UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.*, *Plaintiffs*, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 1:25-cv-10346-AK **(Leave to File Granted Feb. 10, 2025)**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' EMERGENCY MOTION FOR A TEMPORARY RESTRAINING ORDER

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INTRODUCTION

Late on Friday February 7, the National Institutes of Health ("NIH") announced a sea change in its policy governing "indirect cost rates" for federally funded health research grants in direct defiance of an on-point congressional directive. With no prior notice, NIH declared that this change would take effect the very next business day—not just for new grants, but as to existing grants too. If allowed to stand, this change will devastate medical research at American universities. Cutting-edge work to cure disease and lengthen lifespans will suffer, with consequences for the health outcomes of millions of Americans. At stake is not only Americans' quality of life, but also our Nation's enviable status as a global leader in scientific research.

In addition to being a disaster for science, NIH's action is an affront to the separation of powers. When the executive previously attempted to accomplish what the February 7th directive purports to mandate, Congress exercised its constitutional power of the purse and forbade the executive from expending appropriated funds on trying to do so again. Yet NIH defied Congress's express directives as to this core congressional power and issued the February 7th directive anyway—and NIH will continue to violate Congress's express commands so long as the directive remains in force. NIH's actions also run afoul of the longstanding regulatory frameworks governing federal grants and foundational principles of administrative law. Judicial relief is amply justified and urgently needed.

For decades, universities have built their research institutions on NIH's commitment to fund the costs of the research it sponsors. Some of those costs are "direct"; that is, they are readily attributable to specific projects. Others are "indirect"; that is, they are necessary for the research to occur but harder to attribute to individual projects. Examples of the latter include biocontainment laboratories needed for pathogenic research; blood banks and animal facilities for clinical testing;

computer systems to analyze enormous volumes of data; information-technology and utility systems providing the backbone for those efforts; and researchers and administrative staff who keep the systems running. All are indispensable to cutting-edge research, but their costs typically cannot be allocated to a single project.

Congress understood that NIH would "make grants-in-aid to universities" via a bespoke process accounting for each institution's unique cost structures and grants. 42 U.S.C. § 241(a)(3). That is *why* Congress gave the Executive Branch the quintessentially administrative task of identifying institution-specific metrics and did not itself set across-the-board rules. Hence, pursuant to regulations promulgated by the Department of Health and Human Services ("HHS"), institutions have long negotiated indirect cost rates with NIH through a carefully regulated process, based on each institution's unique needs and cost structure. This negotiation yields a rate that is intended to reflect the *actual*, *verified* indirect costs incurred by the institution. Audits ensure that the negotiated rate matches actual indirect costs. Agencies may deviate from the negotiated rate only in limited circumstances, and only via procedures that provide ample notice and protections to ensure the basic terms of engagement are not changed precipitously. The regulatory framework thus recognizes that there is no one-size-fits-all approach and that participating institutions have profound reliance interests in the negotiated rates—rates that are tailored to their circumstances and that facilitate the work that makes the United States a world leader in cutting-edge research.

This is not the first time an administration has considered limiting indirect cost rates and superimposing a one-size-fits-all regime on what has long been a tailored, negotiated process. In 2017, the Executive Branch similarly proposed slashing indirect costs. Congress's reaction was immediate and explicit: Congress enacted an appropriations rider providing that regulatory "provisions relat[ed] to indirect costs . . . including with respect to the approval of deviations from negotiated rates, shall

continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat 348, 740. The rider further prohibits HHS or NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." *Id.* Consolidated Appropriations Act, 2018, PL 115-141, 132 Stat 348, § 226. Congress has repeatedly reenacted that rider in the appropriations laws governing HHS, including the now-operative statute. *See* Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677.

In direct defiance of these statutes, and in flagrant disregard of the reliance interests they aim to protect, NIH issued guidance[1] (the "NIH Guidance" or "Guidance") on Friday February 7 that purports to overturn its decades-long approach with no advance warning or exceptions for existing grants. Effective Monday February 10, the Guidance immediately lowers indirect cost rates to 15% across the board, for new and existing grants alike. The Guidance does not even acknowledge the statutes that expressly prohibit NIH from taking this step. Nor does it justify its stark departure from binding regulations and longstanding executive branch practice. And the Guidance make no serious attempt at compliance with the Administrative Procedure Act: The Guidance ignores all the obvious ways that its unprecedented change will thwart its stated goal that the "United States should have the best medical research in the world"; does not acknowledge the reliance interests that this unannounced step subverts; and rests on a facile comparison between NIH grants and those from private foundations (which often fund different types of research and, in all events, presuppose government funding).

[1] Office of The Director, National Institutes of Health, *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates*, NOT-OD-25-068 (Feb. 7, 2025), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-068.html.

The effects of NIH's unlawful actions will be immediate and devastating. Medical schools, scientific research programs, and other grant recipients across the country have already budgeted for their individual, substantially higher indirect cost recovery rates that had been negotiated with the agency through the designated legal process. Even at larger, well-resourced institutions, this agency action will cause significant harms, including with respect to these institutions' ability to contribute to medical and scientific breakthroughs. Institutions will be forced to shrink their research agendas to avoid infrastructure expenditures that will not be compensated. Smaller institutions will fare even worse—many will not be able to sustain any research at all and could close entirely. Nor can the consequences of grinding vital scientific work to a halt be unwound. The pace of scientific discoveries to improve human health will be slowed. Diagnoses, treatments and cures for debilitating and life-threatening illness will be obstructed. Beyond all that, the executive's unilateral action in defiance of a clear congressional prohibition inflicts the irreparable harm of a constitutional injury. The separation of powers exists to protect individual rights, not to protect the branches of the federal government from each other. *See Bond v. United States*, 564 U.S. 211, 222-23 (2011). And the appropriations riders here were designed to prevent just the kind of disruption that this unlawful guidance inflicts. A temporary restraining order should issue to avoid these imminent harms.

STATEMENT OF FACTS

A. Federal Grant Funding for Indirect Costs

The NIH is the primary source of federal funding for medical research in the United States. Those grants have made the United States the world leader in medical research. NIH grants have supported research that has resulted in pathbreaking discoveries—ranging from breakthroughs in genomic sequencing, to MRI technology, to treatments of cancers of all types—that have enhanced Americans' health and longevity. In Fiscal Year 2023, NIH spent over $35 billion on almost 50,000

competitive grants to more than 300,000 researchers. Most research funded by these grants occurs at outside institutions, including universities. The NIH can thus fund a diverse array of institutions, promote competition for research grants, and help train the next generation of researchers. For decades, academic institutions have availed themselves of these funding opportunities to partner with the federal government to advance national security, health, and prosperity through critical research. *See* Testimony of Mr. James D. Luther before the House Committee on Science, Space, and Technology 55 (Mar. 24, 2017), Ex. 32 ("Luther Testimony").

Universities and other recipients generally do not receive lump-sum grants from NIH. Instead, they use cost-based accounting systems, under which they recover their actual, documented costs for conducting research. NIH grants typically allow the recovery of two types of costs. The first is "direct costs"—costs that can be attributed to a specific research project. Those might include, for example, the salary for a graduate student dedicated to working on a particular project. The second category is "indirect costs"—costs that are necessary for research but that cannot be attributed to any one specific research project.

"[I]ndirect . . . costs" have two components: "[f]acilities" and "[a]dministration." 45 C.F.R. § 75.414(a). The "[f]acilities" category is "defined as depreciation on buildings, equipment and capital improvements, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses." *Id*. This category includes the costs of the physical infrastructure necessary for carrying out research, such as construction and maintenance of laboratories. Those costs are indirect because a single building might house numerous research groups engaged in multiple distinct projects.

