IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HARRIS COUNTY, TEXAS, *et al*., *Plaintiffs*, v. **ROBERT F. KENNEDY, JR.**, in his official capacity as Secretary of Health and Human Services, *et al*., *Defendants*.	Case No. 1:25-cv-01275-CRC

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

In the wake of the COVID-19 pandemic, Congress appropriated billions of dollars to the public health departments of Plaintiffs and other localities to stave off the harm from that pandemic, and to develop the capacity to prevent future-such pandemics. Defendants unilaterally terminated the funding, citing an unsupported basis that "the grants and cooperative agreements are no longer necessary." *See* Compl., ECF No. 1 at ¶ 85. This flagrant violation of statutory commands will cause the Plaintiffs irreparable harm, including the termination of critical members of their public health force, and the abrupt end to their vital efforts at keeping their residents safe. As such, Plaintiffs seek to enjoin the Defendants' unconstitutional and statutory violations.

Defendants incorrectly argue that sovereign immunity and the Tucker Act shield them from this Court's jurisdiction over Plaintiffs' claims for injunctive and declaratory relief. But the individual Defendants are not protected by sovereign immunity because their actions directly contravene the congressional commands and are thus ultra vires. Additionally, this is not a contract dispute about the termination of individual grant agreements that belongs in the Court of Federal Claims ("CFC"), but is instead a challenge to Defendants' discrete action to terminate all COVID-19-related funding. Plaintiffs do not seek money damages, but rather the equitable, prospective reinstatement of the same grants with the same statutory strings attached. Plaintiffs have standing to raise these claims. Their harm is not only discrete, particularized, and imminent, but also likely to be redressed by the injunction they seek. AFSCME also has standing because both the organization and its members were directly affected by the funding termination.

Plaintiffs are likely to succeed on the merits of their claims against Defendants. Once obligated, Defendants had no authority to unilaterally terminate the funding, and their decision to do so anyway cannot be reconciled with the Constitution, the appropriating statutes, or Congress's

decision to keep the funding in place even after the public health emergency ended. And, because Defendants' termination decision and the implementation of that decision are unconstitutional and unlawful, they also violate the Administrative Procedure Act ("APA").

Without the Court's intervention, Plaintiffs will face irreparable harm. The termination threatens not only to cripple their public health workforce, but also to gut vaccination campaigns, to impede efforts to track and respond to threats of infectious disease, and to stymie the modernization of public health infrastructure. For these reasons, the balance of equities and the public interest decidedly weigh in favor of granting injunctive relief. Given the significant harms that Plaintiffs face, nationwide injunctive relief is warranted.

ARGUMENT

I. This Court has subject matter jurisdiction over Plaintiffs and Plaintiffs' claims.

A. The Court has jurisdiction over Plaintiffs' constitutional claims, which do not require any waiver of sovereign immunity.

This Court has jurisdiction over each of Plaintiffs' three constitutional claims. *See* Compl. at ¶¶ 133–153. Those claims, brought against only individual officials, do not hinge on any sovereign immunity waiver. *Pollack v. Hogan*, 703 F.3d 117, 121 (D.C. Cir. 2012). When an "'officer is not doing the business which the sovereign has empowered him to do,'" "there is no sovereign immunity to waive—it never attached in the first place." *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1329 (D.C. Cir. 1996) (quoting *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949)).

This so-called *Larson-Dugan* exception applies here because the Mass Termination Decision "conflict[s] with the terms of [Defendants'] valid statutory authority," namely the various congressional appropriations at issue here. *Larson*, 337 U.S. at 695. Those appropriations specifically designated significant funds to localities for pandemic surveillance, increased

distribution of vaccines, expansion of public health workforce, and the development of other disease preparedness and response activities. *See* Pls.' Mem. in Support of Prelim. Inj. ("Pls.' Br."), ECF No. 14-1, at 3–6. Defendants' Mass Termination Decision, which unilaterally terminated those funds, was made without any authority from Congress and contradicts Congress's own actions in extending the funding after the public health emergency of COVID-19 ended. Such unconstitutional action is not protected by sovereign immunity. *Local 2677, Fed'n of Gov't Emps. v. Phillips*, 358 F. Supp. 60, 68 (D.D.C. 1973); *ABA v. U.S. DOJ*, No. 25-CV-1263 (CRC), 2025 WL 1388891, at *4 (D.D.C. May 14, 2025).

B. The Court also has jurisdiction over Plaintiffs' APA claims, which do not turn on any contract and do not seek money damages.

