research officer to determine how much his or her position involves dealing with research compliance-related activities (athletic compliance is another very important and complex topic for academic institutions but resides outside the domain of research compliance). Seek to determine how staffing levels related to research compliance have changed at your institution over the past twenty years, and the sources of funding used to support those changes. What specific positions have been added, modified, or eliminated, and what changes are on the horizon? Ask your senior research officer whether compliance with research rules and regulations, in terms of researcher behavior, has changed during the past twenty years, and the extent to which these changes have mirrored investments in compliance staffing.

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