The "[a]dministration" category is defined as "general administration and general expenses such as the director's office, accounting, personnel, and all other types of expenditures not listed

specifically under one of the subcategories of 'Facilities"' (including cross allocations from other pools, where applicable). 45 C.F.R. § 75.414(a). This category includes costs related to the administrative and compliance activities required to conduct federally sponsored research, such as human and animal research review boards, financial reporting and purchasing, training and education, and managing potential conflicts of interest. Such costs are indirect because a single group of employees may handle them for multiple projects. Together, these indirect cost categories, or "F&A costs," pay for critical research infrastructure, without which the funded research projects could not proceed. *See* Luther Testimony at 55.

The computation and determination of indirect costs are subject to extensive regulation—and then fixed for a specified period of time in recognition of the institutions' needs for predictability and planning. *See* Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs), part C; *see also* 45 C.F.R. §§ 75.414, 75.501. Research institutions must express their indirect costs as a rate that is multiplied by the direct costs of each individual research grant associated with those costs to yield reimbursement for the actual cost of the research. *See* Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs), part C. This methodology ensures that more expensive and resource-intensive research projects are allocated a higher share of indirect costs. As a simplified example, suppose a single laboratory houses two research projects—one funded by an annual $75,000 grant and one funded by an annual $25,000 grant. Suppose, too, that the laboratory's sole indirect cost is the cost of electricity, which costs $10,000 per year. Because the cost of electricity ($10,000) is 10% of the total grant amount ($100,000), the indirect cost rate would be 10%. Thus, $7,500 of electricity costs would be allocated to the first project, and $2,500 of electricity costs would be allocated to the second project.

Federal regulations also set forth a detailed methodology for negotiating indirect cost rates. Typically, a single agency, such as HHS, negotiates an indirect cost rate with an institution. 45 C.F.R. § 75.414. That indirect cost rate then applies to all of that institution's grants across the federal government. *Id.* § 75.414(c). As part of those negotiations, federal regulations require institutions to conduct comprehensive cost analyses that follow detailed federal guidelines governing reasonable and allowable indirect costs. *Id.* § 75.414(c)(1); *see also* 45 C.F.R. §§ 75.100(c), 75.2; Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs). For example, if an institution seeks to recover the cost of building maintenance, it must document those costs and then allocate those maintenance costs across research and non-research programs, resulting in extensive back-and-forth negotiation until the parties reach agreement on an indirect cost rate. Again, this rate reflects the *actual*, *verified* indirect costs incurred by the institution. Once a cost rate is agreed upon, it binds the entire federal government for a specified period—typically one year, but sometimes up to four. Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs), part C; *see also* 45 C.F.R. §§ 75.414, 75.501. After the costs are incurred, federal agencies conduct audits to ensure that the negotiated indirect cost rate conforms to the actual indirect costs that were incurred. 45 C.F.R. §§ 75.2, 75.501(b), 75.504, 75.514. The indirect cost rate for the next period is then adjusted if the audit establishes that the institution has recovered excess costs. *See* Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs).

The NIH's regulations and policies reflect these precepts. NIH is required to use that negotiated indirect cost rate unless a deviation therefrom "for a class of Federal awards or a single Federal award" is "required by Federal statute or regulation" or is "approved by a Federal awarding

agency head or delegate based on documented justification as described in [45 C.F.R. § 75.414(c)(3)]." 45 C.F.R. § 75.414(c)(1). Documented justification for a deviation from a negotiated indirect cost rate, pursuant to 45 C.F.R. § 75.414(c)(3), requires that "[t]he HHS awarding agency must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." The NIH Grants Policy Statement ("Policy Statement") sets out for NIH grant recipients "the policy requirements that serve as the terms and conditions of NIH grant awards." Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Servs., *NIH Grants Policy Statement* at ii (rev. Apr. 2024), https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf. As to reimbursement of indirect costs, the Policy Statement confirms that these rates are to be negotiated with one of several "agenc[ies] with cognizance for F&A/indirect cost rate (and other special rate) negotiation." Policy Statement at IIA-68. The Policy Statement further provides that "[i]f a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used." *Id.* at IIA-69.

Negotiated rates differ significantly among universities primarily because different institutions conduct different kinds of research. There is simply no one-size-fits-all rate. Certain facilities, like specialized laboratories, are more expensive than others. Schools that engage in biomedical research, for example, are likely to have higher rates than those doing social science. Specifically, facility-intensive research—including biocontainment laboratories that support immunology, virology, and microbiology research involving dangerous biological pathogens; animal facilities; and resources to support genomic, proteomic and metabolomics analysis and processing—typically incurs the highest indirect costs.

B. Plaintiffs and Their Member Universities' Federally Funded Research Programs

As set forth more fully in its contemporaneously filed complaint, Plaintiffs are several associations of universities and individual universities—the Association of American Universities ("AAU"), the Association of Public and Land-Grant Universities ("APLU"), the American Council on Education ("ACE," and collectively, the "Organizational Plaintiffs"), Brandeis University, Brown University, the Regents of the University of California, the California Institute of Technology, Carnegie Mellon University, the University of Chicago, Cornell University, the George Washington University, Johns Hopkins University, Massachusetts Institute of Technology, the Trustees of the University of Pennsylvania, the University of Rochester, and the Trustees of Tufts College.

AAU is an association composed of 71 leading research universities with the goal of transforming lives through education, research, and innovation. Plaintiffs' member universities receive significant research funding from NIH grants. *See, e.g.*, Ex. 4 (Brandeis Decl.) ¶ 3; Ex. 5 (Brown Decl.) ¶ 3; Ex. 6 (UC Decl.) ¶ 16; Ex. 7 (Caltech Decl.) ¶ 3; Ex. 8 (CMU Decl.) ¶ 3; Ex. 11 (Cornell Decl.) ¶ 4; Ex. 15 (JHU Decl.) ¶ 3; Ex. 17 (MIT Decl.) ¶ 9; Ex. 21 (Penn Decl.) ¶ 6; Ex. 24 (Rochester Decl.) ¶ 5; Ex. 27 (Tufts Decl.) ¶ 3. Many of Plaintiffs' member universities have negotiated an indirect cost rate that is significantly higher than 15%. *See, e.g.*, Brandeis Decl. ¶ 11; Ex. 14 (Harvard Decl.) ¶ 10; MIT Decl. ¶ 8. These negotiated rates have already been relied upon by Plaintiffs' members in budgeting for their NIH-funded research programs.

APLU is a membership organization that seeks to "foster[] a community of university leaders collectively working to advance the mission of public research universities," including "more than 230 public research universities, land-grant institutions, state university systems, and affiliated organizations spanning across all 50 U.S. states, the District of Columbia, and six U.S. territories." Ex. 3 (APLU Decl.) ¶ 3. APLU member institutions conduct "a wide variety of vital research on

behalf of American citizens," based in no small part on grant funding from HHS and NIH, including $11 billion in NIH grant funding in fiscal year 2024. *Id.* ¶ 5.

ACE is a membership organization composed of more than 1,600 colleges and universities, related associations, and other organizations in America and around the world. Ex. 2 (ACE Decl.) ¶ 3. Its members "conduct a wide variety of vital research on behalf of United States citizens, funded in part by agency awards from across the federal government, including but not limited to" HHS and NIH. *Id.* ¶ 7. Those NIH awards support research that advances "important health issues, saves and improves lives, and adds immeasurably to our national welfare and our economy." *Id.*

Brandeis University, Brown University, the Regents of the University of California, the California Institute of Technology, Carnegie Mellon University, the University of Chicago, Cornell University, the George Washington University, Johns Hopkins University, Massachusetts Institute of Technology, the Trustees of the University of Pennsylvania, the University of Rochester, and the Trustees of Tufts College are research universities that house significant scientific study and innovation supported by NIH grants. They collectively receive hundreds of billions of dollars to support thousands of projects. *See* Brandeis Decl. ¶ 3; Brown Decl. ¶ 7; UC Decl. ¶ 16; Caltech Decl. ¶ 3; CMU Decl. ¶ 3; Cornell Decl. ¶ 4; JHU Decl. ¶ 3; MIT Decl. ¶ 9; Penn Decl. ¶ 6; Rochester Decl. ¶ 5; Tufts Decl. ¶ 3. Those projects range from advanced cancer research to neurological disease treatment to prevention of infectious disease.