Defendants argue that the Tucker Act, 28 U.S.C. § 1491(a)(1), forbids relief in the District Court and requires Plaintiffs to bring their claims in the CFC.[1] Defs.' Opp. to Pls.' Prelim. Inj. Mot. ("Defs.' Br."), ECF No. 21 at 11–25. The CFC, however, does not have jurisdiction over Plaintiffs' claims, which have no basis in the grant agreements Defendants seek to fold into this dispute. Plaintiffs instead seek the enforcement of congressional appropriations through injunctive and declaratory relief—something the CFC cannot grant. "This court retains the power to make rational distinctions between actions sounding genuinely in contract and those based on truly independent legal grounds." *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 969–70 (D.C. Cir. 1982). To draw this distinction, this Court must examine (1) the source of the right upon which the plaintiffs

[1] It is unclear whether the CFC's jurisdiction over contract claims against the government is exclusive, because as the Supreme Court has pointed out, no "language in the Tucker Act" makes the Court of Federal Claims' jurisdiction over contract claims "exclusive." *See Bowen v. Massachusetts*, 487 U.S. 879, 910 n.48 (1988). As the D.C. Circuit has itself recognized, there is a "strong case" that, in fact, "the Tucker Act should not be read to 'impliedly forbid'" district courts from considering "contract actions for specific relief." *Transohio Sav. Bank v. Dir., Off. of Thrift Supervision*, 967 F.2d 598, 612 (D.C. Cir. 1992), *overruled in part on other grounds*, *Perry Cap. LLC v. Mnuchin*, 864 F.3d 591, 620 (D.C. Cir. 2017). Plaintiffs reserve the right to seek reconsideration of this precedent in an appropriate forum.

base their claims; and (2) the type of relief sought. *Id.* at 968. Both factors weigh in favor of this Court's jurisdiction.

1. The source of Plaintiffs' claims is the Constitution, the congressional appropriations, agency regulation, and the APA.

At their core, Plaintiffs' claims challenge Defendants' violation of Congress's appropriations via the Mass Termination Decision and Defendants' unlawful procedures in implementing the Mass Termination Decision. *See* Pls.' Br. at 23–29. Plaintiffs' rights spring not from the grants themselves, but from the Constitution, the specific statutory appropriations that Defendants violated, agency regulation, and the APA. *Transohio,* 967 F.2d at 609. That the appropriations do not "specify amounts dedicated to any . . . particular recipients," Defs.' Br. at 17, does not make this a contracts case. Plaintiffs challenge Defendants' unilateral and wholesale termination of congressionally authorized funding, and they specifically do not challenge any individual grant termination. *Contra Twin Metals Minn. LLC v. United States*, No. 22-CV-2506 (CRC), 2023 WL 5748624, at *6 (D.D.C. Sept. 6, 2023) (concerning the cancellation of an individual entity's leases with Department of Interior). Nor could they, as Defendants did not make individualized decisions to terminate the grants at issue for violation of their terms. Where, as here, "determining whether the [defendants] infringed [plaintiffs'] rights as alleged in the complaint requires primarily an examination of the statutes the [defendants] ha[ve] purportedly violated, not of [plaintiff's] contract with [defendants]," the district court has jurisdiction over the case. *Crowley Gov't Servs., Inc. v. Gen. Servs. Admin.*, 38 F.4th 1099, 1108–09 (D.C. Cir. 2022).

In *Colorado v. HHS*, a district court in Rhode Island preliminarily enjoined the same Mass Termination Decision, holding that it had jurisdiction because the case "concerns the process the Government undertook when terminating the funding based on the end of the pandemic," something that it could determine by reviewing "the governing federal statute and regulations."

Mem. and Order on Prelim. Inj. at 19, No. 1:25-cv-00121-MSM-LDA (D.R.I. May 16, 2025) ("*Colorado* PI Order"), ECF No. 22, Ex. A (citation omitted). The state plaintiffs there had "assert[ed] constitutional claims alongside [their] APA claims," which made the source of their rights "even clearer." *Id.* at 18. So too here. Plaintiffs contend that the Mass Termination Decision was unlawful under the Constitution, appropriations statutes, agency regulations, and the APA, not under the terms of any particular grant instrument.

2. Plaintiffs do not seek any contractual remedy.

Plaintiffs seek prospective, equitable relief, not money damages under a contract.[2] The relief that Plaintiff seek may result in payments "going forward" to grant recipients after the Mass Termination Decision is rescinded, but this would not be compensation for losses suffered due to breach, and so these funds would not be "money damages." *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 212 (2002); *Md. Dep't of Human. Res. v. HHS,* 763 F.2d 1441, 1446 (D.C. Cir. 1985).

"Though [plaintiff's] challenge might somehow result in it receiving authorization to draw on [grant] funds . . . at core it seeks to enforce [a] statutory [and regulatory] mandate." *Am. Near E. Refugee Aid v. U. S. Agency for Int'l Dev.*, 703 F. Supp. 3d 126, 135 (D.D.C. 2023) (cleaned up); *see also Colorado* PI Order at 20–21. This is not a case where Plaintiffs are seeking damages for past harm, or for expectancy or reliance. *Compare Twin Metals*, 2023 WL 5748624, at *7–8 (damages for harms relating to money already spent and inability to recoup on investment) *with* Pls.' Br. at 41–42 (declaratory and injunctive relief to enforce congressional appropriations).

