Dear colleagues,

My thanks for those of you who are able to read this early draft of *The Republic of Science Grants*. Below, I have included the Introduction and Part I, along with a detailed outline of what I have yet to write. Especially given the early stage of the work, I am excited to hear any of your thoughts and suggestions on the project.

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THE REPUBLIC OF SCIENCE GRANTS

Doni Bloomfield*

Science grants regulate science. This reality is obscured in legal scholarship about grants, which largely treats them—alongside other innovation policies, such as patents and trade secrets—as aimed only at influencing the rate and direction of invention. But seeing science grants as isolated innovation tools misses their role in governing every aspect of the research enterprise, from censoring publications and protecting human subjects to forestalling the risk of catastrophic laboratory accidents. When the state uses grants as a primary mechanism for promoting research it shapes not only what research is done but how and by whom it will be governed. With the current government aiming to reshape science policy by more than any administration since World War II, it is today essential to understand how grantmakers regulate.

This Article flips the typical script of IP literature by studying how science grantmakers shape a vast array of outcomes beyond invention: research ethics, lab safety, data sharing, workplace relations, and much else. Through a close examination of the National Institutes of Health, the world's premier science funder, I show how grantmakers govern research directions, processes, results, and environments. Grantmakers have three main levers of power—funding, data, and prestige—and use them in distinctive ways. Unlike traditional regulators, science funders are especially inclined to foster self-regulation and to shield grantees from exterior oversight. The result is a federally mediated form of self-governance I call the republic of science grants.

Recognizing and evaluating the republic of science grants has important conceptual and normative payoffs. First, it uncovers legal scholarship's blind spot in understanding the relationship between innovation policy decisions and broader governance. Second, it allows us to create a new framework for understanding how grantmakers govern. Third, it reveals benefits and costs of using grants as a primary innovation policy lever beyond their well-recognized strengths (such as supporting basic research) and weaknesses (such as supporting industrial-scale production). Finally, it shows what makes the Trump Administration's policies so historically radical: their rejection of scientific self-governance.

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INTRODUCTION

On May 5, 2025, President Trump signed an Executive Order pausing what he called "dangerous gain-of-function research" with pathogens.[1] The Order's immediate effect was to pause federal funding for such research, which the document defined in sweeping terms.[2] But its explicit aim was much more ambitious: to govern all pathogen research in the United States, whether federally funded or not.[3] The White House is seeking to leverage the National Institutes of Health's $48 billion annual budget to reshape how scientists work and what they can study, even on their own dime.[4] This is only one of many

[1] Exec. Order No. 14,292 § 3, 90 Fed. Reg. 19611 (May 5, 2025). Although the definition of gain-of-function research is contested, it generally refers to experiments designed to make pathogens such as viruses or bacteria better at infecting or killing animals. *See* NICHOLAS G. EVANS, GAIN OF FUNCTION (2025).

[2] *See* Jon Cohen & Jocelyn Kaiser, *Exclusive: NIH Suspends Dozens of Pathogen Studies Over 'Gain-of-Function' Concerns*, SCI. (July 11, 2025), https://www.science.org/content/article/exclusive-nih-suspends-dozens-pathogen-studies-over-gain-function-concerns.

[3] *See* Exec. Order No. 14,292 § 3, 90 Fed. Reg. at §§ 3, 5.

[4] *Budget*, NAT'L INSTS. OF HEALTH (last modified Oct. 3, 2024), https://www.nih.gov/about-nih/what-we-do/budget [hereinafter NIH Budget].

Trump Administration moves to use the government's science funding to govern researchers, universities, and their students: from what they say and study to whom they hire and how they invest.[5]

The Administration's use of science grants is characteristically unilateral. But, as I argue in this Article, what makes it new is not the use of science funding to govern universities. Federal grantmakers have long used their authority to govern researchers and research institutions, mandating everything from biosafety procedures to detailed human-subject and animal-welfare protections.

What makes the current administration's actions novel is, rather, its attack on what I call the republic of science grants, in a nod to physicist Michael Polanyi's famous paean to researcher autonomy.[6] The republic represents the political compact that has allowed for ubiquitous federal control of research by and through scientists themselves. This compromise, born in the early days of the Cold War, balanced Congress's desire for accountability against scientists' desire for autonomy. Federal grantmakers allocate tens of billions of dollars in funding each year, deciding the terrain of scientific merit. They require grantees—and even unfunded scientists—to abide by detailed rules of conduct, shaping which studies are permitted and how research is carried out. Yet scientists have generally seen these levers of control as legitimate because grantmakers are staffed and led by researchers, and largely leave enforcement

[5] *Updates on NSF Priorities*, U.S. NAT'L SCI. FOUND. (May 23, 2025), https://www.nsf.gov/updates-on-priorities (stating research efforts "should not preference some groups at the expense of others" and that research with narrow scope "affecting subgroups of people based on protected class" is not an NSF priority); Jeffrey Mervis, *NSF's Grant Cuts Fall Heaviest on Scientists From Underrepresented Groups*, SCI. (May 16, 2025), https://www.science.org/content/article/nsf-s-grant-cuts-fall-heaviest-scientists-underrepresented-groups (reporting that NSF is "terminat[ing] grants for projects it says preferentially favored one demographic group or excluded participation by certain groups" per the Trump Administration ban on diversity, equity, and inclusion (DEI) programs); Sharon Lurye & Jocelyn Gecker, *How U.S. Colleges are Navigating Cuts to Grants for Research After Trump Restricts Federal Funding*, PBS (Mar. 28, 2025), https://www.pbs.org/newshour/education/how-u-s-colleges-are-navigating-cuts-to-grants-for-research-after-trump-restricts-federal-funding.; Katrina Miller & Carl Zimmer, *National Science Foundation Terminates Hundreds of Active Research Awards*, N.Y. TIMES (Apr. 25, 2025), https://www.nytimes.com/2025/04/22/science/trump-national-science-foundation-grants.html (more than 400 NSF awards cancelled after "an internal review of awards containing words related to diversity, equity and inclusion"); Lexi Lonas Cochran, *Here Are the Actions the Trump Administration Has Taken Against Harvard So Far*, THE HILL (May 15, 2025), https://thehill.com/homenews/education/5290940-harvard-university-garber-trump-funding-cuts-dhs/; Jael Holzman, *Nature Conservancy Allegedly Told to Say 'Gulf of America' or Lose Federal Funding*, HEATMAP NEWS (Feb. 27, 2025), https://heatmap.news/climate/nature-conservancy-gulf-america-trump.

[6] *See* Michael Polanyi, *The Republic of Science: its Political and Economic Theory*, 1 MINERVA 54 (1962).

of the rules in the hands of scientists themselves. More than that, grantmakers proactively create self-governing frameworks to shield scientists from more onerous and centralized oversight. In this republic, the "public" are elite scientists themselves. The Trump Administration's assault is aimed squarely at the republic's independence and self-governance.

To understand the republic of science grants requires us to address several puzzles. What do science funding agencies govern? How does an agency govern without the power to issue binding rules or adjudicatory decisions? How does rule by grant compare to traditional regulatory oversight—and to no federal governance at all? And what can science grantmakers legitimately control?

These questions are a departure from the traditional focus of legal and economic literature on science grants. Scholars studying science grants have chiefly focused on how they influence innovation and access.[7] With a broader aperture, though, we can see that grants govern far more than those two dimensions of production. Grants that are meant to increase invention influence a host of other outcomes such as research ethics, biosecurity, animal welfare, data-sharing norms, academic autonomy, university investments, workplace safety, and much else.[8] By recognizing the bigger picture, and the peculiar nature of grant governance, we can begin to evaluate how science grantmakers govern, what they are good at, and the breadth of their legitimate reach. Historians, political scientists, and sociologists here have a great deal to teach legal scholars and economists about the relationship between innovation policy and governance.[9] And the lessons carry beyond the particular lever of science grants.

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[7] *See, e.g.*, Nicholson Price II, *Grants*, 34 BERK. TECH. L. J. 1 (2019); Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544 (2019); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663 (1996); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303 (2013); Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change)*, 62 EMORY L.J. 1087 (2013). From the economics literature, see, e.g., Sabrina T. Howell, *Government Intervention in Innovation*, 16 ANN. REV. FIN. ECON. 367 (2024); Kevin A. Bryan & Heidi L. Williams, *Innovation: Market Failures and Public Policies, in* 5 HANDBOOK OF INDUSTRIAL ORGANIZATION 281 (Kate Ho, Ali Hortaçsu & Alessandro Lizzeri eds., 2021).

[8] There are important exceptions to this approach in the IP literature. *See, e.g.*, Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999), which considers how patent rights influence scientific norms in addition to inventive output. There is a sense in which this Article mirrors Rachel Sachs' *The Accidental Innovation Policymakers*, which evaluates how agencies tasked with goals distinct from promoting innovation wind up influencing invention. *See* 72 DUKE L.J. 1431 (2023).

[9] *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990); SUSAN WRIGHT, MOLECULAR POLITICS: DEVELOPING AMERICAN AND BRITISH REGULATORY POLICY FOR GENETIC ENGINEERING, 1972–1982 (1994) [hereinafter MOLECULAR

Innovation policy is not just about what gets created and how it's accessed; it's also about who oversees the social machinery of invention and knowledge sharing.

The Article unpacks the republic of science grants through a close study of the NIH, the world's largest science funder. My first task, which occupies Part I, is conceptual and historical. I show that the NIH's power, and its approach to governance, is rooted in its design as a scientist-centered agency, one that is staffed by researchers and intertwined with universities.

The NIH governs four main aspects of the research enterprise: research directions, research processes, research results, and research environments. The agency governs research directions by, among other things, creating and managing grant programs and selecting grantees. Governing research processes entails overseeing potentially risky or harmful practices such as handling extinct pathogens, studying humans, or taking care of non-human animals. Governing research results entails overseeing how scientists share information such as research protocols, pathogen gene sequences, or personally identifiable genetic information. And governing research environments entails controlling how research institutions conduct themselves beyond the laboratory: how they hire and treat workers, invest funds, investigate student misconduct, and so on. Though many NIH policies influence multiple of these streams at once, they remain conceptually distinct.

Lacking traditional regulatory authority, but blessed with cash and scientific talent, the NIH governs using three distinct levers of power: funding, data, and prestige. The NIH sets rigorous terms to access its cash and data, and has used this gatekeeping authority to test and develop novel policies. It then leverages its prestige to spread many of these policies to the corporate sector, to influence agencies at home and abroad to promulgate them as binding rules, and ultimately to convince Congress to codify them in statute. Many of today's laws that look on their face to be Congressional in origin in reality trace their roots to NIH policy experiments that were decades in the making.

This legacy of federally mediated self-governance is far from secure as the Trump Administration seeks to undo the republic of science grants. I chart and

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POLITICS]; DANIEL P. CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (2010); LAURA STARK, BEHIND CLOSED DOORS: IRBS AND THE MAKING OF ETHICAL RESEARCH (2012); DANIEL S. GREENBERG, THE POLITICS OF PURE SCIENCE (1976); DANIEL KEVLES, THE PHYSICISTS: THE HISTORY OF A SCIENTIFIC COMMUNITY (2d ed. 1995). On the question of the role of professional autonomy in U.S. medicine, see PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY (2d ed. 2017).

analyze this ongoing assault in Part II. The administration is centralizing grantmaking decisions and grantee oversight, abolishing advisory committees, reducing reliance on peer review, firing scientist civil servants, and using grant terms to pursue a range of objectives far from the core of the NIH's scientific mission. Although past Congresses and presidents have sought to direct the NIH and its grantees, this White House and its NIH appointees are unique in their wholesale disregard for the ideal of scientific self-regulation.

With this framework and background in hand, in Part III I assess the strengths and weaknesses of traditional NIH oversight. This investigation is necessarily comparative. It requires us to consider how science governance by grant compares both to traditional regulatory governance and to the absence of federal intervention. The NIH's design and history as a scientists' science agency, and its dependence on non-regulatory tools, strongly influences its approach to governance. In overseeing biomedical research, the agency is heavily reliant on self-regulatory bodies, peer review, and cultural influence. Traditional regulators such as the FDA and EPA, by contrast, do more to directly surveil regulated entities, punish rule-breaking, and present themselves as hardened enforcers. In the absence of agency oversight, meanwhile, how scientists act is determined by norms such as professional prestige, individual discretion, and ex-post private law regimes such as tort law.

What emerges is a nuanced story that reveals the costs and benefits of governing research through federal science funders. Grantmakers have distinct strengths, such as technical expertise, flexibility, and scientific prestige. They also have weaknesses, among them vulnerability to capture, incomplete jurisdiction, and open-ended discretion. Moreover, because much of their power relies on reputation, annual appropriations, and local cooperation, grantmakers' authority is fragile. If a grantmaker is not seen as rigorous, trustworthy, and nonpartisan, it is liable to lose a great deal of influence over universities, companies, and other parts of government.

The Article's final task, in Part IV, is normative. Science funders have a crucial role to play in promoting and overseeing research. But their powers are also subject to abuse and failure, endangering scientific progress, human safety, and civil liberties. I consider the question of what science funders such as the NIH may legitimately govern. By legitimate governance, I mean actions that are democratically sanctioned and effective toward a just end. I evaluate the breadth of the NIH's statutory authority and the nature of the tasks that the NIH is relatively competent or incompetent to perform. I argue that the NIH's statutory purview is broad but not unlimited. It is authorized to support promising scientific projects, researchers, and institutions, and to ensure that the work it funds is carried out both ethically and effectively. But the NIH cannot

legitimately use its funds to dictate other elements of institutional behavior, such as hiring practices unrelated to funded research, student discipline, or university investment decisions.

The NIH is also relatively good at some tasks and poor at others. It has a strong track record at selecting promising scientific projects and developing rules to govern research processes. By contrast, it is weak at recognizing when researcher autonomy is excessive or enforcing its own rules. The NIH has earned its place of preeminence in biomedical funding, and it should continue to use scientific self-governance to allocate its funds, craft oversight policies, and govern research. The Trump Administration's policies reversing this autonomy have been deeply damaging to scientific progress and civil scoiety. But when self-regulation is inappropriate—when egregious errors are difficult to spot, academic incentives are strongly at odds with the public interest, or the consequences of mistakes are dire—lawmakers should charge a more enforcement-minded agency with oversight.

There is a risk, in writing about reform at a time of crisis, of appearing small-minded in an *aside from that, Mrs. Lincoln, how was the play?* sort of way. The Trump Administration's assault on science funding and governance is devastating American competence in research, and it is hardly a good faith effort to make grantmakers more effective or publicly accountable. But understanding the historical and institutional backdrop to today's assault remains essential. It will allow us to analyze the pre-Trump baseline, draw principled bounds on grantmaker power, and chart a path to rebuilding our scientific grantmakers.

I. The Republic of Science Grants: Operations

At hundreds of universities in the United States, research involving genetic material is overseen by a regulatory system dictating everything from what gloves scientists wear to how air and water circulate in their labs.[10] Government-mandated committees of biosafety experts scrutinize research proposals to decide which studies can move forward, and under what conditions.[11] Scientists can only begin the most dangerous experiments—like those conferring drug resistance on a virus—with sign-off from officers in Washington.[12] Bureaucrats have written hundreds of pages of dense regulatory text to block researchers

[10] *See* NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES, NAT'L INSTS. OF HEALTH (2024), https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf [hereinafter NIH GUIDELINES].
[11] *See id*. at § IV-B-2 (discussing Institutional Biosafety Committees).
[12] *See id*. at § II-A-1-a.

from initiating risky experiments and prevent dangerous pathogens from escaping laboratories.