C. Prior Attempts to Limit Indirect Cost Rates Governing NIH Grants.

The NIH's recent action is not the first attempt to supplant institution-specific negotiated rates, developed through a careful and long-established process, with a one-size-fits-all approach. In 2017, the Executive Branch proposed slashing the indirect cost rate to 10% across the board. The proposal spurred widespread criticism and alarm.

To avert disaster, Congress enacted an appropriations rider providing that regulatory "provisions relat[ed] to indirect costs . . . including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348, 740. The appropriations rider also prohibits HHS or NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." *Id.* That rider has been repeatedly renewed and remains in effect in the now-operative statute. *See* Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677.

D. The Challenged Guidance

The NIH has now attempted to effectuate via administrative action what Congress has forbidden by law, using funds that Congress has prohibited it from spending. On February 7, 2025, the Office of the Director of NIH issued a document titled "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates." *See* NIH Guidance. The Guidance announced that "[p]ursuant to this Supplemental Guidance, there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." It further established that, "[f]or any new grant issued, and for all existing grants to [institutions of higher education, or 'IHEs'] retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate." *Id.*

The Guidance does not so much as acknowledge the on-point congressional statutes that prohibit NIH from spending appropriated funds to take any action to modify the approach to indirect cost rates in effect in 2017. Given that the appropriations riders were a direct response to an earlier

effort to displace negotiated rates with a single rate and that the Guidance could not be issued without expending appropriated funds, that omission is remarkable. The Guidance purports to rely on 45 C.F.R. § 75.414(c)(1) as authority for its setting of a single, uniform indirect cost rate of 15%. But that regulatory provision is no answer to a statutory prohibition. And in all events, this regulation requires that, in order to deviate from a negotiated indirect cost rate absent a statutory or regulatory requirement to do so, NIH must comply with 45 C.F.R § 75.414(c)(3)'s requirement that the agency "implement, and make publicly available, the policies, procedures, and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." 45 C.F.R § 75.414(c)(3). And pursuant to the next provision, NIH "must include" such "policies relating to indirect cost rate reimbursement" "in the notice of funding opportunity." 45 C.F.R § 75.414(c)(4). Plaintiffs' notices of funding opportunity did not contain policies issued pursuant to 45 C.F.R § 75.414(c)(3) upon which NIH now seeks to justify deviations from their negotiated rates to the 15% rate announced in the Guidance. Rather, according to NIH, the Guidance itself "implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance." NIH Guidance.

E. Imminent and Irreparable Harm to Plaintiffs' Members' and Plaintiffs' Ongoing Research

As detailed in their complaint, reducing Plaintiffs' members' and Plaintiffs' individually negotiated indirect cost rates to a uniform rate of 15% would wreak havoc on their ongoing federally funded research programs. *See* ECF No. 1 ¶ 1. Having already budgeted for their individualized negotiated rates, Plaintiffs' members would be forced to take significant steps, including laying off personnel, closing laboratories, and/or ceasing certain research programs altogether. *See, e.g.*,

Brandeis Decl. ¶¶ 6, 8; Brown Decl. ¶¶ 12-17; CMU Decl. ¶¶ 12-15; Ex. 10 (Columbia Decl.) ¶¶ 9-10; Cornell Decl. ¶¶ 12-14; Ex. 9 (CWRU Decl.) ¶¶ 4-8, 12; Ex. 12 (Dartmouth Decl.) ¶¶ 12-14; Ex. 13 (U. of Florida Decl.) ¶¶ 4-5, 14; Harvard Decl. ¶¶ 13-14; MIT Decl. ¶¶ 12-17, 21-23; Ex. 19 (MSU Decl.) ¶¶ 9-13; Ex. 20 (Oregon Decl.) ¶¶ 15-18; Penn Decl. ¶¶ 19-21; Ex. 23 (Rice Decl.) ¶¶ 4-8; Ex. 26 (SUNY SBU Decl.) ¶¶ 12-13; Ex. 29 (Vanderbilt Decl.) ¶¶ 13-15; Ex. 30 (Washington University Decl.) ¶¶ 4-8, 13-14; Ex. 31 (UW–Madison Decl.) ¶¶ 7-10. This threat is imminent, as the Guidance states that it is to be applied to all current grants for expenses starting on February 10, 2025. To redress those irreparable harms, Plaintiffs filed this suit and now seek a temporary restraining order.

LEGAL STANDARD

The burden of proof for a temporary restraining order is the same as that for a preliminary injunction under Federal Rule of Civil Procedure 65. *178 Lowell St. Operating Co., LLC v. Nichols*, 152 F. Supp. 3d 47, 53 (D. Mass. 2016). The moving parties must show that the weight of the following factors favors granting preliminary relief: "[1] likelihood of success on the merits; [2] potential for irreparable injury, [3] balance of the relevant equities; and [4] effect on the public interest if the Court grants or denies the TRO." *New York v. Trump*, No. 25-CV-39, __ F. Supp. 3d __, 2025 WL 357368, at *1 (D.R.I. Jan. 31, 2025) (citing *Planned Parenthood League of Mass. v. Bellotti*, 641 F.2d 1006, 1009 (1st Cir. 1981)). When defendants are government entities or officials sued in their official capacities, the balance of equities and public interest factors merge. *See Does 1-6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021).

ARGUMENT

I. The Organizational Plaintiffs Have Standing.

The organizational plaintiffs—AAU, APLU, and ACE—have standing to bring this suit on behalf of their university members. An association has standing to bring suit on behalf of its individual

members when: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Adv. Comm'n*, 432 U.S. 333, 343 (1977). "Actions for declaratory, injunctive and other forms of prospective relief"—as the Organizational Plaintiffs seek here—are "particularly suited to group representation." *Camel Hair & Cashmere Inst. of Am., Inc. v. Assoc. Dry Goods Corp.*, 799 F.3d 6, 12 (1st Cir. 1986).

First, these organizations' members have standing to sue as individuals. *See Housatonic River Initiative v. U.S. Env't Prot. Agency, New Eng. Region*, 75 F.4th 248, 265 (1st Cir. 2023). The university members face immediate and severe consequences should the Guidance take effect—deleterious results that could be averted if this Court were to enjoin the NIH's action. *See Plazzi v. FedEx Ground Package System, Inc.*, 52 F.4th 1, 4 (1st Cir. 2022) (quoting *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021)). The declarations accompanying this motion demonstrate the injuries member schools will suffer. For example, if the indirect cost rate was reduced to 15%, schools will face immediate short-term consequences, which may include layoffs of crucial personnel supporting research facilities and administration, the interruption of clinical trials directed at significant health problems, and/or the loss of a significant part of the healthcare workforce. *See* Brown Decl. ¶¶ 15, 17-19; CMU Decl. ¶¶ 12-15; Columbia Decl. ¶¶ 9-10; Cornell Decl. ¶ 13; CWRU Decl. ¶ 12; Dartmouth Decl. ¶¶ 12-13; U. of Florida Decl. ¶ 14; Ex. 18 (Michigan Decl.) ¶ 8; MIT Decl. ¶¶ 15-17; MSU Decl. ¶¶ 9-10, 14; Oregon Decl. ¶¶ 15-17; Penn Decl. ¶¶ 14-15, 19-21; Rice Decl. ¶¶ 6-8; Ex. 25 (Rutgers Decl.) ¶¶ 10-11; SUNY SBU Decl. ¶¶ 12-13; Tufts Decl. ¶ 11; Vanderbilt Decl. ¶¶ 7, 13-15; Washington University Decl. ¶¶ 13-14; UW–Madison Decl. ¶¶ 9-10. There will also be major long-term effects, including the closure of clinical trials—critical for patient

care—that will be difficult if not impossible to restart and the derailment of years of cumulative work in critical research into significant health conditions like cancers, dementia, heart disease, and childhood illnesses. *See* Brown Decl. ¶¶ 5, 15, 17; Cornell Decl. ¶¶ 5, 13; CWRU Decl. ¶¶ 4-5, 13-14; Dartmouth Decl. ¶¶ 6, 12-13; Harvard Decl. ¶¶ 4, 6, 17; MIT Decl. ¶¶ 15-17; MSU Decl. ¶¶ 5, 11-13; Oregon Decl. ¶¶ 8, 15; Penn Decl. ¶¶ 14-15, 21; Rice Decl. ¶¶ 4, 14-15; Ex. 28 (USC Decl.) ¶¶ 4-7, 11; UW–Madison Decl. ¶ 9; Washington University Decl. ¶ 16. These imminent injuries would be redressed by the relief requested: declaratory and injunctive relief preventing Defendants' harmful Guidance from taking effect. *See Housatonic River Initiative*, 75 F.4th at 265.[2]