In any event, any order that results in Defendants paying Plaintiffs, or the employers of AFSCME members, under the relevant appropriations would not be a "free and clear transfer of

[2] Money damages "refers to a sum of money used as compensatory relief" that "substitutes for that which ought to have been done." *Bowen*, 487 U.S. at 895, 910 (cleaned up).

money," but instead a "strings-attached disbursement" that qualifies as equitable relief, not money damages. *Lummi Tribe of the Lummi Reservation v. United States*, 870 F.3d 1313, 1318–19 (Fed. Cir. 2017). Plaintiffs do not seek unrestricted sums of money, but instead, declaratory and injunctive relief that would likely lead to the reinstatement of grant funding subject to the same restrictions to which the grantees will remain bound, including limitations on the use of funding for specified activities. As the government recently argued before the Federal Circuit, the CFC lacks jurisdiction over such claims for relief, because that "would allow [plaintiffs] to avoid the strings-attached nature of the [grant program]." *See* Opening Br. of Def.-Appellant at 30–34, *112 Genesee St., LLC v. United States*, No. 25-1373 (Fed. Cir. Mar. 14, 2025), ECF No. 15.

3. *Department of Education v. California* does not render this Court an improper forum.

Defendants rely heavily on the Supreme Court's recent decision in *Department of Education v. California,* 145 S. Ct. 966 (2025) (per curiam), to challenge this Court's jurisdiction. But *California* does not divest this Court of jurisdiction.[3] As an emergency stay decision, it has limited precedential value.[4] *See Colorado* PI Order at 22 ("The Supreme Court's brief treatment of *Bowen* and *Great-W. Life* in *California* and the cursory mention of potential jurisdictional issues do not appear to settle all jurisdictional issues here."). Indeed, just one month before that stay decision, the Supreme Court denied the government's stay application in a different grant

[3] Numerous other district courts that have faced the question of how to treat *California* in the grant termination context have held that the case does not divest them of jurisdiction. *See, e.g.*, *Climate United Fund v. Citibank, N.A.*, No. 25-CV-698 (TSC), 2025 WL 1131412, at *11 (D.D.C. Apr. 16, 2025), *appeal docketed*, No. 25-5122 (D.C. Cir. Apr. 16, 2025); *New York v. Trump*, No. 25-cv-39, 2025 WL 1098966, at *1–2 (D.R.I. Apr. 14, 2025), *appeal docketed*, No. 25-1413 (1st Cir. Apr. 28, 2025); *Maine v. USDA*, No. 1:25-cv-131-JAW, 2025 WL 1088946, at *19 (D. Me. Apr. 11, 2025); *Rhode Island v. Trump*, No. 1:25-CV-128-JJM-LDA, 2025 WL 1303868, at *6 (D.R.I. May 6, 2025); *Woonasquatucket River Watershed Council v. USDA*, No. 25-cv-97-MSM-PAS, 2025 WL 1116157, at *14 (D.R.I. Apr. 15, 2025), *appeal docketed*, No. 25-1428 (1st Cir. May 18, 2025).

[4] The Supreme Court can stay the issuance of an injunction only to affirm the issuance of an injunction later on. *See, e.g., Allen v. Milligan*, 599 U.S. 1 (2023).

termination case, *Dep't of State v. AIDS Vaccine Advoc. Coal.*, 145 S. Ct. 753 (2025), rejecting the position that "sovereign immunity deprived the District Court of jurisdiction to enter its enforcement order." *Id.* at 755 (Alito, J., dissenting). Given the limited precedential value of both stay decisions, this Court remains bound by *Bowen* (which *California* cites and does not overrule, *see* 145 S. Ct. at 968). And *Bowen* dictates a finding of jurisdiction here. *See* Pls.' Br. at 30–34.

Moreover, the plaintiffs in *California* did not raise any constitutional claims, relying instead on the APA alone to challenge the termination of their education grants. *ABA*, 2025 WL 1388891, at *6. That distinction persuaded this Court to conclude that *California* did not affect its determination that it had jurisdiction over the ABA's request for injunctive relief from the termination of grants on constitutional grounds. *Id.* The same result should hold here.

C. The CFC does not have jurisdiction over Plaintiffs' claims and thus cannot divest this Court of jurisdiction.

Plaintiffs' claims are not contract claims covered by the Tucker Act, and thus the Plaintiffs could not have brought their claims in the CFC. The Tucker Act gives the CFC jurisdiction over contract claims and confers a corresponding waiver of sovereign immunity in that court, "when the constitutional provision, statute, or regulation in question expressly creates a substantive right enforceable against the federal government for money damages." *LeBlanc v. United States*, 50 F.3d 1025, 1028 (Fed. Cir. 1995) (citing *United States v. Testan*, 424 U.S. 392, 398 (1976)). That waiver of sovereign immunity does not apply here.