Surprisingly, this regime is not overseen by the CDC—the United States' public-health authority—or by OSHA, which provides minimal biosafety standards in its role as regulator of U.S. workplaces.[13] With the exception of research involving deadly pathogens such as smallpox, Congress has not tasked any federal agency with regulating biological research.[14] Instead, without congressional mandate or approval, the NIH has voluntarily assumed the mantle of regulating biological research safety. The NIH's Office of Science Policy has become a de facto regulator, overseeing thousands of self-policing bodies and promulgating minute rules to determine the limits of permissible research.[15]

The NIH exercises regulatory power not through formal rulemaking but by informally leveraging its grant budget. The NIH's $48 billion budget in 2024 was larger than the GDP of two-thirds of the world's nations.[16] More than 80% of those funds are earmarked for grants, giving the NIH enormous power over the thousands of institutions that depend on it.[17]

With that authority, the agency requires that institutions receiving its grants for genetic research comply with its biosafety rulebook, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.[18] These rules are not limited to direct NIH grantees. The NIH insists that institutions taking NIH funds for genetic research apply the NIH Guidelines to all such research in the institution, whether federally funded or not. The agency's regulatory reach in this way extends beyond the projects it funds, reshaping the bounds of permissible research even for privately funded scientists.

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[13] *See* 29 C.F.R. § 1910.1450 (2024).
[14] *See* 42 U.S.C. § 262a (2024).
[15] By one count, in 2022 there were more than 2,700 Institutional Biosafety Committees registered with the NIH, each of them tasked with applying NIH safety rules to local institutions. *See* Daniel Kavanagh, *Highlighting the Growing Importance of Institutional Biosafety Committees in Clinical Research*, ASS'N OF CLINICAL RSCH. PROS. (Aug. 16, 2022), https://acrpnet.org/2022/08/16/highlighting-the-growing-importance-of-institutional-biosafety-committees-in-clinical-research. In 2024, the NIH provided at least $1 million in funding to more than 1,200 external institutions. *See NIH Awards by Location & Organization*, NAT'L INSTS. OF HEALTH, https://report.nih.gov/award/index.cfm?fy=2024&ot= (data frozen as of Oct. 4, 2024; released on Jan. 10, 2025).
[16] NIH Budget, *supra* note 4; *GDP (current US$)*, WORLD BANK (2024), https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?most_recent_value.
[17] *See* NIH Budget, *supra* note 4.
[18] *See* NIH GUIDELINES, *supra* note 10, at § I-C-1-a-(1).

The NIH Guidelines are just one striking example of how the agency not only promotes research but also governs almost every aspect of the biomedical research enterprise. In this Part, I show *what* the agency governs—research directions, processes, results, and environments—and *how* it governs, using funding, data, and prestige.

The NIH has historically carried out its broad regulatory function not primarily through its centralized bureaucracy, but rather through the decisions of distributed, highly local groups of experts. The main organs of decision-making at the NIH are boards of experts operating in their fiefs: study sections making funding recommendations, institutional review boards evaluating research proposals, institutional biosafety committees ensuring adequate lab safety, data access committees filtering requests for NIH-funded data, and so on. Although many U.S. agencies rely on outside experts,[19] the NIH and other science funders are unique in placing the object of their governance—scientists—so firmly in the driver seat. As the theoretical physicist Kenneth Watson once remarked, "scientific research is the only pork barrel for which the pigs determine who gets the pork." [20]

A. Research Directions

The NIH's main function is conducting research and distributing grants to advance human knowledge and health. The influence of its grantmaking over the direction of biomedical research is hard to overstate. More than 80% of basic biology labs in the United States receive NIH funding.[21] In recent years, its extramural grants have annually supported the work of more than 300,000 researchers.[22] Since 1948—the year of the NIH's modern founding—the agency has disbursed $1.18 trillion in 2024 dollars in research grants. Its campus for basic biological research in Bethesda is the largest collection of biologists in the world, and its research hospital, the National Clinical Center, is the largest hospital in the world devoted entirely to research. The NIH has supported the

[19] *See generally* JASANOFF, *supra* note 9.
[20] Kenneth M. Watson, A Comment on the Motivation for Studying Elementary Particle Physics, *in* NATURE OF MATTER (1965), *quoted in* GREENBERG, *supra* note 9. Or, as one health lawyer quipped to me, "The [Defense Department] doesn't have Boeing review Northrop Grumman's applications."
[21] Danielle Li, *Expertise versus Bias in Evaluation: Evidence from the NIH*, 9 AM. ECON. J.: APPLIED ECON. 60, 64 (2017).
[22] *See* NIH Budget, *supra* note 4.

work of more than 35% of all scientists to have won the Nobel Prize in Chemistry or Physiology/Medicine.[23]

The NIH's funding discretion inevitably influences the direction of biomedical research.[24] By issuing calls for research in specific areas of interest, and using a consensus-driven approach to application selection, the agency induces scientists to shift their work toward its priorities and preferred style of work. By generating deep knowledge in select arenas, the NIH influences what discoveries are instantiated in patents and turned into medicine. And by making or breaking careers through its research- and career-support grants, the agency helps determine who gets to do scientific research—not only in the immediate grant period, but at all. In all of these instances, as we will see, the NIH puts much of its decision-making discretion in the hands of scientists.

The agency also leverages its prestige and control over data repositories to shape research. For example, NIH study sections—discipline-specific peer-review committees that rank grant proposals by merit—have also served as important social hubs for solidifying research agendas in fields as diverse as cell biology, genetics, and antibiotics. The agency's flagship investments in data, like the Human Genome Project and the Roadmap Epigenetics Project, turn scholars' focus on questions those data can help address. And the NIH's control over access to valuable human health and genetics data gives it the power to open new channels of study, as well as to favor some forms of research over others. Here too, the agency's enormous power is often exercised by and through independent scientists.

The place to start is the bread and butter of NIH power, extramural research funding. The NIH's grantmaking decisions shape the nature of research that scientists carry out. This influence is causal and directional: grants induce scholars to move their work toward NIH priorities. For example, although most of the agency's grants fund work received in response to open calls—application processes that consider biological research across the NIH's entire portfolio—it has increasingly also allocated money for more targeted requests for applications (RFAs), like those addressing a particular disease or approach to therapy.[25] Kyle

[23] *See Nobel Laureates*, NAT'L INSTITUTES OF HEALTH (last reviewed Mar. 6, 2025), https://www.nih.gov/about-nih/nih-almanac/nobel-laureates; *All Nobel Prizes*, NOBELPRIZE.ORG (2025), https://www.nobelprize.org/prizes/lists/all-nobel-prizes/.

[24] There is much more to say on this topic than I can cover here. Considering the breadth of the NIH's work, including both its own research and the research of external scientists it supports, one could write many books just on this topic alone. Here, I aim not to be comprehensive but to show that the NIH's influence is extensive, that it shifts the direction of research, and that the agency puts much of the discretion over *how* it influences science in the hands of scientists.

[25] Kyle Myers, *The Elasticity of Science*, 12 AM. ECON. J.: APPLIED ECON. 103, 130 (2020).

Myers has found that RFAs induce a significant, 10% increase in applications aimed at the targeted area, and that funded scientists substantially move their research toward the RFA's area of interest.[26]

NIH funding decisions are also immensely influential on the direction of industrial research. About 44% of all life-sciences patents granted in the United States between 1980 and 2012 cite NIH-funded research,[27] and 10% of NIH grants lead directly to at least one patent.[28] This is not the result of the NIH "crowding out" alternative funding that would have led to the same patents regardless.[29] Instead, Azoulay and colleagues have shown that marginal NIH funding decisions—those that determine funding between sets of applications deemed similar in quality—causally influence the amount and focus of later patenting. By comparing groups of applications that the NIH deemed *barely* fundable to those it deemed *almost* fundable, they show that areas of research that happen to receive more funding generate significantly more downstream patents than those that receive less funding. It is no surprise, then, that patents associated with drugs in disease areas of particular NIH focus rely heavily on NIH-funded research. Bhaven Sampat and Frank Lichtenberg report that 95% of patents associated with HIV/AIDS drugs cite NIH-funded research, one of the NIH's chief priorities beginning in the 1980s.[30]

NIH funding also influences *who* conducts research, both by selecting early- and mid-stage scientists to support and through its typical project-level grant process. The NIH has supported scientists through fellowship awards since the

[26] *Id.* at 130 ("[T]he instrumented grants induce a roughly 37 percent increase in the similarity between scientists' publications and the RFA's objectives"); *see also id.* at 120 ("[C]ompared to open applications, RFA applications are 25 percent less similar to the scientist's prior work, on average.").

[27] Pierre Azoulay et al., *Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules*, 86 REV. ECON. STUD. 117, 131 (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC6818650/.

[28] Bhaven N. Sampat & Frank R. Litchenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFFS. 332 (2011).

[29] Here, the empirical worry is that if the NIH did not fund a given area of research, others would have stepped in and funded it, leading NIH funding to be less causally influential than it appears. In that scenario, the NIH would merely have (in economics parlance) crowded out other sources of funding.

[30] *See* Sampat & Litchenberg, *supra* note 28, at 335. The NIH directed $69 billion toward HIV/AIDS research between 1982 and 2018. *See* Tara A. Schwetz & Anthony S. Fauci, *The Extended Impact of Human Immunodeficiency Virus/AIDS Research*, 219 J. INFECTIOUS DISEASES 6, 6 (2019). The agency's internal scientists—at the National Cancer Institute, curiously enough—also discovered the first drug that was effective in combating the disease. *See* DAVID FRENCH, HOW TO SURVIVE A PLAGUE (2016).

1930s.[31] The agency expanded the program rapidly following World War II, and by the early 1970s, more than a third of U.S. graduate students in medical sciences were supported by NIH grants.[32] Today, though the program is somewhat more modest, the NIH continues to fund thousands of external undergraduates, Ph.D. candidates, postdocs, and mid-career scientists—more than 5,100 people in a given year.[33] Between 2000 and 2022, the NIH funded almost 78,000 Ph.Ds.[34] These career grants are competitive, with only about a third of postdocs securing funding.[35]

Winning an NIH postdoc significantly helps grantees in their careers. Brian Jacob and Lars Lefgren find that applicants who were just barely funded have 24% more publications in the five years following the application than those who were almost funded, and are 14% more likely to receive at least $200,000 in NIH funding in the following 10 years.[36] Project-level grants (that is, those funding projects rather than people) are also career determinative in many cases.[37] Yang Wang and colleagues, for example, found that junior primary investigators who fell just short of securing an R01 were 10% more likely than

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[31] STEPHEN P. STRICKLAND, THE STORY OF THE NIH GRANTS PROGRAMS 44-45 (1989) [hereinafter STORY]; HOWARD H. GARRISON & PRUDENCE W. BROWN, THE CAREER ACHIEVEMENTS OF NIH POSTDOCTORAL TRAINEES AND FELLOWS 1 (1986), https://www.ncbi.nlm.nih.gov/books/NBK549605/; *id*. at 3, tbl 1.1.

[32] COMM. ON NAT'L NEEDS FOR BIOMEDICAL AND BEHAVIORAL RSCH. PERS. STUD. AND SURVS. UNIT, NAT'L RSCH. COUNCIL, MEETING THE NATION'S NEEDS FOR BIOMEDICAL AND BEHAVIORAL SCIENTISTS 97 (1994) ("By 1971, NIH training grants and fellowships supported or assisted 37.5 percent of the nation's full-time graduate students in the medical sciences."); GARRISON & BROWN, *supra* note 27. In 1974, Congress restricted federal support grants to areas in which an agency could show the need for personnel. *See* COMM. ON NAT'L NEEDS FOR BIOMEDICAL AND BEHAVIORAL RSCH. PERS. STUD. AND SURVS. UNIT, *supra*, at 11.

[33] *Research Training and Career Development*, NAT'L INSTS. OF HEALTH (May 6, 2025), https://grants.nih.gov/funding/funding-categories/research-training-and-career-development; *see also* Price, *Grants*, *supra* note 7, at 9.

[34] Dror Shvadron et al., *Funding the U.S. Scientific Training Ecosystem: New Data, Methods, and Evidence* (Nat'l Bureau of Econ. Rsch. Working Paper No. 33944, 2025), at 2-3, 50 tbl. 2.

[35] *Research Career Development Awards: Competing Applications, Awards, and Success Rates*, NAT'L INSTS. OF HEALTH (last updated Jan. 2025), https://report.nih.gov/nihdatabook/report/211. Note that this data provides success rates for "k" awards, which make up a subset of all research training grants.

[36] Brian A. Jacob & Lars Lefgren, *The impact of NIH postdoctoral training grants on scientific productivity*, 40 RSCH. POL'Y 864, 865, 872 (2011), https://www.sciencedirect.com/science/article/pii/S0048733311000564?via%3Dihub. The authors show that applicants who were just-barely funded and almost funded are very similar in observable characteristics.

[37] *See* Matt Faherty, New Science's Report on the NIH § 4.3, New Sci. (April 2022), https://newscience.org/nih/ (reporting that, according to interviews with multiple U.S. biomedical researchers, U.S. "universities de facto *require* the attainment of multiple NIH or comparable federal grants to become professors and attain tenure.").

narrow winners to never again apply for an NIH grant—suggesting that they fell out of academic biomedicine altogether.[38] On a more macro level, recent research suggests that government funding of PhDs does not crowd out other sources, but increases the total number of PhDs educated in the United States.[39]

How does the agency decide which projects and people to fund? Largely by turning to scientists themselves. Congress sets broad research goals by allocating funds to individual NIH institutes and centers, like the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute.[40] And it occasionally instructs agencies to target specific areas, such as Alzheimer's Disease.[41] But the main work of setting priorities and deciding among competing projects for NIH's extramural cash is done by external scientists through peer review.[42] Let us first look at grants before turning to fellowships.

Historically, NIH grants were awarded almost entirely on the basis of peer review scores assigned by volunteer external scientists. The substantial majority of NIH grants are unsolicited, that is, awarded to applications responding to standing, open-call programs that receive applications of interest to any NIH Institute or Center.[43] Even the more targeted Requests for Applications are generally developed in conversation with external scientists.[44]

Consider the process for open-call R01 grants, the most commonly used NIH grant, which is awarded for discrete projects.[45] NIH staff assign grant

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[38] Yang Wang et al,. *Early-career setback and future career impact*, NATURE COMMC'N, Oct. 2019, at 1. Interestingly, Wang and colleagues find that those who just missed securing a grant *and* stayed in the field were then overall more successful than those who just cleared the line to secure the grant.

[39] *See* Shvadron et al., *supra* note 34, at 2.

[40] KAVYA SEKAR, CONG. RSCH. SERV., R43341, NATIONAL INSTITUTES OF HEALTH (NIH) FUNDING: FY1996-FY2025 6 (2024).

[41] *Id*. at 4. Even these measures are controversial, and Congress itself has recognized that "recommend[ing] a specific amount of NIH funding" for a particular purpose is a departure from "longstanding practice" that would "establish a dangerous precedent that could politicize the NIH peer review system." *See* 160 CONG. REC. H9832 (daily ed. Dec. 11, 2014); *see also* ELI DOURADO & JOANNE PENG, CURING ALZHEIMER'S BY INVESTING IN AGING RESEARCH 2 (2022), https://ifp.org/curing-alzheimers-by-investing-in-aging-research/; 161 CONG. REC. H9674 (daily ed. Dec. 17, 2015) (statement of Rep. Tom Cole), https://www.congress.gov/114/crec/2015/12/17/161/184/CREC-2015-12-17.pdf.

[42] Price, *supra* note 7, at 7.

[43] Price, *supra* note 7, at 22-23.

[44] Price, *supra* note 7, at 23 nn. 109, 112-13.

[45] *Research Project (R01)*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/funding/activity-codes/R01; *R01-Equivalent Grants: Average Size*, NAT'L INSTS. OF HEALTH (last updated Jan. 2025), https://report.nih.gov/nihdatabook/report/158; Li, *supra* note 21, at 64.

applications to a standing committee, known as a study section, made up of mostly external scientists who are experts in a particular discipline.[46] There are today more than 200 study sections focusing on topics such as Adaptive Immunity and Gene Regulation in Cancer.[47] Each section is led by a Scientific Review Officer, an NIH employee scientist in the field who recruits peer reviewers and runs the study process. More than 28,000 reviewers sit on study sections every year, considering more than 37,000 applications.[48] The Officer assigns individual applications to be reviewed in depth by a subset of the section, who rank them based on criteria such as importance, rigor, and investigator suitability.[49] After the weakest applications are discarded, the section meets to discuss the remainder, and rate them from 1.0 (best) to 5.0 (worst); the average of the members' votes is then used to rank the applications.[50]

This ordering almost entirely decides the fate of grant applicants. Although study section rankings are reviewed by another body made up of scientists and interested citizens, Advisory Councils, and finally by Institute directors, NIH

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[46] *NIH Grants Policy Statement: 2.4.1 Initial Review*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.1_initial_review.htm (last updated April 2024).