Second, the interests at stake are not only "germane" to the organizations' purposes, but are intrinsically tied to their missions. *See id.* at 264-66. AAU's "primary goal is to provide a forum for the development and implementation of institutional and national policies promoting strong programs of academic research and scholarship and undergraduate, graduate, and professional education." Ex. 1 (AAU Decl.) ¶ 3. In particular, AAU is dedicated to "protecting its member universities' ability to conduct research that is supported by NIH grants." *Id.* ¶¶ 4-6. The interests threatened by the Guidance are therefore intrinsically tied to AAU's core purpose of supporting its member universities' research and innovation efforts. Similarly, ACE is a major coordinating body for the nation's colleges and universities that strives to promote the role of higher education in supporting flourishing communities, including by educating a huge proportion of America's students and through successful academic research programs. *See* ACE Decl. ¶¶ 3-4. It is thus likewise dedicated to protecting its members' research grants and activities. Finally, APLU is similarly situated on both counts. APLU Decl. ¶¶ 3-6, 12-13.

[2] For these reasons, the individual school plaintiffs have standing in their own right.

Finally, the organizations' individual members are not required for the claims asserted or the relief requested by the organizations. Enjoining the Guidance will offer the individual members complete relief. *See Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock*, 477 U.S. 274, 288 (1986) (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)) (reasoning that this requirement is met where "the remedy, if granted, will inure to the benefit" of all members). The Guidance's proposed 15% indirect cost rate would inflict existential injuries to their medical, technological, and research programs and therefore, to their functioning as institutions. As examples, Brown, Case Western, Cornell, Dartmouth, Florida, MIT, Michigan State, Vanderbilt, the University of Oregon, Rice, Washington University, and the University of Wisconsin at Madison agree that the Guidance would grind crucial work to a halt. Brown Decl. ¶¶ 15, 19, 27; CWRU Decl. ¶¶ 5, 13; Cornell Decl. ¶¶ 12-13; Dartmouth Decl. ¶¶ 12-13; U. of Florida Decl. ¶¶ 4-5; MIT Decl. ¶¶ 16-17; MSU Decl. ¶¶ 11-14; Oregon Decl. ¶ 15; Rice Decl. ¶¶ 5-8, 11; Vanderbilt Decl. ¶¶ 7, 13-15; Washington University Decl. ¶ 13; UW–Madison Decl. ¶ 7. An injunction here will equally redress the organizations' and its these members' injuries.

II. Plaintiffs Have a Strong Likelihood of Success on Their Claims.

Courts must hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Here, Plaintiffs are likely to succeed in showing that the Guidance violates those standards in myriad respects.

A. The Guidance Violates the Plain Language of Section 224 of the Continuing Appropriations Act of FY24 and the Appropriations Clause.

An "agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). Here, Congress has expressly and unambiguously barred NIH from taking the steps it took via the Guidance in direct response to similar

effort to unilaterally impose a one-size-fits-all reimbursement rate on a multitude of negotiated rates. No more is required to resolve this case or issue a temporary restraining order.

For six years—since the Executive Branch initially attempted to slash indirect cost rates—Congress has explicitly provided that rates are not to be uniformly set, but instead are to be negotiated on an individualized basis according to detailed formulae. That provision remains in effect. In Section 224 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of 2024 ("Section 224"),[3] Congress expressly provided that "the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." *Id.* More than that: The same provision prohibited use of congressional appropriations "to develop or implement a modified approach to such provisions" or to "intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." *Id.* This provision remains in force today via the further appropriations to HHS through continuing resolutions incorporating this provision.[4]

The Guidance does just what the rider forbids. By displacing all individually negotiated

[3] Contained in the Further Consolidated Appropriations Act, 2024, Public Law No. 118-47, as division D, 138 Stat. 460, 677.

[4] In particular, these continuing resolutions provide appropriations subject to "the authority and conditions provided in" the fiscal year 2024 appropriations legislation. Continuing Appropriations and Extensions Act, 2025, Public Law No. 118-83 § 106; *see also* Further Continuing Appropriations Act, 2025 (division A of Public Law No. 118-158) (extending effective date of Public Law No. 118-83 to March 14, 2025).

indirect cost recovery rates and substituting a uniform rate of 15%, NIH has both "develop[ed]" and "implemented" a "modified approach" to the "provisions relating to indirect costs" in "part 75 of title 45, Code of Federal Regulations." Consolidated Appropriations Act, 2018, § 226, Pub. L. No. 115-141, 132 Stat 348, 740. None of that could occur without the expenditure of appropriated funds, and thus all of it is ultra vires. The Guidance also has the effect of "intentionally or substantially expand[ing] the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." In particular, the Guidance purports to invoke the authority in 45 C.F.R. § 74.414(c)(1) to "approve" a "deviation[] from negotiated rates." *See* NIH Guidance. And the "fiscal effect" of that approval—which yields across-the-board 15% indirect cost rate, compared with the near 30% historical average—plainly goes beyond "the proportional effect of such approvals" in the third quarter of Fiscal Year 2017.

History makes clear beyond cavil that the Section 224 appropriations rider forbids precisely what the Guidance purports to do. Congress first enacted this rider in 2018, Consolidated Appropriations Act 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348, 740, in direct response to a similar attempt to reduce indirect cost rates. And Congress has maintained that prohibition—precisely to prevent what the NIH has attempted here.

Given the clarity of the rider, NIH has violated not just the rider, but the Appropriations Clause of the United States Constitution. The Appropriations Clause provides that "[n]o Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law . . . ." U.S. Const. art. I, § 9, cl. 7. This "straightforward and explicit command . . . means simply that no money can be paid out of the Treasury unless it has been appropriated by an act of Congress." *Off. of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 424 (1990) (quotation omitted). Here, NIH not only lacks appropriated funds but, by issuing the Guidance, is acting in direct defiance of Congress's express prohibition in Section

224 on expending funds for purposes of modifying the NIH reimbursement process. And by implementing the Guidance, NIH will continue to violate Section 224. This violation of the Appropriations Clause also justifies injunctive relief against the unlawful expenditure of funds. *See, e.g.*, *United States v. McIntosh*, 833 F.3d 1163, 1172-73 (9th Cir. 2016) (enjoining the government from conducting a criminal prosecution that violated an appropriations rider and explaining that although courts normally cannot enjoin prosecutions, litigants can properly seek to "enjoin DOJ from *spending funds* … on such prosecutions"); *accord United States v. Bilodeau*, 24 F.4th 705, 712 (1st Cir. 2022) (endorsing *McIntosh* to entertain an appeal of an appeal claiming that a prosecution violated an appropriations rider). Indeed, that unlawful expenditure—in direct defiance of an appropriations rider designed to protect Plaintiffs—inflicts irreparable harm on Plaintiffs. *See infra* 33-36.