First, Plaintiffs allege constitutional violation of their rights under the separation of powers doctrine and the Spending Clause, neither of which mandate money damages against the government. *LeBlanc*, 50 F.3d at 1028; *Stephens v. United States*, 165 Fed. Cl. 341, 348 (2023) (Article I is not a money-mandating provision of the Constitution). Moreover, "[t]he ability to sue to enjoin unconstitutional actions by state and federal officers is the creation of courts of equity,

and reflects a long history of judicial review of illegal executive action, tracing back to England." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 327 (2015). If Congress wanted to remove a district court's long-established ability to enjoin unconstitutional action through the Tucker Act, it would have had to do so clearly. *Webster v. Doe*, 486 U.S. 592, 603 (1988). A "heightened showing" is required "in part to avoid the 'serious constitutional question' that would arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim." *Id.* The Tucker Act lacks the requisite clear intent to foreclose judicial review of Plaintiffs' constitutional claims. *See also Bowen*, 487 U.S. at 908.

Second, the CFC cannot provide the prospective relief that Plaintiffs seek. *Me. Cmty. Health Options v. United States*, 590 U.S. 296, 327 (2020) ("[T]he Court of Federal Claims 'does not have the general equitable powers of a district court to grant prospective relief.'" (quoting *Bowen*, 487 U.S. at 905)); *Tootle v. Sec'y of Navy*, 446 F.3d 167, 176 (D.C. Cir. 2006). In other words, Plaintiffs have nowhere else to go. Because the CFC does not have jurisdiction to decide Plaintiffs' claims, this Court does not lose jurisdiction over them. *Tootle,* 446 F.3d at 176 ("We categorically reject the suggestion that a federal district court can be deprived of jurisdiction by the Tucker Act when no jurisdiction lies in the [CFC].").

Third, Plaintiff AFSCME is not subject to Tucker Act jurisdiction for an independent reason: AFSCME and its members are not grantees here at all, but rather third parties harmed as a result of Defendants' unlawful withholding. They thus indisputably seek relief that is unavailable in the CFC, and so the Tucker Act cannot be read to deprive them of any redress for their claims. *See id.*; *see also U.S. Enrichment Corp. v. United States*, 117 Fed. Cl. 548, 553 (2014) (recognizing that "[s]ubcontractors and other third parties are generally not permitted to raise [contract] claims directly against the government").

D. Plaintiffs have standing.

Plaintiff Local Governments are likely to succeed in establishing a substantial likelihood of standing. *Green v. U.S. Dep't of Justice,* 54 F.4th 738, 744 (D.C. Cir. 2022). Though all Plaintiffs have standing, Plaintiffs only need establish that one Plaintiff has standing with respect to each Defendant in order for each claim to proceed. *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 264 & n.9 (1977). Defendants dispute Plaintiffs' standing to challenge the Mass Termination Decision, asserting that their injury does not stem from that decision but, instead, from individual grants. Defs.' Br. at 20–21. Binding precedent says otherwise.

To establish Article III standing, a party must show that: (1) they have suffered an injury in fact, (2) the injury is fairly traceable to the challenged action of the defendant, and (3) it is likely that the injury will be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Here, the Mass Termination Decision caused Plaintiff Local Governments to suffer concrete, particularized, and actual and imminent harm, including layoffs of staff and termination of vital public health care programming. *See infra* pp. 19–21; *see also* Pls.' Br. at 34–40. These injuries are traceable to the Mass Termination Decision, without which Plaintiff Local Governments would still have funding to maintain their public health programs. Thus, an injunction against that decision would likely provide redress to Plaintiffs. *See Nat'l Wildlife Fed'n v. Hodel*, 839 F.2d 694, 705 (D.C. Cir. 1988) ("a party seeking judicial relief need not show to a certainty that a favorable decision will redress [its] injury").

AFSCME also has both associational and organizational standing. For associational standing, it must show that "(1) at least one of its members would have standing to sue in [the member's] own right; (2) the interest [it] seeks to protect is germane to its purpose; and (3) neither the claim asserted nor the relief requested requires the member to participate in the lawsuit."

Advocs. for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin., 41 F.4th 586, 592 (D.C. Cir. 2022). Defendants dispute the first and third prongs of this test.

As to the first prong, an organization need only set forth "specific facts . . . that one or more of [its] members would be directly affected." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (cleaned up). To do so, the organization may produce declarations from the affected member, *or* it may submit "declarations from leaders of organizations describing their organizations' membership in sufficient detail to support a finding of standing." *League of United Latin Am. Citizens v. Exec. Off. of the President*, No. CV 25-0946, 2025 WL 1187730, at *24 (D.D.C. Apr. 24, 2025) (collecting cases).