[47] *Regular Standing Study Sections and Continuing Special Emphasis Panels (SEPs)*, NAT'L INSTS. OF HEALTH, https://public.csr.nih.gov/StudySections/StandingStudySections (last updated Nov. 16, 2023); BHAVEN SAMPAT, THE HISTORY AND POLITICAL ECONOMY OF NIH PEER REVIEW 2 (2023).

[48] *See* U.S. Dep't of Health & Human Servs., *NIH Data Book: Peer Reviewers, by Fiscal Year and Type of Review*, NAT'L INST. OF HEALTH (2025), https://report.nih.gov/nihdatabook/report/285; U.S. Dep't of Health & Human Servs., *NIH Data Book: R01-Equivalent Grants: Competing Applications, Awards, and Success Rates*, NAT'L INST. OF HEALTH (2025), https://report.nih.gov/nihdatabook/report/29.

[49] *See* Li, *supra* note 21, at 64-65. The NIH for many years asked peer reviewers to evaluate applications primarily based on five factors: significance (the study's potential importance), innovation (novelty), approach (soundness), investigator (the primary investigator's suitability), and environment (institutional support). *See* Price, *supra* note 7, at 27 n. 135; *see also* 42 C.F.R. § 52h.8 (codifying these factors, among others). After years of reviewing this approach—as usual, in conversation with scientists—the NIH in early 2025 simplified its peer review framework to focus on three factors: importance, rigor & feasibility, and expertise & resources. *See Simplified Peer Review Framework,* NAT'L INSTS. OF HEALTH, https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/framework (last updated Aug. 19, 2024); *Frequently Asked Questions (FAQs)*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/faqs#/simplifying-review.htm (last updated Aug. 2, 2024); SIMPLIFYING REVIEW CRITERIA WORKING GROUPS, CSR ADVISORY COUNCIL, RECOMMENDATIONS FOR SIMPLIFYING R01 REVIEW CRITERIA 7 (April 27, 2021), https://public.csr.nih.gov/sites/default/files/2021-04/Recommendations_of_the_CSRAC_Working_Group_on_Simplifying_Review-non-CT_and_CT.pdf. These are very close to the criteria the NIH employed in 1946, presumably after much less rigorous study. *See* C. J. Van Slyke, 104 SCI. 559, 562 (1946).

[50] *See* Li, *supra* note 21, at 65.

Institutes have historically followed study-section rankings almost mechanically. They fund applications in order of their score until running out of money to allocate.[51] A 2017 study by Danielle Li found that fewer than 4% of R01 applications are funded out of the order assigned by their study sections, and these decisions are often made in response to later-arriving data.[52]

The NIH has relied on peer review to allocate grant funds since its modern founding in the 1940s—indeed, since before the term peer review was coined.[53] The agency's first head of extramural grants, physician and veteran scientist Cassius Van Slyke, sought to attract strong talent to the agency by giving scientists broad autonomy.[54] In rolling out the new program, he compared the agency's approach to selecting applicants to the scientific method, declaring that it was founded on "[t]he integrity and independence of the research worker and his freedom from control, direction, regimentation, and outside interference."[55] Though no law required it, the agency created study sections staffed by external scientists to make funding recommendations and promote research in the field.[56] NIH officials were keen for the study sections to shield the new agency from

[51] Every funding Institute or Center has a Council, which is made up of scientists and other members of the public with an interest in the Institute's mission. *NIH Grants Policy Statement: 2.4.3 National Advisory Council or Board Review*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.3_national_advisory_council_or_board_review.htm (last updated April 2024). Each Council is tasked with reviewing the work of the study sections and weighing the Institute's broader policy goals, but in practice they do little to alter funding outcomes. *See* Price, *supra* note 7, at 28; Li, *supra* note 21, at 65; Pierre Azoulay et al., *National Institutes of Health Peer Review: Challenges and Avenues for Reform* 5, 20 fig. 1 (Nat'l Bureau Econ. Rsch. Working Paper No. 18116, 2012); DARYL E. CHUBIN & EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 21-22 (1990).

[52] Li, *supra* note 21, at 66. This has also been the case historically. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO/RCED-87-87FS, UNIVERSITY FUNDING: INFORMATION ON THE ROLE OF PEER REVIEW AT NSF AND NIH 13 (1987); CHUBIN & HACKETT, *supra* note 51, at 22; RICHARD MANDEL, A HALF CENTURY OF PEER REVIEW 1946-1996, at 249 n.73 (1996).

[53] *See* MANDEL, *supra* note 52, at 20-23; Sampat, *supra* note 47, at 5. The very first reference to "peer review" in English-language literature is in a discussion of the work of NIH study sections. *See* Melinda Baldwin, *Scientific Autonomy, Public Accountability, and the Rise of "Peer Review" in the Cold War United States*,109 ISIS 538, 547 (2018).

[54] *Cassius James Van Slyke, M.D.*, NAT'L INSTS. OF HEALTH, https://www.nih.gov/about-nih/nih-almanac/cassius-james-van-slyke-md (last updated Feb. 21, 2025); *Medicine: Man of Millions*, TIME (Nov. 18, 1957) https://time.com/archive/6805634/medicine-man-of-millions/.

[55] *See* Van Slyke, *supra* note 49, at 559; *see also* STRICKLAND, STORY *supra* note 31, at 22-25; Kayte Spector-Bagdady & Paul A. Lombardo, *Something of an Adventure: Postwar NIH Research Ethos and the Guatemala STD Experiments*, 41 J.L. MED. & ETHICS 697, 700 (2013).

[56] STRICKLAND, STORY, *supra* note 31, at 22-25; *see also* U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, THE DIVISION OF RESEARCH GRANTS OF THE NATIONAL INSTITUTES OF HEALTH: ITS HISTORY, ORGANIZATION, AND FUNCTIONS 1945-1962 2-3 (1963).

accusations of meddling with scientific freedom.[57] As Van Slyke wrote in the journal *Science*, the research grant "program is a scientific one, scientific guidance of which lies wholly in the hands of scientists."[58] That early choice is now the law. In 1985, Congress made peer review mandatory for all NIH grants.[59]

As with grants, peer review has played an important role in the NIH's fellowship decisions.[60] Fellowships are subject to a similar study-section level review process, with ratification by Advisory Councils.[61] Compared to research grants, the NIH relies on outsider evaluations more in some respects and less in others. In many institutes, agency staff take an active and discretionary role in considering applicants for the most prestigious NIH fellowships. Donna Ginther and Misty Heggeness find that, between 1996 and 2002, about 60% of postdoc awards were funded out of order of the score ranks assigned by peer reviewers.[62] On the other hand, the NIH's training funding is largely allocated in block grants to institutions, rather than individual students, leaving person-level funding decisions almost entirely up to universities themselves.[63]

Alongside its direct funding lever, the NIH's prestige has also allowed it to set biomedical research agendas. Consider the early influence of NIH study sessions. In the 1950s and 1960s, besides their grant review work, members of these committees—often the leading scientists in their field—would debate and

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[57] *See* STARK, *supra* note 9, at 10.

[58] Van Slyke, *supra* note 49, at 564. Presumably in part to impress his readers with the prestige of NIH appointees, Van Slyke proceeded to list all members of the national advisory councils and study sections over three dense pages. *See id*. at 564-567.

[59] Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 874 (codified at 42 U.S.C. § 289a).

[60] For brevity, by "fellowships" I also include grants for training (which are awarded to institutions) and career development (offered to scientists at many career stages). *See Parent Announcements (For Unsolicited or Investigator-Initiated Applications)*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/funding/nih-guide-for-grants-and-contracts/parent-announcements (last accessed July 6, 2025).

[61] *See NIH Grants Policy Statement: 12.5 Review*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/grants/policy/nihgps/html5/section_12/12.5_review.htm (last updated April 2024); *Changes to the Fellowship Review Criteria,* NAT'L INSTS. OF HEALTH, https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/revisions-nih-fellowship-application-review-process/changes-to-fellowship-review-criteria (last updated Aug. 19, 2024).

[62] Donna K. Ginther & Misty L. Heggeness, *Administrative Discretion in Scientific Funding: Evidence From a Prestigious Postdoctoral Training Program*, 49 RSCH. POL'Y 1, 7 (2020).

[63] *See, e.g.*, MARY MUNGER, HISTORY OF THE EXTRAMURAL PROGRAMS 1946-1958 44 (1960); MANDEL, *supra* note 52, at 80-82.

define key issues and methods.[64] For example, in 1958 the NIH's study section on Biophysics and Biophysical Chemistry, which included three future Nobel Prize winners, held a four-week, government-funded retreat in which it prepared a "study program" on "cell physiology, neurobiology, and biophysics."[65] Decades later, a prominent expert in RNA biology recalled how the volume, a "unique and definitive statement" of its field, influenced his path into science.[66]

The NIH's Genetics Study Section was also active in fostering its nascent field.[67] Led by its executive secretary, NIH employee Katherine Wilson, the section scientists published three volumes in the 1960s outlining essential methods in genetics, compiled a public registry of geneticists working in the United States, and released an influential report on the risks posed by mutagenic chemicals.[68] Other study sections helped create standard definitions and processes in the fields of antibiotics, syphilis, viral tumors, model organisms, and more.[69] The NIH's work of convening and wrangling leading scientists of the day helped define the bounds of scientific disciplines, all of which were growing quickly on the NIH's dime. Here too, the government gave extraordinary discretion to private scientists to use the NIH brand, and public funding, to shape the direction of science.

Finally, the NIH's control over data has allowed it to shape the direction of scientific discovery. This power has been especially visible in the NIH's governance of human genetic data.[70] As one of the primary funders of the

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[64] James H. Cassedy, *Stimulation of Health Research*, 145 SCI. 897, 899 (1964) ; James F. Crow & Ray D. Owen, *Kay Wilson and the NIH Genetics Study Section*, 155 GENETICS 1, 1 (2000) (cited and discussed in Danielle Li & Pierre Azoulay, *Scientific Grant Funding, in* INNOVATION AND PUB. POL'Y *117, 130* (Austan Goolsbee & Benjamin F. Jones eds., 2021)); STRICKLAND, STORY *supra* note 27, at 39-40; MANDEL, *supra* note 52, at 35-37, 91.

[65] Thoru Pederson, *The "study" role of past National Institutes of Health study sections,* 23 MOLECULAR BIOLOGY CELL 3281, 3283(2012) (citing JOHN L. ONCLEY ET AL., BIOPHYSICAL SCIENCE—A STUDY PROGRAM (1959)). The study section also helped found the National Biophysical Society and organized the creation of "relatively inexpensive but accurate atomic models for use in research and training." Cassedy, *supra* note 64, at 900-901.

[66] Pederson, *supra* note 65, at 3283.

[67] Crow & Owen, *supra* note 64, at 5; Li & Azoulay, *supra* note 64; James F. Crow, *Chemical Risk to Future Generations*, 10 SCIENTIST & CITIZEN 113 (1968); Cassedy, *supra* note 64, at 901.

[68] Crow & Owen, *supra* note 64, at 5; Li & Azoulay, *supra* note 64. The functions of a study section "executive secretary" are today carried out by Scientific Review Officers. *See* DIVISION OF RESEARCH GRANTS, NAT'L INSTS. OF HEALTH, THE DIVISION OF RESEARCH GRANTS OF THE NATIONAL INSTITUTES OF HEALTH: ITS HISTORY, ORGANIZATION AND FUNCTIONS, 1945-1962 (1963); Price, *supra* note 7, at 26; STRICKLAND, STORY, *supra* note 27, at 29.

[69] Cassedy, *supra* note 64.

[70] *See* Janet Freilich & Nicholson Price, *Data as Policy,* 66 BOSTON U.L. REV. (forthcoming 2025) (manuscript at 2).

Human Genome Project launched in the late 1980s,[71] the international effort to sequence the human genome, the NIH faced early questions about when to require grantees to release data to the public, and on what terms.[72] The path the agency and its allies chose has changed the norms of open science and allowed for an outpouring of new genetics research.

Geneticists in the 1980s viewed the full human genome as a keystone to understanding human health and the underlying causes of disease.[73] Scientists and companies, if racing to understand the genome piecemeal, might have kept their discoveries largely secret to prevent others from publishing competing research first, and to ensure priority over genome patents.[74] To coordinate scientific efforts, promote the broad and speedy diffusion of genetic learnings, and prevent genetic patents, the NIH announced a new policy in 1992 requiring its grantees to publish full genetic sequences within six months of generation.[75] This ran against the norm in most of biology of releasing data only with the publication of results, which helped protect the curator's scientific credit.[76]

Four years later, with many competing and overlapping efforts at compiling the human genome springing up, the NIH and other major funders realized that they needed to do more to coordinate data generation and release.[77] The consortium convened a meeting in Bermuda of influential scientists and policymakers to set out new principles for sharing genetic data.[78] The result was

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[71] *See* SIDDHARTHA MUKHERJEE, THE GENE: AN INTIMATE HISTORY 303-304 (2016). The Department of Energy was the first U.S. agency involved, but the NIH moved quickly to seize the lion's share of the project. *See* James D. Watson, *The Human Genome Project: Past, Present, and Future*, 248 SCI. 44 (1990). The U.K.'s Wellcome Trust was another major funder. *See The Human Genome Project: a new era of scientific progress*, WELLCOME TR. (Feb. 6, 2025), https://wellcome.org/news/human-genome-project-new-era-scientific-progress.

[72] Jorge L. Contreras, *Prepublication Data Release, Latency, and Genome Commons*, 329 SCI. 393, 393 (2010).

[73] *See, e.g.*, MUKHERJEE, *supra* note 71, at 295-97, 301-303.

[74] *See* Freilich & Price, *supra* note 70, at 5; Contreras, *supra* note 72; Kathryn Maxson Jones et al., *The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project*, 51 J. HIST. BIOLOGY 693 (2018). The Supreme Court later held that genetic sequences found in nature were unpatentable under Section 101 of the Patent Act, *see* Ass'n for Molecular Biology v. Myriad Genetics, 569 U.S. 576, 591 (2013), but scientists at the time had no way to predict this holding.

[75] Contreras, *supra* note 72; Robert Cook-Deegan, et al., *Sharing Data to Build a Medical Information Commons: From Bermuda to the Global Alliance*, 18 ANN. REV. GENOMICS HUM. GENETICS 389, 395 (2017).

[76] Cook-Deegan, et al., *supra* note 75; Contreras, *supra* note 72.

[77] Maxson Jones et al., *supra* note 74, at 728-34; Cook-Deegan, et al., *supra* note 75, at 391-92.

[78] Kayte Spector-Bagdady et al., *"A Double-Edged Sword": A Brief History of Genomic Data Governance and Genetic Researcher Perspectives on Data Sharing*, 52 J.L. MED. ETHICS 399, 400 (2024); Contreras, *supra* note 72; Cook-Deegan, et al., *supra* note 75.

a short document that called on scientists to release sizable genetic data within 24 hours of creation. By 1997, these recommendations, later termed the Bermuda Principles, became an NIH mandate.[79] They would soon become the template for biological data sharing practices more generally.[80]

Although the Bermuda Principles remained aspirational—daily data release, though technically required by the NIH, was often impossible or sidestepped by contributors—their influence was nevertheless profound. By 2003, the human genome had been fully sequenced and was available for public download.[81] Scientists have since built a vast ensemble of research on the Human Genome Project's work.[82] The Bermuda Principles influenced the direction of research by making many sequences publicly available that plausibly would not have been absent government intervention. Heidi Williams has found that sequences temporarily held secret by the private company Celera, which sequenced the genome in parallel to the public effort, generated 20-30% fewer publications and reduced product development compared to publicly disclosed genes.[83]

Although government agencies and nonprofits bankrolled the Human Genome Project, and turned the Bermuda Principles into binding policy, geneticists played a key role in crafting the Principles. As Kathryn Maxson Jones and colleagues have shown, those norms sprang from a surprising source: worm scientists. Biologists studying the simple worm *C. elegans* had, beginning in the 1970s, pioneered the idea of pre-publication data disclosures to create standardized results and avoid duplicating work.[84] Their international effort to map the worm's genome impressed James Watson, the co-discoverer of DNA's double helix and the NIH's initial lead on the Human Genome Project.[85] Influential *C. elgans* experts, and their allies such as Watson, were dedicated to

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[79] *See Reaffirmation and Extension of NHGRI Rapid Data Release Policies: Large-Scale Sequencing and Other Community Resource Projects*, NAT'L HUM. GENOME RES. INST. (2003), https://www.genome.gov/10506537/reaffirmation-and-extension-of-nhgri-rapid-data-release-policies (last visited July 16, 2025).