NIH's development and implementation of the Guidance also violates the Anti-Deficiency Act—though Plaintiffs do not seek relief based on that violation. That statute protects Congress's power of the purse by prohibiting government officials from "mak[ing] or authoriz[ing] an expenditure or obligation exceeding an amount available in an appropriation or fund for the expenditure or obligation." 31 U.S.C. § 1341(a)(1). A violation of this section requires "appropriate administrative discipline," *id.* § 1349(a), including possible suspension without pay or removal from office, and, if the violation was knowing and willful, a fine of up to $5,000 and/or imprisonment of up to two years, *id.* § 1350. In addition, violations must be reported by the head of the agency concerned to the President and Congress. *Id.* § 1351. With exceptions not relevant here, a "violation of a condition or internal cap within an appropriation … constitute[s] a violation of the Antideficiency Act." *Applicability of the Antideficiency Act to a Violation of a Condition or Internal Cap Within an Appropriation*, 25 Op. O.L.C. 33, 35, 2001 WL 36175929, at *2 (2001). For as long as NIH continues to implement the Guidance, its officials remain in violation of this statute.

B. The Guidance Violates 45 C.F.R. § 75.414 and the NIH Grants Policy Statement.

The Guidance also unlawfully conflicts with the plain text of both 45 C.F.R. § 75.414 and the Policy Statement by substituting negotiated indirect cost rates with an across-the-board 15% rate. "An agency may not, . . . simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is axiomatic . . . that an agency is bound by its own regulations." (internal quotation marks and citation omitted)). The Guidance's conflict with NIH's regulations independently requires an injunction.

The NIH's regulations state clearly that the agency may not depart from a negotiated rate without complying with a set of specific requirements—requirements that it ignored in promulgating the Guidance. Section 75.414(c)(1) states that an agency "may use a rate different from the negotiated rate for either a class of Federal awards or a single Federal award *only when* required by Federal statute or regulation, or when approved by the Federal awarding agency [in accordance with] paragraph (c)(3) of this section." 45 C.F.R. § 75.414(c)(1) (emphasis added). Hence, an agency's use of a rate other than the negotiated indirect cost recovery rate (absent a statutory or regulatory requirement to do so) requires compliance with 45 C.F.R. § 75.414(c)(3). In turn, 45 C.F.R. § 75.414(c)(3) states that NIH "must implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." or regulatory requirement to do so) requires compliance with 45 C.F.R. § 75.414(c)(3).

By pronouncing a single, uniform "policy" setting indirect cost rates at 15% regardless of the otherwise applicable negotiated rate, the Guidance violated Section 75.414(c)(3). Section 75.414(c)(3) authorizes NIH to announce *procedures* governing *subsequent* decisions to make *individualized* deviations from the baseline negotiated rate—not a unilateral decision to wipe out all

negotiated rates for all universities.

Section 75.414(c)(1) provides the general rule that "negotiated [indirect] cost rates must be accepted." Similarly, Section 7.4 of the Policy Statement provides that "[i]f a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used." Policy Statement at IIA-69. Section 75.414(c) then specifies that when the requirements of 75.414(c)(3) are met, NIH may use a "rate different" only for either "a class of Federal awards or a single Federal award." These provisions contemplate that the negotiated cost rates will be the baseline, and that a *subset* of awards—a "class" of awards or even a "single" award—may be subject to departure from that baseline. They do not permit a single across-the-board rate cut for all awards.

Similarly, Section 75.414(c)(3) provides that "[t]he HHS awarding agency must implement, and make publicly available, the policies, procedures *and* general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." 45 C.F.R. § 75.414(c)(3) (emphasis added). The plain text of this provision requires NIH to enact three different things—policies, procedures, *and* general decision making criteria. Here, NIH enacted one thing—a single, uniform "policy" setting indirect cost rates at 15% across the board. The plain text of this provision also states that NIH *will* follow those procedures and criteria *to seek and justify* deviations. In other words: first the procedures and criteria will be enacted, and then they will be used to seek and justify deviations. NIH skipped the first step: it never enacted any procedures or criteria and it never sought or justified anything. It just set rates at 15% across the board.

Reinforcing the point, Section 75.414(c)(3) authorizes "deviations" from negotiated rates. A "deviation" is a "departure from a standard or norm." *Deviation*, Dictionary.com, https://www.dictionary.com/browse/deviation (last visited Feb. 10, 2025). And authority to provide

for "deviations" does not empower NIH to eliminate the standard use of negotiated rates; rather, negotiated rates must remain the norm, with deviations just narrow exceptions. *Cf. MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 228-29 (1994) (holding that statutory authority to "modify" a requirement "does not contemplate fundamental changes"); *Biden v. Nebraska*, 143 S. Ct. 2355, 2368 (2023) (similar). Finally, the Guidance's contravention of NIH's regulations is particularly egregious as to existing grants, including those that Plaintiffs seek to preserve through this temporary restraining order. Section 75.414(c)(4) states that "the HHS awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved." 45 C.F.R. § 75.414(c)(4). And the Federal Register notice promulgating the provision on which Section 75.414(c) is modeled makes clear that any attempt to depart from negotiated rates must first be "established" and then "inclu[ded] … in the announcement of funding opportunity." Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 78 Fed. Reg. 78,590, 78,600 (Dec. 26, 2013). Yet Plaintiffs' notices of funding opportunity did not contain policies issued pursuant to 45 C.F.R § 75.414(c)(3) that would justify NIH's deviations from their negotiated rates. Rather, according to NIH, the Guidance *itself* "implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance." NIH Guidance. That reverse sequencing maneuver patently violates Section 75.414(c).

C. NIH's Promulgation of the Guidance was Arbitrary and Capricious.

The Guidance several times over runs afoul of the APA's prohibition on arbitrary and capricious agency action. 5 U.S.C. § 706(2)(A). Under the APA, an agency must provide a reasoned basis for its actions. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463

U.S. 29, 48 (1983) ("[A]n agency must cogently explain why it has exercised its discretion in a given manner."). Although the standard is deferential, it requires, at minimum, a "rational connection between the facts found and the choice made." *Id*. at 43 (quotations omitted). And an agency cannot fail to consider "important aspect[s] of the problem" in setting forth its policy explanation. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020) (quoting *State Farm*, 463 U.S. at 43). Moreover, when an agency "changes course . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Id.* (internal quotation marks and citation omitted). Courts must judge the adequacy of an agency's rationale based only on "the grounds that the agency invoked when it took the action.'" *Id.* at 20 (citing *Michigan v. EPA*, 576 U.S. 743, 758 (2015)); *SEC v. Chenery Corp*., 318 U.S. 80, 87 (1943)). Thus, to survive arbitrary-and-capricious review, the agency's articulated explanation must be sufficient to enable a court to conclude that it "was the product of reasoned decisionmaking." *State Farm*, 463 U.S. at 52.

First, the Guidance wholly fails to consider that its across-the-board 15% rate amounts to a decision to fund only part of the costs of the research it supports. As explained above, both direct and indirect costs are genuine costs of undertaking research, differing largely in how specifically they can be allocated to particular grants. Indirect costs account for the wide range of physical infrastructure and equipment, facilities (such as animal testing facilities), ethics review boards, and other overhead costs that are essential to conducting world-class research, but they are not limited to any one specific grant. The Guidance says that "as many funds as possible" should "go towards direct scientific research costs rather than administrative overhead" in order to ensure "the best medical research in the world." NIH Guidance. But the Guidance does not rationally explain (or even address) how removing reimbursement for indirect costs relates to the goal of furthering medical research or ensuring that it is the "best . . . in the world." Nor does it explain why its own audit system would not accomplish the

task of preventing administrative waste that NIH invokes in the Guidance. And the Guidance simply ignores how a decision to limit funding of indirect costs is simply a decision to fund *less research* of particular types—including types of research that rely heavily on expensive facilities and administrative costs, as cutting-edge research often does.