Plaintiffs have provided specific facts demonstrating that AFSCME's members are directly affected by the Mass Termination Decision. As a result of this decision, Heidi Heddings was transferred to a different job that is harder and more taxing, with a longer commute that has caused her to incur greater expenses. Heddings Decl., ¶¶ 12, 14. Eva Rose Hewitt lost her jobs two months early, and lost the opportunity to renew her employment, as a result of her employer's loss of funding. Hewitt Decl., ¶ 8. These are all injuries in fact. *See Nat'l Weather Serv. Emps. Org., Branch 1-18 v. Brown*, 18 F.3d 986, 989 (2d Cir. 1994) (union had standing on behalf of members who "would be forced to relocate or undergo long commutes").[5]

As to the third prong for associational standing, individual AFSCME members do not need to be joined. Defendants assert that each member must join this suit because it "require[s]

[5] Defendants also ignore the declarations of John Henry Jr. and Megan Peters-Wiseman, both of which specify that AFSCME members have been terminated because of the funding cuts. Peters-Wiseman Decl., ¶ 8; Henry Decl., ¶¶ 9, 10, 14. Defendants overread *Summers* to require individuals to submit declarations attesting to their own personal harm. But *Summers* requires no such thing: it rejected the notion that an organization could establish standing by "self-descri[bing] the activities of its members" and relying on "a statistical probability" (rather than a certainty) "that some of those members are threatened with concrete injury," 555 U.S. at 498, but did not reject the type of specific evidence set forth in the Henry and Peters-Wiseman declarations. These declarations demonstrate that AFSCME members have lost their jobs as a result of Defendants' funding cuts, and thus they have "sufficient detail to support a finding of standing." *League of United Latin Am. Citizens*, No. CV 25-0946, 2025 WL 1187730, at *24.

identification of the specific grants at issue with respect to AFSCME members," Defs.' Br. at 37, but this is a non sequitur. As a matter of law, "'individual participation' is not normally necessary when an association seeks prospective or injunctive relief for its members," as Plaintiffs do here. *United Food & Com. Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996).

AFSCME also has standing to sue on its own behalf through organizational standing. An organization has standing to challenge actions that "perceptibly impair[]" its ability to provide services, thereby "interfer[ing] with [its] core business activities." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 395 (2024). AFSCME has been required to divert significant resources away from its efforts to improve member workplace conditions to support members who have lost jobs because of the Mass Termination Decision. O'Brien Decl., ¶ 7. Unlike other advocacy organizations, AFSCME has a statutory duty to represent its members with respect to their terms and conditions of employment. *See, e.g.*, *Kollodge v. State,* 757 P.2d 1028, 1034 (Alaska 1988) ("A union has a duty to fairly represent its members"). This mandatory diversion of resources has impeded AFSCME's "core business activities" representing employees in affected bargaining units. *All. for Hippocratic Med.*, 602 U.S. at 395; *see also Equal Rights Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1140 (D.C. Cir. 2011). AFSCME has also suffered lost dues and diminished bargaining power from the Mass Termination Decision. Spiegel Decl., ¶ 14; Henry Decl., ¶ 14. These are also injuries in fact. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 345 (1977); *see also Am. Library Ass'n v. Sonderling*, No. CV 25-1050 (RJL), 2025 WL 1262054, at *2 (D.D.C. May 1, 2025) (AFSCME loss of bargaining power constitutes irreparable harm).

II. Plaintiffs are likely to succeed on the merits of their claims.

Plaintiffs have a strong likelihood of success on the merits. Although Plaintiffs bring six claims, they "need only show a likelihood of success on one [claim] to obtain preliminary relief, provided the other preliminary-injunction factors are satisfied." *ABA*, 2025 WL 1388891, at *4.

A. Plaintiffs are likely to succeed on the merits of their constitutional and equitable *ultra vires* claims.

Defendants' primary argument that Plaintiffs are unlikely to succeed on the merits of their constitutional claims is that Congress only required HHS to *obligate* the funds, not to follow through on those obligations. Defs.' Br. at 28, 32. That argument is absurd. Defendants have not provided any authority that supports this proposition. Their reading would upend the structure of Congressional appropriations, such that the Executive Branch could, at any time after earmarking Congressionally authorized funds on paper, withdraw or revoke those allocations without violating the statute. The obvious intention of Congress was for the grant recipients to receive these funds to use for particular purposes that Congress outlined. Courts should not lightly "conclude that Congress enacted a self-defeating statute." *Quarles v. United States*, 587 U.S. 645, 654 (2019); *see Colorado* PI Order at 46 (HHS's "decision to *allocate*, in some cases, more than it was statutorily required to does not alleviate HHS of its obligation to *expend* the appropriated funds pursuant to Congress's intent" (emphasis added)); *see also In re Aiken Cnty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013) (the Executive "does not have unilateral authority to refuse to *spend* the funds" appropriated by Congress) (emphasis added)). If Defendants' Mass Termination Decision stands, those obligations will not be liquidated via actual spending, and the Congressional directives embodied in the appropriations acts will never be fulfilled.[6]

Defendants also contend that the Mass Termination Decision does not run afoul of the Spending Clause because the HHS "for cause" regulation was "written into the grants at the time

[6] Some of the appropriations statutes at issue here imposed deadlines for Defendants to obligate the appropriated funds by 2024. *See, e.g.,* CARES Act, tit. VIII, Pub. L. No. 116-136, 134 Stat. 281, 554 (2020). Having done so, Defendants have five years to liquidate—that is, complete the expenditure—of the funds they have obligated. 31 U.S.C. §§ 1552(a), 1553(a). Defendants could not now re-obligate those funds for new purposes after the 2024 deadline has passed. In other words, if the Mass Termination Decision were permitted to stand, it would be impossible for Defendants to find another means for them to comply with the terms of the appropriations statutes, even if they wished to do so.