[80] *See* Jorge L. Contreras, *Bermuda's Legacy: Policy, Patents and the Design of the Genome Commons*, 12 MINN. J.L. SCI. & TECH. 61 (2011); Toronto Int'l Data Release Workshop Authors, *Prepublication Data Sharing*, 461 NATURE 168 (2009).

[81] Maxson Jones et al., *supra* note 74, at 754 ("Even amongst the NIH's grantees, daily data sharing was a paradigmatic standard to which only a few were able to adhere, with rapid, pre-publication sharing being the much more essential result."); Cook-Deegan et al., *supra* note 75.

[82] Freilich & Price, *supra* note 70. As I discuss below, the NIH has put in place rules governing the terms on which this data can be released and accessed. *See infra* Part I.C.

[83] Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 4 (2013).

[84] Maxson Jones et al., *supra* note 74, at 709-19, 738; Cook-Deegan, et al., *supra* note 75, at 395.

[85] Watson, *supra* note 71. Watson stepped down in 1992 in part because he viewed the NIH's policies as too patent friendly. *See* Cook-Deegan et al., *supra* note 75, at 393.

placing the human genome in the public domain and avoiding genetic patenting.[86] Watson modelled the NIH's initial data policies on those of the "worm community," and *C. elegans* experts later promoted the daily-data-sharing policy at the Bermuda conference.[87]

This is not to suggest that scientists' views were uniform, or that NIH civil servants were irrelevant in setting the agency's data policy; far from it. The policy was controversial, and opposed by some important geneticists.[88] But the advocacy of the scientific leaders of the most productive genetic labs in the world (on both worms and humans) won the day. As with so many NIH policies, it was widely respected scientists who created the precedent for, and successfully promoted the NIH's implementation of, the Bermuda Principles.

As we have seen, the NIH's funding, prestige, and data give it enormous power to steer the direction of scientific research. The agency's grants push scientists and firms to write different papers, seek different patents, and develop different drugs than they would in the agency's absence. NIH funding decisions help decide which scientists stay active and publishing, and which leave the field. The agency's prestige has allowed it to set research agendas, and its data policies open (and, as we will see later, sometimes foreclose) vistas of scholarship. But though the NIH's influence is everywhere, its mode of governance is one of controlled self-abnegation, allowing scientists to determine and implement many of its key policies. Through study sections, Advisory Councils, and constant researcher consultations, the NIH has sought to direct science as elite scientists would like it directed.

B. Research Processes

The NIH influences not only what scientists study, but how they study—how they recruit participants, obtain consent, pose questions, design their wet labs, treat animals, and much else. Here, I will consider two chief examples of the agency's influence on research processes: human-subjects research rules, and biosafety requirements. Although the NIH no longer administers human-subject rules, its early work on institutional review boards (IRBs) laid the foundation for regulations that apply across the United States and beyond. When it comes to laboratory safety, NIH governance remains central. And even the more stringent biosafety regimes for specified pathogens regulated by the CDC

[86] Jacob S. Sherkow & Henry T. Greely, *The History of Patenting Genetic Material*, 49 ANN. REV. GENETICS 161, 166-67 (2015); Maxson Jones et al., *supra* note 68, at 738-39.
[87] Maxson Jones et al., *supra* note 74, at 736-40.
[88] *See, e.g.*, Freilich & Price, *supra* note 64 (on NIH administrators' role); Cook-Deegan et al., *supra* note 75, at 394-396 (discussing some scientists' disagreement with the daily-release policy).

and USDA explicitly incorporate NIH grant terms. In both cases, we can see the NIH's signature governance style at work. The agency used its levers of power, particularly its funds and prestige, to create and preserve regimes in close cooperation with scientists, leaving essential governance decisions in local, chiefly scientific, hands.

The IRB is today the leading tool of federal research oversight. Congress has vested boards with the power to protect research subjects by vetting all federally funded studies involving human subjects, as well as those used to support FDA approval. By combining ubiquitous federal authority with broad discretion modelled on peer review, the IRB represents the paradigm of NIH-style governance.[89] These boards extend the federal hand to govern the most minute details of research procedure—a misspelled word in a consent form, the phrasing of a delicate item on a questionnaire, the type of birth control required of study participants—but give the exercise of that power to bodies chosen by, and representing the interest of, research institutions.

IRBs have wide jurisdiction. The government tasks IRBs with ensuring that researchers minimize risk to participants by employing "sound" procedures, confirming that a study's risks to participants are "reasonable in relation to anticipated benefits," that subject selection is "equitable," and that scholars obtain and record participants' informed consent.[90] IRBs must also have a modicum of independence. Out of a minimum quorum of five members, at least one must have chiefly "nonscientific" concerns, and one must be unaffiliated with the institution conducting the research.[91] The regulations also call for the board to possess diversity of gender, race, and "cultural background[,]" but do not quantify these requirements.[92]

IRBs change how research is done. In a recent study by RAND, more than 70% of surveyed NIH grantees reported that they had modified the protocol of their most recent human-subjects study in response to board review.[93] The most common change was updating the consent process or materials, but more sweeping changes were common: 12% of modifications changed the scientific

[89] Private delegation is a peculiarly American approach to regulation, as scholars have shown in fields as diverse as mortgage regulation to health care. *See, e.g.*, SARAH BABB, REGULATING HUMAN RESEARCH: IRBS FROM PEER REVIEW TO COMPLIANCE BUREAUCRACY (2020); KIMBERLY J. MORGAN & ANDREA LOUISE CAMPBELL, THE DELEGATED WELFARE STATE: MEDICARE, MARKETS, AND THE GOVERNANCE OF SOCIAL POLICY (2011).
[90] 45 C.F.R. § 46.11 (2025).
[91] 45 C.F.R. § 46.107 (2025).
[92] *Id*.
[93] Sandra H. Berry et al., *Profile of Institutional Review Board Characteristics Prior to the 2019 Implementation of the Revised Common Rule*, RAND CORP., 49 (2019), https://www.rand.org/pubs/research_reports/RR2648.html.

design of the study.[94] Twelve percent of respondents also said that protocol modifications involved considerable or extensive project costs and time delays.[95] IRB effects can also be less visible, because researchers design their projects with IRB review in mind. Almost one in five respondents reported abandoning or not pursuing a project because of the prospect of IRB vetting.[96]

IRBs owe their origin to NIH practices from the 1950s.[97] That history reveals how the modern IRB emerged from the peculiarities of science grantmaker governance. The NIH's scientist-centered staffing, its intramural work, and its identification with researchers led it to develop a form of oversight designed to accord researchers extensive autonomy. The agency then used its funding and prestige to spread, defend, and entrench the IRB process. The result was that the FDA patterned its binding rules on the NIH approach, and when Congress mandated ethical review for federally funded studies in 1974, it did so by copying the NIH model. Although research oversight has changed considerably since the NIH's early governance efforts, key features from those years remain—especially the decentralized nature of discretion, the reliance on peer review, and the weakness of federal oversight.

The NIH in the early 1950s confronted a problem. It wanted the power to prevent scandalous research (and lawsuits) in its new research hospital, the Clinical Center, while at the same time fending off accusations that federal money would corrupt the direction of research through bureaucratic oversight.[98] The agency came up with a novel answer. It required researchers to seek the advice of a Clinical Review Committee if a study subjected humans to "unusual hazards" or involved healthy volunteers.[99] Although the NIH continued, in its words, to "place primary responsibility for the formulation and conduct of

[94] *Id.*
[95] *Id.* at 49–50.
[96] *Id*. at 48. For a striking modern example of IRB difficulties leading an investigator to abandon a project studying child abuse, *see* STARK, *supra* note 9, at 28–30; STORY *supra* note 27, 51 at 28–30.
[97] *See* STARK, *supra* note 9; DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING (2000); BABB, *supra* note 89, at 17–19.
[98] STARK, *supra* note 9 at 102–04.
[99] *Id.* at 107, 108; *see also* ROTHMAN, *supra* note 97, at 54–56; NATIONAL INSTITUTES OF HEALTH, GROUP CONSIDERATION OF CLINICAL RESEARCH PROCEDURES DEVIATING FROM ACCEPTED MEDICAL PRACTICE OR INVOLVING UNUSUAL HAZARD, at 321–24 (Nov. 17, 1953), *reprinted in* ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, SUPPLEMENTAL VOLUME 1: ANCILLARY MATERIALS, FINAL REPORT (1995) [hereinafter GROUP CONSIDERATION]; At the time, formal procedures to review the ethics of study protocols were unusual. Even in the early 1960s, NIH-funded researchers found that only 9 out of 52 surveyed medical schools had formal procedures for approving human experiments. *See* ROTHMAN, *supra* note 97, at 60.

clinical research . . . on the principal investigators," it now cabined researchers' freedom of action through peer review.[100] The result was a regulatory regime that appeared strict on the surface but which was in practice highly deferential to individual scientists.[101]

NIH leaders had an additional reason to preserve researcher autonomy: they were scientists themselves. From the head of the NIH's parent agency on down, physician scientists dominated the agency leadership in the early 1950s. The Surgeon General, who at the time oversaw the NIH, was Leonard Scheele, a doctor and former head of the National Cancer Institute.[102] NIH director William Sebrell was a world-leading nutritionist.[103] James Shannon, the head of intramural research at the NIH, was a nephrologist and malaria expert.[104] The first chairman of the Clinical Center's Medical Board, Terry Luther, was a cardiologist who joined the NIH after facing research restrictions in an earlier job.[105] And the policy group that devised the committee review system was chaired by Russell Wilder, a diabetes researcher.[106]

Shannon in particular exemplifies the NIH's intertwining of government oversight with fierce advocacy for scientific autonomy and researcher discretion.[107] He was the key figure navigating the agency's paradoxical role as a new behemoth bestriding biomedicine that gave much of its power to its beneficiaries.[108] Shannon was a skilled administrator who ran the U.S. anti-malaria research effort during World War II and went on to head the NIH between 1955 and 1968.[109] As director, Shannon worked with allies in Congress to expand the agency's budget by more than 1,200% while insisting that the NIH

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[100] GROUP CONSIDERATION, *supra* note 99, at 321.
[101] STARK, *supra* note 9, at 106–07.
[102] J.Y. Smith, *Former U.S. Surgeon General Leonard A. Scheele, 85, Dies*, WASH. POST (Jan. 10, 1993).
[103] *William Henry Sebrell, Jr., M.D.*, NAT'L INSTS. OF HEALTH (Feb. 21, 2025), https://www.nih.gov/about-nih/nih-almanac/william-henry-sebrell-jr-md (last visited July 13, 2025).
[104] THOMAS KENNEDY JR., *James Augustine Shannon*, *in* BIOGRAPHICAL MEMOIRS: VOLUME 75 11–12 (1998); STARK, *supra* note 9, at 94–96.
[105] STARK, *supra* note 9, at 92; Eric Pace, *Dr. Luther L. Terry, 73, Is Dead; Warned Public of Cigarette Peril*, N.Y. TIMES (Mar. 31, 1985).
[106] James W. Wheless, *History of the Ketogenic Diet*, 49 Suppl. 8 EPILEPSIA 3, 3–5 (2008); STARK, *supra* note 9, at 102.
[107] Other figures who combine many of Shannon's traits—a belief in energetic government and researcher autonomy—include the Surgeon Generals Thomas Parran, Leonard Scheele, and Terry Luther. Before 1968, the Surgeon General oversaw the NIH. On Parran, see Kayte Spector-Bagdady & Paul A. Lombardo, *Something of an Adventure: Postwar NIH Research Ethos and the Guatemala STD Experiments*, 41 J.L. MED. & ETHICS 697 (2013).
[108] *See* STRICKLAND, STORY *supra* note 27, at 114–15; GREENBERG, *supra* note 9, at 279–283.
[109] *See* KENNEDY JR., *supra* note 104.

would achieve its best outcomes by, as he told Congress, giving cash to "good ideas and good men" with few strings attached.[110] The NIH's early postwar work and funding thus operated with almost no independent ethical scrutiny.

Shannon and the NIH were forced to reckon with the limits of scientific autonomy after a series of scandals in the early 1960s. In 1962, the FDA revealed that the manufacturer of thalidomide, an anti-nausea drug that caused debilitating birth defects, had tested the drug in thousands of women in the United States, many of whom had not been told they were in a clinical trial.[111] Congress responded by strengthening FDA pre-market review authority and empowering the agency to require the consent of participants in human trials designed for drug approval.[112] Two years later, *Science* reported that researchers receiving NIH funding had injected elderly and senile patients with cancer cells without their consent, provoking outrage in Congress.[113] Already under fire in Congress for the NIH's purportedly loose spending and deferential attitude to scientists, and facing tort liability for the cancer-cell injections, Shannon sought to contain the furor by applying the Clinical Center's group-review approach to external scientists taking NIH money.[114]

In 1966, the Surgeon General Stewart accepted Shannon's proposal and required all human-subject studies supported by his department (including the NIH) to undergo "prior review . . . by a committee of [the primary investigator's] institutional associates."[115] The policy demanded that the review be "independent of the investigator" and consider participant rights, the nature of consent, and the risks and benefits of the investigation.[116] Stewart wrote that he was leaving the definition of these terms to "the wisdom and sound professional

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[110] *Id.* at 11–12; STARK, *supra* note 9, at 147–49; GREENBERG, *supra* note 9, at 279–282; MANDEL, *supra* note 52, at 97, 103; Baldwin, *supra* note 53, at 549; Eric Pace, *James A. Shannon, 89, Is Dead; Ex-Director of Health Institutes*, N.Y. TIMES (Mar. 31, 1985).

[111] *See* ROTHMAN, *supra* note 97, at 64; Drug Industry Act of 1962 Hearing, at 517–518. The NIH budget grew from $81 million in 1955 to $1.08 billion in 1968. *See The NIH Almanac: Historical Budget Information—Appropriations Section 1*, NAT'L. INST. HEALTH, https://www.nih.gov/about-nih/nih-almanac/appropriations-section-1.

[112] STARK, *supra* note 9, at 114; CARPENTER, *supra* note 9, at 262–63; PUB. L. No. 75-717, § 501, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 355(i)).

[113] Elinor Langer, *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, 143 SCIENCE 551 (1964).; ROTHMAN, *supra* note 97, at 86–87; STARK, *supra* note 9, at 144–46, 149–150.

[114] STARK, *supra* note 9; ROTHMAN, *supra* note 97, at 89–90; Charles R. McCarthy, *The Origins and Policies That Govern Institutional Review Boards*, *in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 541, 541–42, 545–46 (EZEKIEL J. EMANUEL ET AL. eds. 2008).

[115] Memorandum from William H. Stewart, Surgeon Gen., U.S. Pub. Health Serv., to Heads of Institutions Receiving Pub. Health Serv. Grants, *Clinical Investigations Using Human Subjects* (Policy & Proc. Order No. 129) (Feb. 8, 1966).

[116] *Id.*

judgment" of grantee institutions.[117] Like the Clinical Center's review committee, grantee committees were ultimately self-governance bodies, populated by the investigator's peers.[118] Although the initial policy called only for ad hoc committees, by the end of the year the Surgeon General called on grantee institutions to create standing review committees.[119] The modern IRB system was well on its way.