Second, the Guidance's only fig leaf of a justification is itself plainly irrational. The Guidance points to the lower indirect cost rates provided by private foundations, suggesting that these amounts reflect "market rates." But those private foundations differ from NIH in myriad and obvious ways. For one thing, educational institutions like Plaintiffs' members and Plaintiffs are able to accept grants from private foundations with low indirect cost rates *precisely because* those grants are only part of a broader funding portfolio that also covers indirect costs. As detailed at length in the supporting declarations, federal grant funding—for both direct and indirect costs—supports a wide range of critical research activities for which Plaintiffs' member universities, Plaintiffs, and other institutions would otherwise not be able to obtain private funding. *See* UC Decl. ¶ 21; SUNY SBU Decl. ¶ 18; CMU Decl. ¶ 8; UW–Madison Decl. ¶ 8; CWRU Decl. ¶ 16; Rice Decl. ¶¶ 3-4, 16; MSU Decl. ¶¶ 6-9; Oregon Decl. ¶¶ 5-8, 20; Washington University Decl. ¶¶ 4-7, 18. NIH's justification for the Guidance thus ignores that the system the Guidance seeks to dismantle is what permits lower indirect cost rates from private philanthropy.

There is more. One, federal grants differ from private funds in that they come with a wide range of compliance requirements, auditing obligations, and administrative requirements that increase indirect costs associated with those grants. *See generally* 45 C.F.R. pt. 75. Two, while grants from private foundations can focus on specific research areas or types of projects that can have more limited overheard costs, NIH grants support broad-based research infrastructure. Three, private foundations may both define and calculate indirect costs differently from NIH. For example, the Gates Foundation

(which was cited in the Guidance as a funder with a maximum indirect cost rate of 10% for institutions of higher education) explained in 2017 that it "is more expansive than NIH in defining direct costs, meaning some overhead payments are wrapped in with the grant."[5] Needless to say, a broader definition of direct costs inevitably leads to a smaller universe of indirect costs, and ignoring that difference produces a classic apples-to-oranges mismatch.

Third, the Guidance ignores the reliance interests of the research institutions receiving federal funding. The Guidance recognizes that typically, about 30% of an average NIH grant is earmarked for indirect costs, but some universities receive higher rates. With regard to existing grants, the reliance interests are obvious: budgets have already been determined, people hired, and research predicated on the funding has already begun. But even with respect to new grants, universities have structured their budgetary affairs on the understanding that federal research grant funding will continue to allow them to recover their indirect costs associated with federal funding. Universities have accordingly made costly decisions about long-term investments, such as what physical infrastructure should be built—decisions that were made in reliance on negotiated rates with federal agencies allowing for the recovery of some such costs via depreciation. Nor have universities in doing so relied only on their own unilateral expectations that NIH would continue its longstanding approach: As explained above and below, OMB and HHS regulations generally require NIH to use a negotiated indirect cost rate and permit deviations from that rate only in narrowly limited circumstances.

[5] Jocelyn Kaiser, *NIH Plan to Reduce Overhead Payments Draws Fire*, Science (June 2, 2017), https://www.science.org/content/article/nih-plan-reduce-overhead-payments-draws-fire.

Fourth, NIH has disregarded without explanation its prior factual findings—a choice that imposes a heightened reasoning requirement that the agency has failed to meet. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 106 (2015) (The "APA requires an agency to provide more substantial justification when its new policy rests upon factual findings that contradict those which underlay its prior policy." (internal quotation marks and citation omitted)). Here, NIH's prior policy rested on the view that a uniform indirect cost rate was not appropriate, and that negotiated rates should be both institution-specific and—in most cases—substantially higher. The Guidance provides no justification, much less a "substantial justification," for reversing course on its factual predicates. *Id.*

Fifth, the Guidance is arbitrary and capricious because, in setting a uniform 15% rate, it ignores the dramatic variations in need and circumstances among different institutions across the country. As discussed in more detail above in Section III.B, existing regulations establish extensive procedures for setting institutions' indirect cost rates—in recognition of the fact that not all institutions are similarly situated. For example, as explained in Plaintiffs' supporting declarations, universities specifically negotiate different indirect cost rates to be applied to different types of projects. U. of Florida Decl. ¶¶ 10-11; SUNY SBU Decl. ¶ 11; UW–Madison Decl. ¶¶ 5-6; CWRU Decl. ¶¶ 9-10, 12; Rice Decl. ¶¶ 9-11, 16; MSU Decl. ¶¶ 7, 9; Harvard Decl. ¶ 9; Oregon Decl. ¶¶ 11-13; Washington University Decl. ¶¶ 10-12.

Indeed, the incoherence of NIH's one-size-fits-all approach runs deeper still. If a single across-the-board rate were appropriate in this context, Congress would have simply provided a rate. The principal reason Congress involved the executive branch in this context was because the negotiation of institution-specific rates requires executive action to take into account the circumstances of individual institutions. As the appropriations riders make clear, when Congress involved the executive branch in institution-specific negotiations, the last thing Congress intended

was for the executive to dispense with that whole negotiated process in favor of a quasi-legislative one-size-fits-all approach. If Congress had intended such an approach, it would have legislated it itself.

D. The Guidance Violates Requirements for Indirect Cost Recovery.

The Guidance is furthermore inconsistent with NIH's larger system of regulations governing recovery of indirect costs. Those regulations set forth a reticulated scheme for rate-setting that ensures that grantees can recover their actual indirect costs that are reasonable and attributable to federal projects. *See* 45 C.F.R. § 75.100(c) (establishing "principles for determining the allowable costs incurred by non-Federal entities under Federal awards"). Yet the Guidance sub silentio supplants that detailed system with an across-the-board 15% figure, abandoning both the substance and procedure set forth in existing regulations.

Substantively, the Guidance slashes recoverable costs in contravention of existing law. HHS regulations provide that grantees shall recover reasonable actual indirect costs. 45 C.F.R. § 75.402 ("The total cost of a Federal award is the sum of the allowable direct and allocable indirect costs less any applicable credits."). The agency's guidelines ensure that grantees can recover those costs via a detailed documentation and recovery system. 45 C.F.R. § 75.402; *see generally* 45 C.F.R. § 75.414; Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs). Yet, under the Guidance, grant recipients will not be able to recover those costs. Instead, they will be limited to an arbitrary 15% cost recovery rate across every institution.

The Guidance likewise departs without acknowledgement from the existing, complex process for negotiating an indirect cost recovery rate. Under existing law, institutions must document and submit costs in painstaking detail to support recovery. Subpart E of part 75 of Title 45 "establishes

principles for determining the allowable costs incurred by non-Federal entities under Federal awards." 45 C.F.R. § 75.100(c). 45 C.F.R. § 75.414(e) points to a set of appendices that set forth in detail "[r]equirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans." Those appendices contain "the documentation prepared by a non-Federal entity to substantiate its request for the establishment of an indirect cost rate." 45 C.F.R. § 75.2 (definition of "Indirect cost rate proposal"). For universities, Appendix III establishes the criteria for identifying and computing indirect facilities and administration costs for Institutions of Higher Education (IHEs). *Id*. § 75.414(e)(1); Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs). The Appendix sets forth the processes for a grant recipient to document a significant range of costs and how those costs should be allocated among different government projects. The Guidance, however, dispenses with every bit of this documentation and calculation.

But that is not all—the Guidance displaces the typical process to review and validate indirect cost allocation. By existing law, the government must employ annual audits to determine what is charged to a federal award and ensure that accounting is correct. *See* 45 C.F.R. §§ 75.501(b), 75.504, 75.514. Auditors review in detail how federal funds have been spent. Specifically an auditor may identify "[q]uestioned [c]osts," which are those costs that an auditor "question[s]" because "of an audit finding (1) [w]hich resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; (2) [w]here the costs, at the time of the audit, are not supported by adequate documentation; or (3) [w]here the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances." 45 C.F.R. § 75.2 (definition of "Questioned cost"). The results of the audit and any questioned costs are factored into negotiation of indirect cost rates. *See* Appendix III to Part 75—

Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs) ("The cognizant agency for indirect costs must conduct any necessary negotiations with an educational institution regarding amounts questioned by audit that are due the Federal Government related to costs covered by a negotiated agreement.").