they were awarded" and therefore cannot be an unconstitutional retroactive condition. Defs.' Br. at 32. The relevant condition, however, is not the "for cause" regulation but the condition that Defendants' Mass Termination Decision imposed, namely, the condition that the grants would be terminated because Defendants had concluded that the COVID-19 "pandemic [was] over" and the grants "no longer necessary." Compl. ¶ 85. That condition was never specified and thus is plainly retroactive, as well as impermissibly ambiguous. Pls.' Br. at 21; Compl. ¶ 147.[7]

B. Plaintiffs are likely to succeed on their APA claims.

1. Defendants' Mass Termination is reviewable action.

The Mass Termination Decision is a "final agency action" under 5 U.S.C. § 704, because it (1) "marks the consummation of the agency's decision-making process"; and (2) is either an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 808 (2024) (cleaned up). As the Rhode Island district court just held in *Colorado*, the decision marks the culmination of HHS's decision to cut funding, and there are no other steps HHS must take in that regard. *Colorado* PI Order at 26. And, contrary to Defendants' argument, Defs.' Br. at 26, "there are clear legal consequences" from the Mass Termination Decision—grantees can no longer access previously available funds and consequently have been or will be forced to terminate employees, end infrastructure modernization efforts, and eliminate programs designed to prevent future

[7] Defendants raise two other points in their opposition. They contend that Plaintiffs have not shown that the Mass Termination Decision amounts to a "rescission" under the Congressional Budget and Impoundment Control Act of 1974. Defs.' Br. at 32 n.9. But Plaintiffs do not bring a claim under that statute. The fact that the Mass Termination Decision does not satisfy the Impoundment Control Act simply confirms that Congress did not authorize Defendants' action. Lastly, Defendants' suggestion that Plaintiffs' equitable *ultra vires* claim is wholly "predicated . . . upon" their constitutional claims is inaccurate. Defs.' Br. at 33. As the Supreme Court explained in *Larson*, 337 U.S. at 689, the actions of federal officers can be enjoined as *ultra vires* not only when they are unconstitutional but also when they are "beyond th[e] limitations" set by federal statute. Pls.' Br. at 22. In this case, the fact that Defendants acted without statutory authority supports both the constitutional and *ultra vires* claims.

pandemics, among other harms. *See, e.g.*, Heddings Decl., ¶¶ 12–14; Kiger Decl., ¶¶ 11–12; Johnson Decl., ¶ 19; Sharp Dec., ¶ 20; *see also Colorado* PI Order at 26.

Nor does this case involve a "programmatic" challenge. Although the Supreme Court has disavowed challenges that seek "wholesale improvement" of an entire agency program "by court decree," *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990), it has also recognized the availability of review for a "specific order or regulation, applying some particular measure across the board to all individual classification terminations and withdrawal revocations," *id.* at 890 n.2. Plaintiffs challenge a discrete agency action—the Mass Termination Decision that uniformly terminated CDC's pandemic preparedness grants—but do not seek otherwise to interfere with CDC's lawful discretion. Such a challenge is proper. *Am. Fed'n of Labor & Congress of Indus. Orgs. v. DOL*, No. CV 25-339 (JDB), 2025 WL 1129227, at *12 (D.D.C. Apr. 16, 2025).

2. Defendants' actions violate the APA because they are unconstitutional.

Because Defendants' actions violate the separation of powers principle as well as the Spending Clause of the Constitution, and were ultra vires, *see supra* pp. 12–13, they therefore also violate the APA. 5 U.S.C. § 706(2)(A)–(C). While Defendants have (unsuccessfully) argued that their actions were constitutional, they have not disputed that Plaintiffs' constitutional arguments can form the basis of an APA violation as well.

3. Defendants violated the APA because they lacked statutory authority for their actions.

As discussed above, Congress did not authorize the Mass Termination Decision, and for that reason, Defendants' actions violate the APA. An agency "literally has no power to act—including under its regulations—unless and until Congress authorizes it to do so by statute." *FEC v. Cruz*, 596 U.S. 289, 301 (2022) (cleaned up). Congress must "speak clearly" if it wishes to

charge an agency with a decision of "vast economic and political significance." *Ala. Ass'n of Realtors v. HHS,* 594 U.S. 758, 764 (2021) (cleaned up).