The NIH review-board policy proved to be an enduring template for regulatory and statutory extension. In 1971, the FDA overhauled its human-subjects research requirements to closely follow the NIH approach.[120] The rules required new drug applicants to receive approval from an "institutional review committee" before initiating human trials that would be used to support a drug application.[121] Although the FDA widened the committee membership by mandating "lawyers, clergymen, or laymen" to join scientists on the board, it retained the core features of the NIH approach: the distribution of oversight powers to local boards vested with discretion and staffed largely by researchers.[122] Moreover, rather than create new standards for institutional review, the FDA explicitly adopted the NIH policies embodied in departmental grant terms.[123]

Three years later, in the wake of more health research scandals, Congress passed the National Research Act to protect human subjects in federally funded research. Congress considered several bills that would have centralized

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[117] STARK, *supra* note 9, at 154; Memorandum from William H. Stewart, *supra* note 115.
[118] Memorandum from William H. Stewart, Surgeon Gen., U.S. Pub. Health Serv., to Heads of Institutions Receiving Pub. Health Serv. Grants, *Revised Procedure on Clinical Research and Investigation Involving Human Subjects* (July 1, 1966); ROTHMAN, *supra* note 97, at 89–91.
[119] *See* STARK, *supra* note 9, at 154–55; CARPENTER, *supra* note 9, at 549.
[120] *See* McCarthy, *supra* note 114, at 546–47 (referring to the FDA actions as "piggybacking" on NIH policy). In 1966, shortly after Stewart announced the new human-subject study policy, the FDA promulgated its first rules to protect human subjects in trials aimed at FDA approval. *See* 31 Fed. Reg. at 11415 (Aug. 30, 1966). These minimal rules required only that investigators obtain consent from patients in their trials "except where they deem it infeasible or, in their professional judgment contrary to the interest of such human beings." *Id*. The agency did not provide for pre-study approval from an ethics committee.
[121] Institutional Committee Review of Clinical Investigations of New Drugs in Human Beings, 36 Fed. Reg. at 5037 (Mar. 17 1971); CARPENTER, *supra* note 9, at 549–551; McCarthy, *supra* note 114, at 546.
[122] 36 Fed. Reg. at 5038 (Mar. 17, 1971). In its proposed rule, the FDA had called these bodies "peer committees," but changed the name in its final rule "[i]n view of the need for committee members with varying backgrounds." *Id*.
[123] *Id*. The Department's grant terms implemented the Surgeon General's policy of 1966, *see* STARK, *supra* note 9, at 157, and were enforced by the NIH. *See* NAT'L INSTS. OF HEALTH, NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 1, No. 18, 9 (Apr. 14, 1972), https://grants.nih.gov/grants/guide/historical/1972_04_14_Vol_01_No_18.pdf.

regulation of human trials but, responding in part to NIH lobbying, opted to follow in the NIH's footsteps.[124] The law required science grantees to receive IRB approval before conducting "biomedical or behavioral research involving human subjects."[125] Rather than charting a new path, Congress did little more than endorse the NIH's approach. Indeed, the new body the executive created to enforce IRB rules—including those that applied to the NIH itself—was housed in the NIH for the next quarter century.

The history of the IRB reveals several key themes in science grant governance. The NIH's combination of scientific leadership and intramural research exposed it to ethical questions early, and led it to stake out policy positions that were very favorable to researchers. Its enormous and growing funding authority then allowed it to promulgate that new, peer-review-like approach to ethics policy across the nation. By 1973, just seven years after the NIH policy went into effect, there were more than 600 review boards in operation, each making local decisions about what research was ethically justified.[126] The agency's prestige, and its early agenda setting, created a template for other governmental bodies to pick up. The FDA explicitly modelled its human-subjects rules on the NIH's, noting that they had been "developed by knowledgeable and experienced individuals in the problems of undertaking research in humans."[127] Congress soon followed suit, rejecting calls for an independent or centralized adjudicator of research ethics. Facing the prospect of a national research regulator, the NIH adroitly created the precedent for continued local control.[128]

That the NIH entrenched local peer-review as the paradigm of research oversight did not mean human-subject research continued after the 1970s as it had in the 1950s. The NIH and FDA now had, in political scientist Daniel Carpenter's words, "satellite regulators," extending the reach of the federal government over every detail of research involving human subjects. Once IRBs were empaneled, they went to work: scrutinizing consent forms, study designs, participant eligibility criteria, and much else, requesting changes on most

[124] *See* BABB, *supra* note 89, at 18–21; STARK, *supra* note 9, at 163. On NIH involvement in the drafting of the bill, see McCarthy, *supra* note 114, at 548.
[125] Pub. L. No. 93-348, 88 Stat. 342, 352-353 (1974).
[126] Hearings Before the Subcomm. on Health of the S. Comm. on Labor & Pub. Welfare on S. 974, S. 878 & S.J. Res. 71, 93d Cong., 1st Sess. pt. 3, at 1050 (1973). These boards were given exceptionally little guidance about how to approach the task of ethical weighing. *See id.*; *see also NIH Guide for Grants and Contracts*, NAT'L INSTS. OF HEALTH Vol. 1, No. 18, at 9 (Apr. 14, 1972).
[127] 36 Fed. Reg. at 5038 (Mar. 17, 1971).
[128] *See* McCarthy, *supra* note 114, at 548.

protocols that came before them.[129] With little guidance from Washington beyond broad ethical canons, IRBs push researchers in idiosyncratic directions based on local personnel, practice, and precedent.[130]

In Part III, I will consider how well this system works, and the NIH's (now defunct) role in administering it. What is worth observing here is how unusual IRBs are. They are government-mandated committees, organized by the objects of regulation, composed of private citizens, who are asked to make legal rulings about their peers with limited or no opportunity for higher appeal and in the near-total absence of binding guidance. They represent the republic of science grants at work, actively shaping scientific processes through federally mediated self-governance.

The NIH also controls scientific processes through its detailed biosafety requirements, spelled out in the NIH Guidelines on Recombinant and Synthetic Nucleic Acids, and enforced by local institutional biosafety committees. The story behind the NIH's creation of the Guidelines parallels its invention of IRBs to a remarkable degree. And it similarly illustrates the agency's approach to governing science through delegation.

The story begins with a chimera. In the early 1970s, scientists at Stanford University including Paul Berg and his postdoc Janet Mertz tested whether they could combine bacterial genes with those of a virus known as SV40.[131] They hoped that the resulting recombinant DNA (as Berg would later term it) could be studied, replicated, and set to work in bacterial or mammalian cells.[132] But what a bacterium with SV40 genes would actually do in a lab—or, if one escaped, outside of one—was at the time totally unknown. SV40 caused cancer in monkeys. Would bacterial cells pass cancer-causing viral genes to humans?

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[129] *See* CARL E. SCHNEIDER, THE CENSOR'S HAND: THE MISREGULATION OF HUMAN-SUBJECT RESEARCH 74–105 (2015); *id.* at 81 (collecting studies finding that IRBs more often than not require study changes).

[130] *Id.*; BABB, *supra* note 89; STARK, *supra* note 9; ZACHARY M. SCHRAG, ETHICAL IMPERIALISM: INSTITUTIONAL REVIEW BOARDS AND THE SOCIAL SCIENCES, 1965–2009 (2010).

[131] *See* MUKHERJEE, *supra* note 71, at 204–06; WRIGHT, MOLECULAR POLITICS, *supra* note 9; Sidney R. Kushner, *The Development and Utilization of Recombinant DNA Technology*, *in* RECOMBINANT DNA: SCIENCE, ETHICS AND POLITICS 35, 35–58 (1978); DONALD S. FREDRICKSON, THE RECOMBINANT DNA CONTROVERSY: A MEMOIR—SCIENCE, POLITICS, AND THE PUBLIC INTEREST 1974–1981 7–9 (2001).

[132] These same scientists were also interested in studying if bacterial genes could be placed in viruses, and then used to transmit genes to cells, including those of humans. *See* MUKHERJEE, *supra* note 71, at 203–04; SHELDON KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY 59 (1982).

Would viral genes give bacteria new, expansive capabilities to infect humans? No one knew.[133]

In 1971, with his lab on the verge of transferring SV40 genes into a bacterium, another scientist convinced Berg that the risks of combining the organisms were too serious to hazard alone.[134] Although Berg was skeptical about the risks, he paused the experiments and began to organize efforts to study the problem. Other scientists forged ahead with recombinant DNA research, however, and showed that it was surprisingly easy to interlace genes from different domains of life.[135] In response, a group of biologists led by Maxine Singer, a DNA expert and administrator at the NIH, pushed for the creation of an expert panel to study the risks of recombinant DNA.[136] The National Academy of Sciences appointed Berg to chair the committee, which was composed entirely of scientists.[137] The committee released a report calling on researchers to voluntarily suspend the riskiest recombinant DNA studies, and asking the NIH director to appoint an advisory group to "devis[e] guidelines to be followed by investigators working with potentially hazardous recombinant DNA molecules."[138] The NIH promptly created the advisory group, which consisted of eleven biologists, three of them actively working on recombinant DNA.[139]

Berg and colleagues also recommended that scientists convene an "international meeting" to confront recombinant DNA risk, which the committee and other scientists, including NIH officials, then organized.[140] In early 1975, more than 100 scientists, along with a smattering of lawyers and

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[133] *See* KRIMSKY, *supra* note 132, at 87; FREDERICKSON, *supra* note 131.
[134] *See* Robert Pollack & Matthew Cobb, *Are There Any Good Experiments That Should Not Be Done?*, 20 PLOS BIOL. e3001539 (2022).
[135] MUKHERJEE, *supra* note 71, at 226–29; FREDERICKSON, *supra* note 133, at 13–15.
[136] Maxine F. Singer & Dieter Söll, *Guidelines for DNA Hybrid Molecules*, 181 SCI. 1114 (1973).
[137] KRIMSKY, *supra* note 132, at 82–84; *id*. at 84 ("The final list of eleven signers . . . reads like a Who's Who in molecular biology"). NIH director Donald Frederickson noted that the scientists had turned to the Academy—a private entity composed of scientists—"to share their dilemma 'in the family,' seeking an 'in-house' solution." FREDRICKSON, *supra* note 133, at 29.
[138] Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT'L ACAD. SCI. U.S.A. 1981 (1975).
[139] *See* 39 Fed. Reg. at 39306 (1974); FREDRICKSON, *supra* note 133, at 34; KRIMSKY, *supra* note 132, at 155–56. The committee was chaired by DeWitt Setten, a biochemist and longtime NIH administrator. *See* KRIMSKY, *supra* note 132, at 156; *Asilomar Report*, *infra* note 138. In a sign of the NIH drawing on its expertise, Setten selected the committee members with the help of research grant division staff. *See* KRIMSKY, *supra* note 132, at 156.
[140] FREDRICKSON, *supra* note 133, at 17; HERBERT GOTTWEIS, GOVERNING MOLECULES: THE DISCURSIVE POLITICS OF GENETIC ENGINEERING IN EUROPE AND THE UNITED STATES 87–88 (1998).

journalists descended on the Asilomar conference center in Pacific Grove.[141] The conference, ever since dubbed simply "Asilomar," has entered scientific lore.[142] Over three days, the attendees debated the risks of recombinant DNA research and how they might be reduced. The organizers sculpted the agenda to focus on the biosafety dangers of genetic engineering—that is, the risk of accidentally creating a dangerous agent that might escape a lab.[143] They also framed the meeting as raising a choice: scientists could either proactively adopt safety measures or face government regulation and common-law liability.[144] The prospect of liability and OSHA oversight spooked many of the scientists at the meeting.[145] When the organizing committee put forward a draft report proposing that the earlier research moratorium be lifted in combination with a new, self-regulatory biosafety regime, an overwhelming majority of attendees signed on.[146]

The Asilomar committee report was tailor-made for NIH implementation. The report proposed biosafety rules that were modelled on standards recently released by the NIH to contain tumor-causing viruses.[147] The report suggested that lab safety be overseen by a "local committee," whose "certificate of containment" would be appended to grant proposals to science funders.[148] The report noted that biosafety questions that could not adequately be addressed by local committees should be referred to "the NIH Advisory Committee on Recombinant DNA Molecules or some other body."[149]

The NIH moved quickly to take the regulatory baton. The day after the Asilomar conference ended, the NIH's advisory committee met and adopted the

[141] FREDRICKSON, *supra* note 133, at 17.
[142] *See* MUKHERJEE, *supra* note 71; Luis A. Campos, *Invoking Asilomar*, 387 SCI. 480 (2025).
[143] *See* Susan Wright, *Legitimating Genetic Engineering,* 44 PERSP. BIOL. & MED. 235, 239–40 (2001) [hereinafter, Wright, *Legitimating*]. In this way, the organizers set aside (at times explicitly) other dangers, like the ability of recombinant DNA research to enable biological weapons or human genetic engineering. *See id*.
[144] *Id.* at 239–40; KRIMSKY, *supra* note 132; MICHAEL ROGERS, BIOHAZARD 139–141 (1977).
[145] JOHN LEAR, RECOMBINANT DNA: THE UNTOLD STORY 140–43 (1978) [hereinafter RECOMBINANT DNA].
[146] *Id.*; FREDERICKSON, *supra* note 133; Report of the Organizing Committee of the Asilomar Conference on Recombinant DNA Molecules, *in* U.S. Department of Health, Education, and Welfare, 1 Recombinant DNA Research, at 45-47 [Hereinafter *Asilomar Report*].
[147] *Asilomar Report*, *supra* note 146, at 60–61; *see also* SAFETY STANDARDS FOR RESEARCH INVOLVING ONCOGENIC VIRUSES, NAT'L INSTS. OF HEALTH (1974). The Asilomar report contained many novel suggestions for the context of recombinant DNA, but its basic containment framework was lifted from the NIH document.
[148] *Asilomar Report*, *supra* note 146, at 63.
[149] *Id.* at 63.

Asilomar recommendations as interim guidelines.[150] The NIH committee agreed that local boards should consider the biosafety of individual laboratories, and those decisions should be subject to further review by NIH grantmaking study sections.[151] Over the next sixteen months, the NIH transformed the spare Asilomar report into the massive Recombinant DNA Guidelines that would, from 1976 onwards, control genetic research processes across the United States.[152] In releasing the Guidelines, the agency observed that they "replace[d] the current Asilomar guidelines," conferring quasi-regulatory power on the Asilomar organizers and acknowledging the continuity between the Asilomar regime and that adopted by the NIH.[153]

The agency's grantees were now bound to follow a new, NIH-controlled biosafety framework. The Guidelines barred a small number of especially dangerous experiments, and for permitted studies required scientists to apply progressively greater containment measures as experiments grew riskier (for example, because they involved human-infecting viruses).[154] But as it had done with human-subject research, the NIH delegated significant biosafety decision-making to principal investigators and their institutions. Scientists were tasked with classifying their own experiments for riskiness, and the NIH directed research institutions to create local institutional biohazard committees to ensure that labs met the agency's safety requirements.[155] The NIH only committed to doing its own site visits for the highest-containment labs meant to house "extremely hazardous" organisms.[156] In the years that followed, the NIH pared down these requirements, giving investigators further discretion.[157] The basic structure, with its emphasis on delegation, has remained.[158]

With the initial rules in place, the NIH sought to fend off more stringent regulation. Congressional leaders who had moved to regulate human-subject research saw genetic engineering as the next frontier of concern.[159] Other

[150] FREDRICKSON, *supra* note 133, at 36–37; ROGERS, *supra* note 144, at 101–102; 41 Fed. Reg. at 27,902, 27,903 (July 7, 1976).
[151] FREDRICKSON, *supra* note 133, at 36–37.
[152] 41 Fed. Reg. at 27,902 (July 7, 1976).
[153] *Id.*; *see* GOTTWEIS, *supra* note 140, at 91.
[154] *Id*.
[155] 41 Fed. Reg. at 27,920 (July 7, 1976). The NIH later renamed these committees "institutional biosafety committees."
[156] 41 Fed. Reg. at 27,913, 27,921 (July 7, 1976).
[157] *See* GOTTWEIS, *supra* note 140, at 100–103; WRIGHT, MOLECULAR POLITICS, *supra* note 9; FREDRICKSON, *supra* note 133; KRIMSKY, *supra* note 132.
[158] *See* NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM 45–52 (2004) [hereinafter FINK REPORT].
[159] *See* KRIMSKY, *supra* note 132, at 198–199, 312–337; GOTTWEIS, *supra* note 140, at 99–101; Frederickson, *supra* note 133, at 88–89, 136–37.

agencies, including the EPA and OSHA, considered regulating recombinant DNA research.[160] But the NIH director, Donald Frederickson, was eager to defend his agency's oversight monopoly. A highly cited cardiologist and NIH veteran, Frederickson had experience negotiating research oversight from the struggles over IRBs.[161] In 1976, he took charge of a committee consisting of all the agencies with a hand in recombinant DNA, and used his seat to retain NIH ownership over the topic, aided by the agency's incomparable expertise in molecular biology.[162] At the same time, Frederickson marshalled scientists to defend the status quo in Congress and defeat the bills introduced to regulate genetic engineering research.[163] Scientists were not unanimous; some prominent biologists supported stiffer regulation.[164] The NIH, though, was inclined to back the majority of researchers who sought a green light for experiments that showed mounting commercial application.[165]

The Guidelines framework remains the mainstay of U.S. biosafety regulations. Beginning in the mid-1990s, Congress tasked the CDC and USDA to regulate a small number of especially dangerous pathogens and toxins.[166] The resulting rules require labs working with these so-called select agents to create biosafety plans by reference to the Guidelines.[167] Rather than provide a new biosafety framework, the government has effectively turned the Guidelines, with the same four-level biosafety scheme as in 1976, into binding rules.