E. The Guidance Was Promulgated Unlawfully Without Notice and Comment.

The NIH also violated the APA in failing to utilize notice-and-comment rulemaking to promulgate the Guidance. The Guidance qualifies as a so-called "legislative rule." "[L]egislative rules" are those agency actions carrying the "force and effect of law." *Perez*, 575 U.S. at 96; 5 U.S.C. § 553(b), (c). Such binding regulations may be promulgated only following notice and comment. *Perez*, 575 U.S. at 96; 5 U.S.C. § 553(b), (c). The agency's failure to do so renders the Guidance unlawful.

That the Guidance has the force and effect of law—and thus qualifies as a legislative rule—is clear from its text. It purports to effect both substantive and procedural changes in the rules that every regulated entity must follow. Specifically, the Guidance asserts that it "*implements* and makes publicly available NIH's *updated* policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance." NIH Guidance (emphasis added). The substantive deviation from existing rules is clear. The Guidance makes plain that it sets a new, "standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." *Id.* That percentage represents a binding alteration to the legal framework that previously governed grantmaking, replacing the previous averages that had persisted for many years. Or put otherwise, it is clear that the Guidance has the force and effect of law because it "includes materially different policy options that alter" substantive existing rules with respect to indirect cost rates under NIH grants. *N.H. Hosp. Ass'n v.*

Azar, 887 F.3d 62, 73 (1st Cir. 2018); *see also Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (reasoning that agency action has the force and effect of law because it "effectively amends" existing criteria). Those changes, moreover, are manifest not only with respect to the rate itself, but also with respect to the reticulated process by which the rates were previously set on an individualized basis, which is not compatible with a single, across-the-board rate. Twice over, therefore, this action represents "a new position inconsistent with" the existing regulatory and legislative regime governing NIH grants. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995).

HHS itself has recognized that similar changes are legislative rules generally requiring notice and comment. When HHS recently adopted amendments to the uniform regulation governing federal grants at 2 C.F.R. Part 200, it asserted that there is "good cause under 5 U.S.C. 553(b)(B) . . . to dispense with the opportunity for advance notice and for public comment," and it made the amendments immediately effective. Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 89 Fed. Reg. 80,055, 80,056 (Oct. 2, 2024). But an agency needs to assert the good-cause exception only if a rule is legislative; notice-and-comment is generally unnecessary for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(4)(A).[6] Here, the Guidance is equally legislative, but NIH did not assert that any good cause

[6] HHS has similarly recognized that similar changes are subject to the rules governing notice-and-comment. *See* Health and Human Services Grants Regulation, 81 Fed. Reg. 45,270, 45,271 (July 13, 2016) (addressing HHS restriction of training grants, foreign organizations, and foreign public entities to a maximum 8% indirect cost rate).

justified a failure to use notice-and-comment rulemaking. Nor could good cause exist for making such an immediate—and immediately disruptive—change.

F. The Guidance Conflicts with the Public Health Service Act.

The Guidance also conflicts with NIH's congressionally delegated authority to award research grants. That authority is set forth in Section 301(a) of the Public Health Service Act, as amended, which authorizes the Secretary of Health and Human Services to "make grants-in-aid to universities" and other research institutions for the purpose of "promot[ing] the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." 42 U.S.C. § 241(a). For all of the reasons discussed above, the Guidance not only does not serve that purpose, but is also likely to have devastating effects on health research across the country.

Indeed, if the executive branch had adopted this approach in the absence of the appropriations rider, the change from the longstanding institution-specific approach to a one-size-fits-all rule that treats all institutions the same and radically reduces their funding would put this case in the category of "extraordinary" cases where the Court should closely scrutinize whether Congress meant to confer authority on an agency to make the decision at issue. Specifically, courts consider whether the "history and the breadth of the authority that [the agency] has asserted" and "the economic and political significance of that assertion" counsel in favor of "hesitat[ing] before concluding that Congress meant to confer such authority." *West Virginia v. EPA*, 597 U.S. 697, 721 (2022) (internal quotation marks omitted) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-60 (2000)). But here there is no need to guess whether Congress thought a radical change from institution-specific negotiated rates to a single across-the-board rate was a major question. When the executive branch tried this maneuver once before, Congress reacted promptly and emphatically to

make clear that this deviation was contrary to Congress's will. That congressional judgment cannot simply be cast aside.

G. The Guidance Is Impermissibly Retroactive.

The Guidance is further in excess of NIH's statutory authority because it is retroactive. Agencies do not, absent express statutory authority, have the power to promulgate retroactive rules. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("[A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms."). Why that is so is clear enough: Retroactive rules are profoundly disruptive and raise significant fairness concerns. *See Brimstone R.R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic" and "ought not to be extended so as to permit unreasonably harsh action without very plain words.").

Here, there is no indication whatsoever that NIH has the authority to make the Guidance retroactive. Congress did not authorize NIH to retroactively modify indirect cost rates when it enacted NIH's grantmaking authority, or in any other statute. *See* 42 U.S.C. § 241. To the contrary, as addressed in Count I, Congress explicitly rejected the proposition NIH could retroactively modify indirect cost rates. And yet, that is precisely what NIH purports to do. The Guidance asserts that it has changed the terms of existing grants with already-negotiated rates. In so doing, the Guidance is retroactive thrice over: It "impair[s] rights a party possessed when [it] acted, increase[s] a party's liability for past conduct, [and] impose[s] new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The Guidance's retroactivity is a final, independent reason that it is unlawful.

III. The Other Factors Favor a Temporary Restraining Order.

The remaining factors—irreparable harm, balance of the equities, and the public interest—also weigh strongly in favor of emergency injunctive relief here.

A. The Guidance Is Already Causing Irreparable Harm.

Plaintiffs face irreparable harm to their primary missions, core infrastructure and facilities, research agendas, clinical trials, critical personnel, and operating budgets. Those harms are substantial, likely in the absence of an injunction, and not adequately compensable by money damages. *Doe ex rel. Doe v. Portland Pub. Schs.*, 701 F. Supp. 3d 18, 38 (D. Me. 2023).

Plaintiffs' members drive significant advances in knowledge through scientific and medical research. *See, e.g.*, MIT Decl. ¶¶ 4-5, 16-17; Brown Decl. ¶¶ 3-5; Cornell Decl. ¶¶ 4-5; Dartmouth Decl. ¶ 6; U. of Florida Decl. ¶ 4; Michigan Decl. ¶ 4; Ex. 22 (Princeton Decl.) ¶¶ 6-7; SUNY SBU Decl. ¶¶ 4-5; CMU Decl. ¶¶ 4-5; Rochester Decl. ¶¶ 5-9; Vanderbilt Decl. ¶¶ 4-6; UW–Madison Decl. ¶¶ 4, 7, 9-10; CWRU Decl. ¶¶ 4, 13; Rice Decl. ¶ 4; MSU Decl. ¶¶ 4-5, 11-13; Oregon Decl. ¶¶ 4, 8; Washington University Decl. ¶¶ 4, 16; Penn Decl. ¶¶ 3-4; Columbia Decl. ¶ 6. Uniformly reducing facilities and administration cost rates of Plaintiffs' research grants and contracting to 15% thereby presents "[o]bstacles [that] unquestionably make it more difficult for . . . [Plaintiffs] to accomplish [their] primary mission." *Nat'l Council of Nonprofits v. Off. of Mgmt. & Budget*, No. 25-cv-239, __ F. Supp. 3d __, 2025 WL 368852, at *12 (D.D.C. Feb. 3, 2025) (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016)). *See, e.g.*, MIT Decl. ¶¶ 15-17; Brown Decl. ¶¶ 12-18; Cornell Decl. ¶¶ 12-14; Dartmouth Decl. ¶¶ 12-14.