Moreover, Congress has made clear that HHS *did not* have the authority to terminate these grants once obligated. Congress specifically appropriated the funds for grantees' use during and beyond the COVID-19 pandemic. Congress expressly identified funds and programs in the COVID-19 appropriations laws that would no longer be available after the end of the public health emergency, and, after the public health emergency ended, it reviewed all of the COVID-19 appropriations laws, leaving in place all of the programs and funding at issue here. *See* Pls.' Br. at 13; Fiscal Responsibility Act, Pub. L. No. 118-5, 137 Stat. 10 (2023) Div. B., § 2(3). Defendants do not address Congress's overt decision to keep the funds in place. As the *Colorado* Court correctly determined, "Congress's express decision to eliminate some COVID-era public health funding, but leave alone the funding at issue here, signals its intent to continue that funding." *Colorado* PI Order at 33. The Mass Termination Decision "usurped Congress's power to control these public health appropriations," a power that Congress clearly did not delegate to HHS. *Id.*

4. Defendants' actions violate the APA because they are arbitrary and capricious.

Defendants further violated the APA by arbitrarily and capriciously terminating the grants in violation of HHS's own regulations and without reasoned explanation. In determining whether an agency's action is arbitrary and capricious, a court must be able to "ensure" that the agency has offered "a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (cleaned up). Defendants have not provided any evidence of such a satisfactory explanation, or any evidence of rational decision-making leading to the Mass Termination Decision.

First, Defendants failed to follow the relevant HHS regulation for termination. 45 C.F.R. § 75.372(a). It is axiomatic that "an agency is bound by its own regulations." *Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) (cleaned up); *Climate United Fund*, 2025 WL 1131412, at *16. Defendants cited no authority in the grant termination notices, but they now assert that they followed 45 C.F.R. § 75.372(a)(2), which permits termination of a federal grant "for cause." But the "cause" that defendants purportedly relied on for termination is not what HHS long understood "cause" to mean—noncompliance with terms and conditions. *See* Pls.' Br. at 25 (citing cases and regulations); *Colorado* PI Order at 37–38. Indeed, as Plaintiffs pointed out, Pls.' Br. at 25, the "for cause" provision itself is in a section entitled "Remedies for Noncompliance." 45 C.F.R. §§ 75.371-375.

Defendants do not engage with this historic interpretation but instead point to the current HHS Grants Policy Statement[8] to imply that "cause" could include "the best interests of the federal government." Defs.' Br. at 29–30. But this citation is inapt: it applies to decisions to approve funding for a new budget period (following a specified application and reporting process), not to terminate funds. HHS Grants Policy Statement at 21.[9] In fact, the Grants Policy Statement strongly reinforces that HHS equates "for cause" with "noncompliance." In the only section addressing terminations, entitled "Suspending Award Activities or Terminations," the HHS Grants Policy Statement states that "[t]he HHS awarding agency generally will suspend [and provide opportunity for corrective action], rather than immediately terminate, a federal award. . . . The HHS awarding agency may terminate without first suspending the federal award if the problem is serious enough

[8] Defendants attach the HHS Grants Policy Statement as Exhibit L to the Legier Declaration, but Plaintiffs have not been able to access that Exhibit via ECF. The latest version, effective April 16, 2025, is attached hereto as Exhibit B.

[9] "Recipients must submit a continuation application or annual report to get approval and funding for each new budget period within the approved period of performance. The HHS agency will make its decision to fund the next budget period by issuing a [Notice of Award] which shows the new budget period and amount of new funding. Funding is based on adequate performance, availability of funding, and the best interests of the federal government."

or if public health or welfare concerns require immediate action." *Id.* at 58–59; *see also id.* ("consistent with 45 CFR § 75.372(a)," an awarding agency or pass-through entity may suspend, pending corrective action, or terminate all or part of your award activities pending your corrective action if you fail to materially comply with the award terms and conditions." (emphasis added)).[10] Defendants' new interpretation of "cause" for purposes of this litigation thus reflects a textbook case of "'post hoc rationalization advanced by an agency seeking to defend past agency action against attack.'" *Colorado* PI Order at 37 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155–56 (2012)).

Second, Defendants now argue they adequately explained their changed policy through their minimal statement that the pandemic was over. But a "fundamental" requirement of administrative law is that an agency "set forth [ ] reasons" for its decision. *Tourus Recs., Inc. v. DEA*, 259 F.3d 731, 737 (D.C. Cir. 2001). An agency may not depart from a prior policy without providing "good reasons for the new policy" and showing "that the new policy is permissible under the statute." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). "It is not that further justification is demanded by the mere fact of policy change"—formal or informal, *cf.* Defs.' Br. at 30—"but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy," *Fox Television Stations*, 556 U.S. at 515. That same reasoned explanation is required here, where HHS's "sudden change in position that appropriations Congress determined were needed to fund public health initiatives beyond the pandemic were no longer necessary" reflects a "drastic change of course." *Colorado* PI Opinion

[10] In any event, as the General Terms and Conditions acknowledge, where the HHS Grants Policy Statement conflicts with "applicable statutes/appropriations acts . . . then statutes and regulation take precedence." ECF 21-11, Defs. Ex. J. As explained herein, those statutes and regulations provided no basis for HHS's determination. *See Colorado* PI Order at 43 (HHS's claim that the end of the pandemic was "cause" for termination is "contrary to statutory and regulatory authority and inconsistent with Congress's directive that the funds remain available beyond the pandemic.").

at 40–41. Defendants have provided no real reason at all for the Mass Termination Decision, other than now claiming that it is in the "best interest of the government." Defs.' Br. at 31. To the extent Defendants now try to recast their "for cause" terminations as ones based on agency priorities (without articulating what those priorities are), this too is an impermissible post hoc rationalization. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 49–50 (1983); *Massachusetts v. NIH*, 25-CV-10338, 2025 WL 702163, at *21 (D. Mass. Mar. 5, 2025).