Just as noteworthy as its influence on technical regulation is how the NIH and its clientele shaped the narrative over what questions mattered when it came to humanity's newfound ability to directly manipulate genes.[168] The new technology raised a host of social and policy questions about what experiments and procedures were appropriate, and who should decide whether they should

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[160] *See* WRIGHT, MOLECULAR POLITICS, *supra* note 9.
[161] *See* STARK, *supra* note 9, at 111.
[162] *See* WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 257–259; FREDERICKSON, *supra* note 133, at 89–91.
[163] *See* KRIMSKY, *supra* note 132, at 198–205, 312–337; FREDERICKSON, *supra* note 133, at 137–140. As Susan Wright argues, the NIH was not the sole locus of opposition; outside scientists organized successfully to push back against legislation. WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 256–278. But the NIH helped guide scientific efforts in Congress, where it had close and effective relationships. *See id.* at 272–274.
[164] WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 269–272; KRIMSKY, *supra* note 132, at 341.
[165] Fredrickson estimates that he spent half of his time between 1976 and 1978 on recombinant DNA policy. *See* FREDRICKSON, *supra* note 133, at 72.
[166] *See* PUB. L. No. 104-132, § 511, 110 Stat. 1214, 1278 (1996).;
[167] *See* 42 C.F.R. § 73.12(c) (2025); 9 C.F.R. § 121.12(c) (2025). Licensees must also consult the biosafety manual that the NIH creates jointly with the CDC.
[168] *See* GOTTWEIS, *supra* note 140; KRIMSKY, *supra* note 32; WRIGHT, MOLECULAR POLITICS, *supra* note 9.

proceed. But the Asilomar report and the NIH officials who carried it forward focused policymakers on the narrow question of how to avoid harm to lab staff and what would now be called "lab leaks." NIH officials and their scientist associates were especially well equipped to answer that technical question.[169] Here we can see the NIH's "gatekeeping" and "conceptual" powers, to use Daniel Carpenter's terms: the ability to define social problems and to sculpt modes of thinking.[170]

The NIH's role in regulating DNA research reveals several features of how science grantmakers govern.

First, the NIH's staffing and relationships gave it a head start in designing the government response to the emerging scientific and political questions around genetic engineering—and entrenching its chosen approach. NIH officials took part in the earliest conversations about the risks of recombinant DNA experiments, led scientific self-organizing efforts before the Asilomar conference, helped design and fund the conference, and created a technically formidable advisory committee to turn the resulting framework into enforceable grant terms.[171] The NIH director then worked the executive branch (including chairing an interagency working group) and Congress to retain control over the rules and avoid more onerous (and statutory) research controls.[172]

Second, the NIH's funds and prestige gave it freedom of action to quickly disseminate new research process rules across the biomedical world. The agency adopted the Asilomar framework as its interim policy the day after the conference met, and was ready to promulgate a safety framework—developed virtually from scratch—in sixteen months.[173] As the dominant funder of biomedical research, it could impose terms on its grantees without having to wait for a new statute or promulgate rules consistent with Administrative Procedure Act processes.

More impressive than its speed was the NIH's ability to invent and spread a biosafety policy that it had no mandate to create. Without Congressional imprimatur, the NIH created a novel biosafety framework complete with local committees, a central review body, and detailed safety processes. The

[169] For an example of an NIH official rubbing into his audience how technical this question was, *see* FREDRICKSON, *supra* note 133, at 113–124.
[170] *See* CARPENTER, *supra* note 9, at 15.
[171] On NIH funding, *see* GOTTWEIS, *supra* note 140, at 87.
[172] *See* FREDRICKSON, *supra* note 133; 250; WRIGHT, MOLECULAR POLITICS, *supra* note 9.
[173] *See* H. DeWitt Stetten, Jr.*, The Early History of the Recombinant DNA Molecule Program Advisory Committee of NIH, in* RECOMBINANT DNA AND GENETIC EXPERIMENTATION 157 (Joan Morgan & W.J. Whelan eds. 1979); 41 Fed. Reg. at 27,902 (July 7, 1976).

Guidelines soon proved influential not just among government grantees but also among private firms, which sought NIH approval for genetic experiments.[174] As local governments looked to regulate genetic research, they too inscribed the Guidelines into law, as did the CDC and USDA.[175] And, flush with the NIH's success in the United States, the agency's director promoted the Guidelines in Europe and the United Kingdom, which adopted similar rules.[176] Today, the World Health Organization's biosafety recommendations closely follow those of the Guidelines.[177]

Third, the agency's approach was dominated by its instinctive protectiveness of researcher autonomy. At Asilomar, the chairman of the NIH recombinant DNA advisory committee (and NIH employee) DeWitt Stetten noted that "[t]he fewer regulations we have to live by the better off we are."[178] Frederickson, the NIH director, refers to biologists in his memoir as his "scientific constituents," and candidly admitted that the NIH "resist[ed] attempts" to regulate genetic engineering "by law."[179] Berg, the scientist who launched the recombinant DNA debate, argued that "[t]he most important lesson of Asilomar" was to "demonstrate that scientists were capable of self-governance."[180] Faced with a novel policy problem, the NIH—like most of the scientists it governed—reached for the familiar tool of peer review to oversee genetic research, just as it had for human-subject studies.

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[174] *See* FREDRICKSON, *supra* note 133, at 250–52; WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 189–191; Krimsky, *supra* note 132, at 202–205.

[175] R.W. Scheffler, *Asilomar Goes Underground: The Long Legacy of Recombinant DNA Hazard Debates for the Greater Boston Area Biotechnology Industry*, 58 J. HIST. BIO.67, 75, 86–87 (2025).

[176] *See* FREDRICKSON, *supra* note 133; GOTTWEIS, *supra* note 140; WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 209.

[177] *See* NAT'L RESEARCH COUNCIL, BIOSECURITY CHALLENGES OF THE GLOBAL EXPANSION OF HIGH-CONTAINMENT BIOLOGICAL LABORATORIES: SUMMARY OF A WORKSHOP (2012); World Health Org., *Laboratory Biosafety Manual* (4th ed. 2020).

[178] LEAR, RECOMBINANT DNA, *supra* note 145, at 147–148. *See also* WRIGHT, MOLECULAR POLITICS, *supra* note 9, at 173–174 (Setten created a subcommittee to write more safety conscious guidelines in part, as he wrote at the time, to fend off "a very distinct implied threat that the Legislature of the United States would tamper in this business"); STETTEN, JR., *supra* note 173, at 157 ("The [Recombinant DNA Advisory] Committee recommended that the Asilomar document, still in preparation at that time, should form the basis of actions by the NIH *and the scientific fraternity* pending the development of its own set of guidelines." (emphasis added)).

[179] FREDRICKSON, *supra* note 133, at 137, 250.

[180] MUKHERJEE, *supra* note 71, at 233.

C. Research Results

The NIH governs research results, overseeing what scientists, including those it does not fund, say to the public. Scholars have given considerable attention to the ways in which science grants and other innovation policies influence the rate and direction of invention.[181] But grantmakers and grants not only promote the creation and spread of information; they also suppress and redirect what they view as dangerous or harmful findings.

In this Section, I analyze this undertheorized power by examining the NIH's oversight of human genetic data and so-called dual-use research of concern. The agency's contractual grip on genetic data allows it to dictate to whom data are disseminated, and on what terms. The government has been less successful in using NIH funding and prestige to prevent the release of what it deems risky research results. But there too officials have sought to tamp down on purportedly dangerous publications, such as those that can teach readers how to resurrect deadly viruses. Both examples showcase the agency's attempts to dampen research results it deems harmful, its leveraging of funding, data, and prestige to control policy, and its mostly deferential approach to research governance.

A significant portion of human genetic data is controlled by the NIH. As the lead funder of the Human Genome Project, the NIH pushed researchers to release data daily, rather than await publication.[182] At the same time as it sought greater transparency, though, the agency recognized a tension with protecting donor privacy. Geneticists drew on a broad range of human samples to construct the model human genome, and not all donors had agreed to the same terms. Might sequencing genes from donors who had not agreed to such analysis conflict with the human-subject protections hammered out decades earlier?

To address this concern, in 1996 the NIH began requiring labs working for the Human Genome Project to obtain informed donor consent and IRB approval before publishing human genetic data, and to strip out identifying details.[183] IRB controls were by now routine, though new to the realm of subsequent sample analysis. What was entirely novel, though, was the NIH's requirement that

[181] *See, e.g.*, Price, *supra* note 7; Frelich & Price, *supra* note 70.
[182] *See supra* Section I.A.
[183] U.S. Dep't of Energy & Nat'l Ctr. for Hum. Genome Rsch., *Guidance on Human Subjects Issues in Large-Scale DNA Sequencing*, DEP'T ENERGY (1996), https://doe-humangenomeproject.ornl.gov/nchgr-doe-guidance-on-human-subjects-issues-in-large-scale-dna-sequencing/; *see also* P3G Consortium et al., *Public Access to Genome-Wide Data: Five Views on Balancing Research with Privacy and Protection*, 5 PLoS GENETICS e1000665 (2009).

scientists de-identify DNA samples, even if donors had consented to identified release. This represented a new frontier in controlling scientific communication.

The 1996 policy was only a baby step when it came to informational control, however. Ethicists' concerns with human genetic data soon proved broader than the Human Genome Project.[184] As scientists drove down the price of gene sequencing, they were increasingly analyzing human samples collected for other purposes (for example, the cells famously derived from cancer patient Henrietta Lacks).[185] Many of these samples had been collected without donor consent, or at least without the donors' agreement to analyze the genes for new research purposes.[186] In addition, even new genetic sampling studies used a dizzying array of consent forms, raising questions about how public the resulting sequences should be. And all the while, ethicists worried that genetic research might be used to target or demean racial minorities.[187] The NIH's stated preference for open data conflicted with its desire for morally unimpeachable research, or so it feared.

To address these concerns, in 2007 the NIH created data access committees to control the release of scientific findings.[188] The NIH tasked these committees, which were staffed by agency employees, with safeguarding human genetic data created with NIH funds. Under the new rules, scientists funded by the NIH were required to deposit human health data in government servers, or in servers that guarded patient privacy to a similar degree.[189] Scientists were also required to

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[184] *See* Jalayne J. Arias et al., *The growth and gaps of genetic data sharing policies in the United States*, 2 J. Law Biosci. 56, 62–63 (2014); W.W. Lowrance & Francis S. Collins, *Identifiability in Genomic Research*, 317 Sci. 600 (2007).

[185] Amy L. McGuire & Richard A. Gibbs, *Genetics: No Longer De-Identified*, 312 Sci. 370 (2006).

[186] *See* Nanibaa' A. Garrison, *Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research*, 38 Sci. Tech. & Hum. Values 201 (2013); Michelle M. Mello & Leslie E. Wolf, *The Havasupai Indian Tribe Case—Lessons for Research Involving Stored Biologic Samples*, 363 N. Eng. J. Med. 204 (2010).

[187] *See* Int'l HapMap Consortium*, The International HapMap Project,* 426 Nature 789 (2003); Int'l HapMap Consortium, *Integrating Ethics and Science in the International HapMap Project*, 5 Nature Rev. Genet. 467 (2004); Morris Foster & Richard Sharp, *Share and Share Alike: Deciding How to Distribute the Scientific and Social Benefits of Genomic Data*, 8 Nature Rev. Genet. 633 (2007); Michaeleen Doucleff, *Decades After Henrietta Lacks' Death, Family Gets a Say on Her Cells*, NPR (Aug. 7, 2013), https://www.npr.org/sections/health-shots/2013/08/07/209807857/decades-after-lacks-death-family-gets-a-say-on-her-cells; McGuire & Gibbs, *supra* note 185.

[188] *Policy for Sharing of Data Obtained in NIH-Supported or -Conducted Genome-Wide Association Studies (GWAS)*, Nat'l Insts. of Health (Aug. 28, 2007), https://grants.nih.gov/grants/guide/notice-files/not-od-07-088.html [hereinafter *2007 NIH GWAS Policy*].

[189] *Id.*

provide a list of limitations on the data's use derived from the consent provided by donors–for example, that the data only be used to study a type of disease, or not be used for ancestry research.[190] Data access committees would then scrutinize requests to view the controlled data to ensure the proposed studies were "scientifically and ethically appropriate and [would] not conflict with constraints or informed consent limitations."[191] Once approved, requesters could access the data if they agreed to protect donor confidentiality, follow NIH security protocols, use data solely for NIH-approved research, and report policy violations to the agency.[192] In short, the NIH asserted broad control over who could access human genetic data generated with federal dollars, and on what terms.

As is traditional for the NIH, its data policy is a meld of self-governance and centralized control. Only researchers–"tenure track professor[s]" or equivalent "[s]enior scientist[s]"–are eligible, under NIH rules, to apply for data access.[193] Researchers and IRBs, rather than the NIH, draft the consent forms whose bounds govern data-use limitations, and data access committees rely on limitations submitted by researchers themselves.[194] It is up to submitting researchers to determine whether genomic summary data is "sensitive," and thus should be prevented from general public view.[195] IRBs determine whether it is appropriate to post data after considering "the risks to individuals, their families,

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[190] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-25-107377, HUMAN GENOMIC DATA: HHS COULD BETTER TRACK USE OF FOREIGN TESTING ENTITIES AND STRENGTHEN OVERSIGHT OF SECURITY MEASURES (2025).

[191] *See 2007 NIH GWAS Policy*, *supra* note 188.

[192] *Id.*

[193] *How to Request and Access Datasets from dbGaP*, NAT'L INSTS. OF HEALTH (2025), https://sharing.nih.gov/accessing-data/accessing-genomic-data/how-to-request-and-access-datasets-from-dbgap.

[194] *See 2007 NIH GWAS Policy*, *supra* note 188 ("The NIH Data Access Committees . . . will approve access [to controlled data] only for research uses that are consistent with an individual's consent *as defined by the submitting institution*." (emphasis added)). Although the NIH says that it expects grantees to obtain consent for sharing data, it permits consent for sharing data only for uses approved by data access committees, which can be quite narrow (e.g., for research on a specific disease, subject to IRB approval). *See id.*; *NIH Genomic Data Sharing Policy*, NAT'L INSTS. OF HEALTH (Aug. 27, 2014), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html [hereinafter *2014 Genomic Data Sharing Policy*]; *Points to Consider in Developing Effective Data Use Limitation Statements*, NAT'L INSTS. OF HEALTH (2015), https://sharing.nih.gov/sites/default/files/flmngr/NIH_PTC_in_Developing_DUL_Statements.pdf.