More specifically, without urgent intervention by the Court, harm is very "likely" to occur. *Winter v. Nat. Res. Defense Council, Inc.*, 555 U.S. 7, 22-23 (2008); *see also Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). If the Guidance remains in force, AAU's members will be

required imminently to layoff critical personnel that support Plaintiffs' members' research enterprise and facilities; interrupt ongoing, critical work in clinical trials directed at major health challenges; reduce utilization of research supplies, equipment, and services; and/or lose significant members of the healthcare workforce. *See, e.g.*, MIT Decl. ¶¶ 15-17 (describing cancer and neurological research that would be jeopardized by a cut in overhead costs); Brown Decl. ¶ 15 ("There is no simpler way to put it: At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); *id.* ¶ 19 (describing estimated layoffs "number[ing] in the hundreds" at Brown's affiliated hospitals and schools if the 15% rate takes effect); Cornell Decl. ¶ 13 (University would need to "consider layoffs" and close research facilities whose "operation and maintenance can no longer be supported"); Dartmouth Decl. ¶ 13 ("Dartmouth would also likely need [to] cut back on the core support facilities and services that [it] provide[s] to our existing researchers, hampering their ability to do critically important research in an efficient, effective, safe, and secure manner."). As a result, Plaintiffs' members' research initiatives—including, but not limited to, biocontainment laboratories that support immunology, virology, and microbiology research, core blood bank and stem cell transplant facilities, animal facilities—will suffer "existential injuries" that undeniably rise to the level of irreparable harm. *See Nat'l Council of Nonprofits*, 2025 WL 368852, at *12-13.

Those harms, moreover, will begin to accrue immediately. The University of Florida, for example, attests that cutting its indirect cost rate to 15% "would end or seriously jeopardize" critical research projects regarding immunotherapy as a cure for malignant brain cancer, treatments for Parkinson's disease, and work to cure ALS, and that the "deeply damaging effects on the University of Florida's ability to conduct research" will occur "from day one." U. of Florida Decl. ¶¶ 4, 14, 17. Likewise, the University of Wisconsin–Madison explains that it faces submission deadline for grants in the next two to seven days—grants that it must now reconsider pursuing in light of NIH's eleventh-

hour slashing of indirect cost rates but that are instrumental in fostering the success of its researchers. UW–Madison Decl. ¶ 11.

These injuries are beyond remediation; there is no "possibility [of] adequate compensatory or other corrective relief . . . at a later date." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297-98 (D.C. Cir. 2006) (quotation omitted). As soon as the indirect cost rate is reduced to 15%, Plaintiffs' member universities will suffer cascading, irreversible effects—including the forced closure of clinical trials where continuity is critical for patient care and for which it would be highly difficult, if not impossible, to restart such trials after a significant pause. *See, e.g.*, Brown Decl. ¶ 17 (explaining that "clinical trials must generally be continuous to be effective, due to concerns for both patient care and trial validity," and "[i]f these trials are forced to undergo a significant pause, they might be difficult, if not impossible, to restart, where the lack of continuity compromises the scientific results"); Cornell Decl. ¶ 13 (explaining that the 15% rate would "impact patients currently enrolled in federally funded clinical trials, who may find their treatment discontinued, leading to potential health risks"); Harvard Decl. ¶ 17; UW–Madison Decl. ¶ 9; CWRU Decl. ¶ 13; Rice Decl. ¶¶ 14, 17; MSU Decl. ¶¶ 10-14; Oregon Decl. ¶¶ 18-19; Washington University Decl. ¶ 16; Penn Decl. ¶ 11, 14-15, 20-21. Even a temporary interruption would derail years of accumulated work in critical research aimed at major health challenges, including cancer, aging, dementia, heart disease, immune disorders, mental health disorders, and childhood illnesses, as well as clinical trials that bring lifesaving medical care to patients. *See, e.g.*, MIT Decl. ¶¶ 15-17; Brown Decl. ¶¶ 5, 15; Cornell Decl. ¶¶ 5, 10; Dartmouth Decl. ¶¶ 6, 12-13; Vanderbilt Decl. ¶ 15; UW–Madison Decl. ¶¶ 9-10; CWRU Decl. ¶¶ 4-8; Rice Decl. ¶¶ 4-5; MSU Decl. ¶¶ 10-14; Oregon Decl. ¶¶ 4-6, 17-18; Washington University Decl. ¶¶ 4-5, 16; Penn Decl. ¶ 21. Because this Guidance "directly impact[s] the [Plaintiffs'] and others' ability to provide and administer vital services and relief," it inflicts irreparable

harm on AAU and its members. *Trump*, 2025 WL 357368, at *4.

Finally, the Guidance inflicts irreparable constitutional injuries. It is well-established that violations of the Bill of Rights inflict irreparable injuries. *See, e.g.*, *Elrod v. Burns*, 427 U.S. 347, 373 (1976). And the Supreme Court has made clear that separation of power principles exists, not to protect the branches from each other, but to safeguard individual rights. *See Bond*, 564 U.S. at 222-23. Here there is no doubt that the appropriations rider was designed to protect Plaintiffs from the precise kinds of disruption the Guidance has inflicted. The Appropriations Clause protects Plaintiffs against those injuries, and the loss of the liberty protected by the Appropriations Clause is a classic irreparable injury.

B. The Balance of the Equities and Public Interest Overwhelmingly Favor Relief.

The balance of the equities and public interest favor granting Plaintiffs their requested relief; these factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, the Guidance will burden Plaintiffs and grossly impair the public interest. That is because irreparable harm that the Guidance inflicts on Plaintiffs' members and Plaintiffs' research programs will also necessarily harm the public. The very purpose of these federal research partnerships is to advance national security, health, and prosperity through critical research, as the declarations submitted with this Motion amply reflect. *See also* Luther Testimony. Curtailing this research due to unexpected budget deficits would undermine the very aims promoted by NIH grants, and federal research funding more broadly. Indeed, it will gut the vital public health work that institutions are already undertaking. Ex. 16 (UMCP Decl.) ¶¶ 4, 11; Caltech Decl. ¶¶ 12-13; U. of Florida Decl. ¶¶ 4-5; UW–Madison Decl. ¶¶ 9-10; CWRU Decl. ¶¶ 4-5, 13; Rice Decl. ¶¶ 4-5; MSU Decl. ¶¶ 9-14; Oregon Decl. ¶¶ 3-5, 22; Washington University Decl. ¶¶ 3-5.

The government, by contrast, will not suffer any harm if the Guidance is enjoined. "It is well

established that the Government cannot suffer harm from an injunction that merely ends an unlawful practice." *C.G.B. v. Wolf,* 464 F. Supp. 3d 174, 218 (D.D.C. 2020) (internal quotation marks and citations omitted). Likewise, "[t]here is generally no public interest in the perpetuation of unlawful agency action." *Open Cmtys. All. v. Carson,* 286 F. Supp. 3d 148, 179 (D.D.C. 2017) (quotation omitted). "To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws—such as the APA, as well as regulations . . . that govern their existence and operations." *Id*. (internal quotation marks and citations omitted). And even aside from the Guidance's patent illegality, the government incurs no cognizable harm from the continuation of the approach to indirect costs that has endured for decades.

CONCLUSION

Plaintiffs respectfully urge this Court to enter an order temporarily restraining Defendants, their agents, and anyone acting in concert or participation with Defendants from implementing, instituting, maintaining, or giving effect to the Guidance in any form; from otherwise modifying negotiated indirect cost rates except as permitted by statute and by the regulations of OMB and HHS; and from expending appropriated funds in any matter contrary to Section 224 of the Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47.

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CERTIFICATE OF SERVICE

Counsel for Plaintiffs certify that they have submitted the foregoing document with the clerk of court for the District of Massachusetts, using the electronic case filing system of the Court. Counsel for Plaintiffs hereby certify that they have served all parties electronically or by another manner authorized by Fed. R. Civ. P. 5(b)(2).

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