[195] *NIH Notice: Update to NIH Management of Genomic Summary Results Access*, NAT'L INSTS. OF HEALTH (Nov. 1, 2018), https://grants.nih.gov/grants/guide/notice-files/not-od-19-023.html; *see also* Adam Candeub, *The NIH's Genomic Data Sharing Policy and the First Amendment*, 5 J. FREE SPEECH L. 65 (2024).

and groups and populations associated with [the] data."[196] And, since 2014, the NIH has abandoned the broad scientific and ethical review it previously tasked data access committees with, instead focusing them on deciding whether a proposed use matched donor consent.[197] In all these respects, federal genetic data policy is devolved to researchers.

At the same time, the NIH retains powerful control over data diffusion. The agency can impose access requirements without reference to donor consent forms. Thus, in early 2025 the NIH began to require all requesters to certify that they were "not aware of significant potential for the research [conducted using NIH data] to cause harm to participants, their families, groups and populations of which they are a part (e.g., from stigma associated with the research results), or the national security of the United States."[198] The agency imposed this bar as to all controlled data, even from donors whose consent had not turned on such limitations.[199] The NIH can also unilaterally move data from fully public view to controlled status, as it did in 2008 when outside researchers revealed that even fairly short, de-identified genetic sequences could be linked to specific individuals.[200] And, as leading geneticists have observed, data access committees retain substantial discretion to approve or deny access requests.[201] Far from a simple checkbox, data access committees routinely deny requests or

[196] *2007 NIH GWAS Policy*, *supra* note 188.
[197] *See 2014 NIH Genomic Data Policy*, *supra* note 194.
[198] *See NIH Data Use Certification Agreement*, NAT'L INSTS. OF HEALTH (2025), https://sharing.nih.gov/accessing-data/accessing-genomic-data/using-genomic-data-responsibly/nih-data-use-certification-agreement.
[199] Indeed, it's hard to imagine that many donor consent forms reference U.S. national security.
[200] *See* Nils Homer et al., *Resolving Individuals Contributing Trace Amounts of DNA to Highly Complex Mixtures Using High-Density SNP Genotyping Microarrays, 4* PLOS GENETICS *e1000167 (2008)*; Nat'l Insts. of Health, *Modifications to Genome-Wide Association Studies (GWAS) Data Access* (Aug. 28, 2008), https://www.genome.gov/sites/default/files/genome-old/pages/About/NACHGR/September2008Agenda/NIHGWASPolicyBackgroundFacts8-28-08.pdf.
[201] *See Compiled Public Comments on NIH Request for Information: Processes for Database of Genotypes and Phenotypes (dbGaP) Data Submission, Access, and Management (NOT-OD-17-044)*, NAT'L INSTS. OF HEALTH (Feb. 21–Apr. 7, 2017) (comments of Daniel MacArthur, Broad Institute) ("There is little consistency between data access committees, or from committees over time…we recently had several previously approved requests suddenly denied because the composition of the DAC in question had changed."); *id.* (comments of Joel Hirschhorn, researcher at Boston Children's Hospital) ("DACs are often slow and do not appear to be consistent or coordinated.")

ask for study changes.[202] In the most recent available data, for fiscal year 2023, committees approved approximately 78% of requests.[203]

The government's data controls influence how important genetic data are distributed. Even today, after years of declining sequencing prices, the NIH's central repository is the single largest publicly controlled collection of human genetic sequences, with data from five million individuals, almost all of them sealed behind data access committees.[204] These controls pose a substantial barrier to scientific use, slowing down access and forcing researchers to turn to other (often much smaller) sources.[205] And because NIH access policies turn on the nature of research—for example, in some cases barring use in studies about intelligence or ancestry—these restrictions shape the direction of science.[206] As with biosafety rules, the NIH here is acting without direct Congressional mandate. Instead, the agency is using its control over funds (grant terms) and data (generated by grantees) to govern the use of research results.

The NIH's data-access policies point to grantmakers' ability not only to spur the creation of new data, but also to suppress it. And these policies show how they do so in practice. The Human Genome Project, as Janet Freilich and Nicholson Price have recently argued, created a form of infrastructure—a large-scale resource that can be used for many purposes. Science grants, in this account, both promoted research and the spread of information. In the absence of government funding, scientists and companies may have created less information or hoarded data through secrecy, as the private company Celera did in its race with the public Human Genome Project.[207] All true. But it is crucial to recognize that science grants are a flexible tool, at times promoting and at

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[202] *See* Erin M. Ramos et al., *A Mechanism for Controlled Access to GWAS Data- Experience of the GAIN Data Access Committee*, 92 AM. J. HUM. GENETICS 479 (2013).
[203] *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 190, at 23.
[204] *Database of Genotypes and Phenotypes (dbGaP) Home*, NAT'L INSTS. OF HEALTH (2025) https://dbgap.ncbi.nlm.nih.gov/beta/home. In 2016, researchers estimated that more than 40% of sequences held in the Sequence Read Archive, a global consortium hosting sequencing data from all domains of life, were controlled by the NIH's Database of Genotypes and Phenotypes or similar restrictions. *See* Abhinav Nellore et al., *Rail-dbGaP: Analyzing dbGaP-Protected Data in the Cloud with Amazon Elastic MapReduce*, 32 BIOINFORMATICS 2551–53 (2016).
[205] *See, e.g.*, Laura L. Rodriguez et al., *The Complexities of Genomic Identifiability*, 339 SCI. 275 (2013) (noting that open-access data sets "are used by many more researchers each year than the related data sets in the controlled-access database of" the NIH); Katrina Learned et al., *Barriers to Accessing Public Cancer Genomic Data*, 6 SCI. DATA 98 (2019).
[206] *See* Candeub, *supra* note 195; Stuart Ritchie, *The NIH's Misguided Genetics Data Policy: Banning Scientists from Using Data to Research Certain Topics is a Bad Move for All Sorts of Reasons*, SCI. FICTIONS (Oct. 25, 2022), https://stuartritchie.substack.com/p/nih-genetics/.
[207] As discussed above, firms also sought to patent genetic sequences, which the Supreme Court only held contrary to statute in 2013. *See* Ass'n for Molecular Biology v. Myriad Genetics, 569 U.S. 576, 591 (2013).

others suppressing information. NIH-funded human genetic data are not, for the most part, freely available. They are controlled through a nexus of self-governance mechanisms and federal oversight that determines who can access data, for what scientific purposes, and on which conditions. NIH data commons are not public highways. They are governed in the researcher-centered manner particular to the republic of science grants.

The government has also used NIH authority to control another kind of information: the results of risky biological experiments. As with data publication timelines, human-subjects protections, and biosafety, when it comes to biosecurity the NIH has been a key, if less visible, policymaker. Drawing on the lessons of past self-governance efforts, scientists and NIH administrators maneuvered to place biosecurity controls in NIH hands—indeed, in the same office that writes the NIH Guidelines. The result was a light-touch framework that would become the subject of significant controversy in the midst of the COVID-19 pandemic and set the terms of the debate over so-called gain-of-function research down to the present.[208]

The impetus for the NIH biosecurity controls was a worry that new research could enable states or terrorists to create novel biological weapons. Spurred in part by the revelation that the Soviet Union had a large and unlawful biological weapons program into the 1990s, Clinton Administration officials worried that the U.S. was unprepared for biological attacks.[209] Prominent geneticists like Joshua Lederberg (a Nobel laureate and Asilomar Conference attendee) argued at the turn of the century that genetic engineering "open[ed] up a Pandora's box" of biological warfare possibilities, including for terrorists.[210] In the summer of

[208] I discuss the connection between the oversight of dual-use research of concern (where the worry is primarily about dangerous information) and gain-of-function research (where the worry is primarily about lab leaks) in Part II, *infra*.

[209] *See generally* Susan Wright, *Terrorists and Biological Weapons: Forging the Linkage in the Clinton Administration*, 25 POLS. & LIFE SCI. 57 (2006). As Wright argues, several scientists and Defense Department officials took the concerns about state biological weapons programs and transplanted them to the context of terrorism. *See id.*; *see also* GIGI KWIK GRONVALL, PREPARING FOR BIOTERRORISM: THE ALFRED P. SLOAN FOUNDATION'S LEADERSHIP IN BIOSECURITY (2012) [hereinafter, PREPARING FOR BIOTERRORISM]; KEN ALIBEK & STEPHEN HANDELMAN, BIOHAZARD: THE CHILLING TRUE STORY OF THE LARGEST COVERT BIOLOGICAL WEAPONS PROGRAM IN THE WORLD—TOLD FROM INSIDE BY THE MAN WHO RAN IT (2000); MILTON LEITENBERG, RAYMOND A. ZILINSKAS & JENS H. KUHN, THE SOVIET BIOLOGICAL WEAPONS PROGRAM: A HISTORY (2012).

[210] Joshua Lederberg, *The Diversity of Bioweapons*, Speech at the RAND Corporation Symposium, *Bioterrorism: Homeland Defense: The Next Steps*, Santa Monica, Cal. (Feb. 9, 2000); http://www.rand.org/nsrd/ bioterr/agendal.htm, *quoted in* Wright, *Terrorists and Biological Weapons, supra* note 211 at 103); *see also* Matthew Meselson, *The Problem of Biological Weapons*, Presentation at the Symposium on Biological Weapons and Bioterrorism, NAT'L ACAD. OF SCIS., in Washington, D.C. (May 2, 2000).

2001, the National Academies began planning a project to study the biosecurity risks posed by biological research.[211] The world had just witnessed a paradigm example: earlier that year, Australian researchers had shown that genetically modified mousepox could bypass the immune systems and kill mice who had been vaccinated against the virus, a publication one scientist likened to a blueprint for weaponizing smallpox.[212] Such information was, in the jargon, "dual use" because it could be used for good or for ill.

Before the National Academies' committee held its first meeting, the terrorist attacks of Sept. 11 and the anthrax letters of the following month made its work more politically urgent.[213] Led by MIT geneticist Gerald Fink, the committee—composed of scientists alongside several lawyers and social scientists—now faced the prospect that Congress and the president might impose onerous rules on biological experiments and publications.[214] In its final product, known as the Fink Report, the committee recommended that the government follow the Asilomar playbook and create a self-regulatory system built into the NIH Guidelines.[215] The Report contended that expanding knowledge about pathogens was inevitable and that the essential ingredient to

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[211] *See* NAT'L RESEARCH COUNCIL, A SURVEY OF ATTITUDES AND ACTIONS ON DUAL USE RESEARCH IN THE LIFE SCIENCES: A COLLABORATIVE EFFORT OF THE NATIONAL RESEARCH COUNCIL AND THE AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE 20 (2009) [hereinafter SURVEY OF ATTITUDES]; GRONVALL, PREPARING FOR BIOTERRORISM, *supra* note 209, at 77–78

[212] R.J. Jackson et al., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, 75 J. VIROLOGY 1205 (2001); Rachel Nowak, *Killer Mousepox Virus Raises Bioterror Fears*, NEW SCIENTIST (Jan. 10, 2001). The aim of the study had been to render the mice infertile by modifying their immune response, but instead the viruses were immune evasive. *See* Michael J. Selgelid & Lorna Weir, *The Mousepox Experience: An Interview with Ronald Jackson and Ian Ramshaw on Dual-Use Research*, 11 EMBO REP. 18 (2010).

[213] GRONVALL, *supra* note 209.

[214] The PATRIOT Act of 2001, and the Public Health and Bioterrorism Preparedness and Response Act of 2002, already expanded regulation of laboratories that worked with specific pathogens and toxins, *see* PUB. L. NO. 107-56, § 817, 115 Stat. 385; PUB. L. NO. 107–188, 116 Stat. 594, but scientists worried that more stringent rules specifically directed at the types of studies researchers could perform, or results they could publish, were on the horizon. *See* Peter Aldhous, *Biologists Urged to Address Risk of Data Aiding Bioweapon Design*, 414 NATURE 237, 237–38 (2001) ("Biologists must begin a process of self- regulation for projects that have potential applications in developing bioweapons — or risk the imposition of restrictive controls from outside."); Stanley Falkow, *"Statement on Scientific Publication and Security" Fails to Provide Necessary Guidelines*, 100 PROC. NAT'L ACAD. SCI. U.S. 5575 (2003) (member of original Recombinant DNA Advisory Committee advocating for self-regulation over dual-use information); FINK REPORT, *supra* note 158, at 33 & n.56, 42–45; DANA SHEA, CONG. RSCH. SERV., BIOTERRORISM: LEGISLATION TO IMPROVE PUBLIC HEALTH PREPAREDNESS AND RESPONSE CAPACITY (2003).

[215] *See* FINK REPORT, *supra* note 158, at 108–109.

evaluate publication risk was scientific expertise.[216] It recommended that institutional biosafety committees and the Recombinant DNA Advisory Committee review funding proposals for seven "experiments of concern," and establish a new biodefense board made up of scientists and national-security experts.[217] The board would advise scientific journals about whether to withhold publication of sufficiently dangerous reports, but the ultimate publication decisions would remain with publishers.[218]

As it did after Asilomar, the NIH took the work of scientists as a roadmap for creating a self-regulatory system. Soon after the publication of the Fink Report, the Department of Health and Human Services created the National Science Advisory Board for Biodefense, and handed it off to be run by the NIH.[219] At the Board's first meeting Anthony Fauci, Director of the NIH's Institute of Allergy and Infectious Diseases, argued that the Board should emulate the Recombinant DNA Advisory Committee, which had "eliminated the need for Congress to formally legislate oversight," thereby limiting "interfere[nce] with scientific discourse and experimentation."[220] Instead, the Board should seek to draw on its prestige to create a culture of security among scientists. After all, Fauci said, the Guidelines had "become internationally accepted" even though the NIH lacked jurisdiction abroad.[221]

Over the next several years, that is what the Board and U.S. government did. The Board wrote reports, influencing other governments around the world to use the Fink Report's seven experiments of concern as an initial framework for analyzing risky research.[222] But enforceable policy languished until 2012. At the end of 2011, a pair of NIH-funded labs prepared to publish results showing that they had modified H5N1 avian influenza—"mutat[ing] the hell out of [it]" in the words of one of the investigators—to become transmissible by air between

[216] *Id.* at 110–112, 113 ("The experience with [recombinant DNA] experiments emphasizes the importance of guidelines developed by the scientific community itself.").
[217] *Id*. at 115–119.
[218] *Id*.
[219] *See* 69 Fed. Reg. 13,532 (Mar. 13, 2004).
[220] Nat'l Sci. Advisory Bd. for Biosecurity, *Meeting Minutes, June–July 2005*, NAT'L INSTS. OF HEALTH, 18 (2005), https://osp.od.nih.gov/wp-content/uploads/NSABB_Meeting_Minutes_June-July_2005.pdf.
[221] *Id*.
[222] *See, e.g.,* Biotechnology & Biological Scis. Rsch. Council, Med. Rsch. Council & Wellcome Tr., *Managing Risks of Research Misuse: A Joint Policy Statement* (2015); World Health Organization [WHO], *Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research* (2022); Swiss Acad. of Sci., *Misuse Potential and Biosecurity in Life Sciences Research* (2017); World Health Organization, *Responsible Life Sciences Research for Global Health Security: A Guidance Document* (2010).

mammals.[223] The director of the NIH, Francis Collins, joined by Fauci and another NIH employee, publicly defended the value of the research.[224] But the biosecurity Board, concerned that it would be dangerous to reveal the particular mutations to make avian flu airborne, advised the journals *Science* and *Nature* to remove some of the papers' methods sections before publication.[225] Scientists pushed back. At a World Health Organization meeting in early 2012, the leaders of the flu studies rallied a select group of infectious disease experts to oppose the Board's recommendation.[226] Faced with the ire of the scientific world, and new evidence that the flu strains generated by the research was less lethal than wild avian flu, the Board backed down.[227]

Still, the furor prompted the government for the first time to put teeth behind the Fink Report. In 2012, the White House ordered federal science funders to review their projects for experiments resembling the Fink Report's seven experiments of concern involving especially dangerous pathogens.[228] If the research was dangerous enough, the investigator would have to produce a risk-mitigation plan, including a plan to "communicate the research responsibly."[229] At the limit, agencies were ordered to consider classifying information if the researcher would not restrict it voluntarily.[230] In 2014, the government expanded the program by requiring federally funded institutions to create institutional review committees to assess dual-use research themselves, just as they must weigh biosafety and human-subjects protection.[231] These committees were

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[223] Katherine Harmon, *What Really Happened in Malta This September When Contagious Bird Flu Was First Announced*, SCI. AM. (Dec. 30, 2011), https://www.scientificamerican.com/blog/observations/what-really-happened-in-malta-this-september-when-contagious-bird-flu-was-first-announced/; EVANS, *supra* note 1, at 51.

[224] Anthony S. Fauci, Gary J. Nabel & Francis S. Collins, *A Flu Virus Risk Worth Taking*, WASH. POST (Dec. 30, 2011), https://www.washingtonpost.com/opinions/a-flu-virus-risk-worth-taking/2011/12/30/gIQAM9sNRP_story.html.

[225] EVANS, *supra* note 1, at 51–52; Kenneth Berns et al., *Policy: Adaptations of Avian Flu Virus Are a Cause for Concern*, 482 NATURE 153 (2012); NAT'L RESEARCH COUNCIL & INST. OF MED., PERSPECTIVES ON RESEARCH WITH H5N1 AVIAN INFLUENZA: SCIENTIFIC INQUIRY, COMMUNICATION, CONTROVERSY: SUMMARY OF A WORKSHOP app. B (2013); Ron A.M. Fouchier et al., *Restricted Data on Influenza H5N1 Virus Transmission*, 335 SCI. 662 (2012).

[226] Jon Cohen, *WHO Group: H5N1 Papers Should Be Published in Full*, 335 SCI. 899 (2012); EVANS, *supra* note 1, at 56–58.

[227] EVANS, *supra* note 1, at 58–59.

[228] *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, DEPT. HEALTH & HUMAN SERVS.3 (2012), https://aspr.hhs.gov/S3/Documents/us-policy-durc-032812.pdf.

[229] *Id.*

[230] *Id.*

[231] *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, NAT'L INSTS. OF HEALTH (2014), https://osp.od.nih.gov/wp-

empowered to weigh whether studies constituted "dual-use research of concern" and to help develop risk-mitigation plans for sufficiently risky research.

Like the Guidelines, these rules applied to all research at institutions taking federal funds, even as to scientists who took no government money.[232] The NIH required funded institutions to notify it about concerning research conducted by privately funded scientists.[233] These rules are now enforced by committees across the world, often added to the work of the institutional biosafety committees tasked with enforcing the Guidelines.[234] Formally at least, federal grants shaped not only what scientists studied, but how they disseminated research results. In one recent survey, more than 35% of university biosafety officers said scholars in their institution conduct research subject to dual-use-research-of-concern policies.[235]

Science grants can be tools both to promote the spread of information—as with the NIH grant terms for speedy data release—and to control research results, as with data-access committees and dual-use research of concern rules. What unites the NIH's policies in both directions is the agency's interest in crafting researcher-driven oversight that melds federal power and local discretion.

D. Research Environments

Federal grantmakers shape the everyday environment in which biomedical research is done. The NIH's grant terms determine not only what scientists study, how they conduct research, and the terms on which they publish; the agency also oversees the scientific workplace. In this section, I will examine the

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content/uploads/United_States_Government_Policy_for_Institutional_Oversight_of_Life_Sciences_DURC.pdf.

[232] *See NIH Notice: Reminder of Continuing Responsibilities of Recipient Institutions and NIH Staff in Reviewing and Reporting Changes to Institutional Biosafety Committees (IBCs)*, NAT'L INSTS. OF HEALTH (2015), https://grants.nih.gov/grants/guide/notice-files/not-od-15-017.html. ("The Policy applies to all research projects (regardless of funding source) that . . . are conducted at or sponsored by an organization that receives Federal support for life sciences research.").

[233] *See 2014 Genomic Data Sharing Policy*, *supra* note 194.

[234] *See, e.g.,* Univ. of Wash. IBC, *Meeting Minutes* (Nov. 2022), https://www.ehs.washington.edu/system/files/resources/IBC-11-2022.pdf; Bos. Univ. IBC, *Meeting Minutes*, (Nov. 2022), https://www.bu.edu/research/files/2023/06/November-2022-IBC-Meeting-Minutes-WEB.pdf.; Corn. Univ. IBC, *Institutional Biosafety Committee Annual Report 2022–23* (2023), https://bpb-us-e1.wpmucdn.com/blogs.cornell.edu/dist/3/6798/files/2023/06/IBC-Annual-Report-2022-23.pdf.

[235] David Gillum et al., *Bridging Biosafety and Biosecurity Gaps: DURC and ePPP Policy Insights from U.S. Institutions*, 12 FRONTIERS BIOENG'G & BIOTECH. 1476527, 7 tbl. 3 (2024).

NIH's push into regulating sexual harassment and bullying in agency-funded labs.

NIH policies police sexual harassment and discrimination in thousands of labs across the country. According to the agency's grant terms, trainee institutions and NIH-funded labs must "develop and implement policies and practices that foster a harassment-free environment."[236] Since 2018, the agency has investigated more than 1,000 allegations of sexual harassment or discrimination, removing about 170 principal investigators from grants and more than 400 scientists from participating in study sections.[237] By statute, the NIH must require its grantees "to notify the Director when individuals identified as a principal investigator [or similar researcher in an NIH award] are removed from their position . . . due to concerns about harassment, bullying, retaliation, or hostile working conditions."[238]

The NIH began this work not primarily on its own initiative, but in response to pressure from scientists. In 2018, the National Academies released a blue-ribbon report (funded in part by the NIH) on sexual harassment in the sciences.[239] The report concluded that federal science funding agencies "may be perpetuating the problem of sexual harassment" by failing to hold researchers responsible for harassing colleagues and lab workers.[240] Although the NIH had previously asserted it would not tolerate harassment by grantees, the report noted that it had done little to demonstrate its intolerance.[241]

Coming in the midst of the broader #MeToo movement, and with the NSF already moving to combat sexual harassment by its grantees, the NIH responded by acknowledging its failings. The agency's director, Francis Collins, wrote that he was "disheartened" by the National Academies report, and pledged to "do more to change the fundamental culture of our organizations."[242] Over the next

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[236] Francis S. Collins, *Changing the culture of science to end sexual harassment*, NAT'L INSTS. HEALTH (Sept. 17, 2018), https://web.archive.org/web/20250201022119/https://www.nih.gov/about-nih/who-we-are/nih-director/statements/changing-culture-science-end-sexual-harassment.

[237] *Data – Harassment and Discrimination*, NAT'L INSTS. HEALTH (July 23, 2025), https://grants.nih.gov/policy-and-compliance/policy-topics/harassment/data (last visited July 24, 2025).

[238] 42 U.S.C. § 238a-4 (2024).

[239] NAT'L ACADS. SCI., ENG'G, & MED., SEXUAL HARASSMENT OF WOMEN: CLIMATE, CULTURE, AND CONSEQUENCES IN ACADEMIC SCIENCES, ENGINEERING, AND MEDICINE (2018) [Hereinafter NASEM, SEXUAL HARASSMENT REPORT].

[240] *Id*. at 111.

[241] *See id*. at 110-111; Michael Lauer et al., *NIH Push to Stop Sexual Harassment*, 531 NATURE 35 (2016) (NIH administrators discussing agency policy).

[242] *See* Collins, *supra* note 236.

two years, the agency issued a flurry of new reporting and compliance requirements for grantees.[243]

These were a mix of NIH directives and self-governance measures. The NIH released a policy manual that purportedly governed only its own employees and contractors, but observed that it "expect[ed] organizations receiving NIH funds [to] have in place similarly rigorous policies and related procedures."[244] It also created a new route for victims of harassment to report misconduct directly to the agency.[245] But the system largely relies on institutional good faith: the NIH responds to concerning allegations not by conducting its own investigation, but by asking grantee institutions to do so.[246] In a by-now familiar pattern, the agency's informal policies have become law. Years after these measures had gone into effect, Congress belatedly authorized the NIH to demand harassment information from grantees.[247]

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[243] *See Clarification of NIH's Policy Regarding a Change in Program Director's/Principal Investigator's Status*, NAT'L INSTS. HEALTH (May 1, 2018), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-172.html; *Harassment and Discrimination Protections in NIH Training Applications*, NAT'L INSTS. HEALTH (Nov. 7, 2018), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html; *Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award*, NAT'L INSTS. HEALTH (June 11, 2020), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-124.html.

[244] *See Notice of New NIH Policy Manual 1311-Preventing and Addressing Harassment and Inappropriate Conduct and New Policy Statement on Inappropriate Relationships in the Workplace*, 83 FED. REG. 47,634 (Sep. 20, 2018).

[245] *See* Carrie D. Wollentz et al., *Combating Sexual Harassment*, 368 SCI. 1291 (2020) (NIH administrators discussing new policies); *NIH Process for Handling Allegations of Sexual Harassment on an NIH-Funded Project at a Recipient Institution*, NAT'L INSTS. HEALTH (June 10, 2020), https://web.archive.org/web/20200624180335/https://grants.nih.gov/grants/policy/harassment/actions-oversight/allegation-process.htm.

[246] *See NIH Process for Handling Allegations of Harassment on an NIH-Funded Project at a Recipient Institution*, NAT'L INSTS. HEALTH (Sep. 13, 2024), https://grants.nih.gov/policy-and-compliance/policy-topics/harassment/allegation-process. It is worth noting that many forms of harassment and discrimination law are devolved to self-governance by employers, perhaps nowhere more than in academia. *See, e.g.*, Lauren B. Edelman & Mark C. Suchman, *When the "Haves" Hold Court: Speculations on the Organizational Internalization of Law*, 33 L. & SOC'Y REV. 941 (1999), *cited in* NASEM, Sexual Harassment Report, *supra* note 239, at 99. What makes NIH governance notable here is its comportment with the way the agency acts more generally, and (before 2022) the lack of clear Congressional mandate for its oversight in this arena.

[247] Pub. L. No. 117-103, div. H, tit. II, § 239, 136 Stat. 474 (2022).

We have seen just how broad is the NIH's influence in the republic of science grants. The agency oversees (or once oversaw) what scientists and companies study, patent, and produce; how researchers recruit and interact with human subjects and guard dangerous pathogens; what findings scientists release, and to whom; and how researchers interact with their colleagues and employees. The NIH deploys these policies by leveraging its budget, its data, and its prestige. It does so while working closely with leading scientists, and their organizing bodies, like the National Academies, to craft narratives and policies that leave research institutions with substantial discretion and a dominant role in enforcing the rules.

Though the NIH prefers scientific self-governance in form, it remains the pivot point around which science policy turns. Study sections are composed of scientists, but their members are selected by NIH employees, and the questions they answer are posed by the agency. Scientists and the National Academies often draw up the rules that govern them, but the NIH is the frequent kingmaker among scientists—electing, say, Paul Berg and colleagues when it comes to recombinant DNA oversight, the worm researchers when it comes to genetic data sharing, and the virologists when it comes to dual-use research of concern. And the compromises the agency brokers often leave its finger on the pulse (or jugular), with the power to change the rules going forward.

For all of its centrality, since the 1950s the NIH has championed a form of scientific and university self-governance that has largely weathered both Republican and Democratic administrations, the social upheaval of the 1960s and 1970s, the Reagan era, the fall of the Soviet Union and the rise of the internet, the War on Terror and the Great Recession. But it is now facing its most significant challenge: the second Trump Administration's assault on science, to which I now turn.

II. The Assault on the Republic of Science Grants

- This Part will explore the Trump Administration's attack on the NIH and other federal science grantmakers by situating it within the context of the political compact represented by the republic of science grants.

- First, it will examine the Trump Administration's attack on study sections and peer/scientist-led choice over research directions: culling research topics through top-down choice, including targeting research dealing with vaccine hesitancy, transgender persons, diversity, and so on. Overwhelming evidence suggests that this has been a radical departure from normal NIH operations, largely by quite blindly applying

various EOs and DOGE directives without more than a thin veneer of scientific reasoning or consultation.

- Second, it will tackle the administration's policies on research processes, particularly the close scrutiny it applies to IBCs, including public posting of IBC member contact information.

- Third, on research results: the administration's gain-of-function ban is a major expansion of prior policies, with little regard for expertise and involving the direct overruling of NIH staff by political appointees.

- Fourth, the administration has massively expanded the leverage of NIH funds to govern research environments, including on BDS (since rescinded) and simply to harm universities the administration deemed odious, purportedly on grounds of antisemitism. The attacks on Columbia and Harvard are especially notable, though they go well beyond science grants.

III. Assessing the Republic of Science Grants

Overview: The NIH is relatively good at promoting basic research, and spotting safety and ethical problems. But it has a poor track record of enforcement in environments that demand close supervision, and its safety and ethical policies often lean too heavily on self-governance.

A. Science

- This Section will assess NIH influence over the rate and direction of invention through its grants, prestige, and data rules. It will discuss the overall strength of NIH selection processes alongside critiques of study sections as risk averse, bad for younger scientists, and biased toward the status quo (e.g., the Alzheimer's cabal), perhaps reflecting an overly deferential approach as compared to bolder grant policies (e.g., DARPA-style program officers).

- On the whole, NIH comes out favorably on this front, though there is substantial room for improvement even while staying within the lane of peer-review-style allocation methods.

- Self-governance in this domain is not inevitably good—and it can take many forms, some better than others—but it contains real strengths especially when investing a budget the size of the (historical) NIH's.

We're witnessing the problems of relying on administrative and politically appointee discretion at this moment.

B. Safety and Ethics

- This Section will analyze the efficacy of the NIH's enforcement of safety and ethics rules. On the whole, NIH is not culturally equipped to enforce rules against grantees and fellow scientists, and this is shown through a long record of comparatively weak oversight when compared to agencies with comparable frameworks (e.g., FDA for IRBs, CDC/USDA/OSHA for biosafety/IBCs)

- History of enforcement in multiple domains reflects conflicts of interest, poor resources, and inability to stand up to grantees or even internal scientists.

    - Limited oversight of research ethics from group consultation in the 1950s

    - IRBs were almost unenforced by NIH with the exception of the late 1990s; FDA has been doing the enforcement. IRBs themselves operate in extremely divergent ways from one another without obvious logic (as witnessed from IRB supervision in multisite studies).

    - Limited oversight of biosafety/NIH Guidelines: site visits are extremely rare, as is enforcement.

    - Poor operation of data-access committees

IV. Legitimacy and Reform

A. Legal Authority and Legitimacy

- Congress designed the NIH to instantiate the balance inherent in the republic of science grants—giving scientists room, within reason, to pursue open-ended and self-governed basic science research that will hopefully contribute to the public good. This balance is also what lends the agency legitimacy among scientists and the public.

- Transforming the agency into just another regulator would undermine what makes the agency effective—its closeness to science and scientists—and in some respects is contrary to the law.

- The current administration's across-the-board attack on the republic is dangerous to U.S. scientific leadership, and not just because it threatens major cuts to the budget, devastating current and future projects, pushing leading scientists to leave the country, and undermining the next generation of U.S. scientists. The threat to the NIH's role as advocate for self-governance also risks weakening researcher autonomy and creativity.

B. Reform

- In rebuilding science grantmakers, though, lawmakers should not simply recreate the pre-Trump republic of science. The NIH has been startlingly adept at protecting scientific autonomy, and is frequently unwilling to enforce its own fairly light grant terms.

- When it comes to policy arenas that are especially inappropriate for self-regulation—when researcher and public interest diverge, and failure is highly consequential—the NIH should no longer be in the driver's seat. That is likely the case, for instance, when it comes to biosecurity and biosafety oversight, as has already been recognized to a limited degree when it comes to IRB oversight.

CONCLUSION