Third, Defendants do not address the point that they ignored serious reliance interests when terminating these grants. *See* Pls.' Br. at 28–29. Instead, they argue that Plaintiffs' reliance interests are not "legitimate" or "serious" because HHS had awarded more than the amounts specifically earmarked for state and local governments by Congress. Defs.' Br. at 31. But once Defendants did so, Plaintiff Local Governments depended on these grants in hiring employees, executing subcontracts, obtaining certifications, developing community relationships, and procuring equipment. Pls.' Br. at 28–29*; see also infra* pp. 19–21. They acted in reasonable reliance on the expectation that Defendants would observe the terms of their appropriations statutes and devote the full range of appropriated funds to pandemic preparedness. As the *Colorado* Court found, and no evidence in this record disputes, "HHS gave no consideration to the programs and services that would be impacted by these terminations when it decided the funds were no longer necessary based on the end of the pandemic," *Colorado* PI Order at 41.

Finally, Defendants are wrong to argue that they were not required to consider "reasonable alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives," *Spirit Airlines, Inc. v. Dep't of Transp.*, 997 F.3d 1247, 1255 (D.C. Cir. 2021), because there was no "formal policy." An agency's failure to "consider significant alternatives to the course [it] ultimately cho[se]," is a telltale sign that its decision-making process cannot "be

regarded as rational." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000). Defendants do not even try to argue that they considered any alternatives, such as reviewing the grants at issue to see whether each had continued utility beyond the COVID-19 pandemic.

III. Plaintiffs will be irreparably harmed absent a preliminary injunction.

Despite Defendant's cursory assertions to the contrary, Defs.' Br. at 33–34, Plaintiffs have submitted copious evidence of non-speculative irreparable harm caused by the Mass Termination Decision. These harms are concrete and imminent: The decision will result in the termination of thousands of state and local public health employees across the country. *see* O'Brien Decl., ¶ 7; Spiegel Decl., ¶ 11; Johnson Decl., ¶ 17; Maddox Decl., ¶¶ 9–10, 15; Sharp Decl., ¶ 17.[11] Other employees have already been or will be transferred to inferior jobs. *See, e.g.*, Heddings Decl., ¶¶ 12–14. The Mass Termination Decision has already diminished Plaintiff Local Governments' ability to detect emerging diseases and outbreaks and develop public health interventions, or will shortly do so. *See*, *e.g.*, Kiger Decl., ¶¶ 11–12, 27; Johnson Decl., ¶ 19. And it has had or threatens to have significant impacts on efforts to vaccinate children and other vulnerable populations. *See* Kiger Decl., ¶ 18; Sharp Decl., ¶ 20. It has additionally stymied efforts to make public health infrastructure more robust. *See, e.g.*, Johnson Decl., ¶ 22; Jones Decl., ¶¶ 7–9.

On the whole, Plaintiff Local Governments relied on the federal funding at issue to support mission critical public health programming. The abrupt and illegal termination of these grant programs has damaged and will continue to damage the country's public health systems and

[11] Defendants cite *Sampson v. Murray*, 415 U.S. 61 (1974), for the proposition that loss of employment generally does not constitute irreparable injury. But AFSCME's members who are affected here are employees of state and local government, not federal employees who could pursue a remedy for damages or for back pay against the federal Defendants. Regardless, loss of employment is not the sole basis for Plaintiffs articulation of irreparable harm. Loss of funds have threatened *both* public health programs *and* the public health workforce, and together damage Plaintiff Local Governments' ability to protect the health of their residents. *See, e.g, ABA v. U.S. DOJ*, 2025 WL 1388891, at *8 (finding irreparable harm where layoffs or threat of layoffs will jeopardize movant's operations).

detrimentally impact public health employees across the country absent the issuance of a preliminary injunction. *See Colorado* PI Order at 49; *see also Sierra Club v. U.S. Dep't of Agric., Rural Utilities Serv.*, 841 F. Supp. 2d 349, 358 (D.D.C. 2012). Moreover, several of Plaintiffs' grants have performance periods that end in June of 2025. *See* Jones Decl., ¶ 8; Tong Decl., ¶ 6; Kiger Decl., ¶ 14. Plaintiffs had plans to expend the obligated funds by the end of their performance periods, Jones Decl., ¶ 8; Tong Decl., ¶ 6, but absent a preliminary injunction they will have no opportunity to finish out the planned programming. Without prompt relief, there might not be an effective remedy at the end of the judicial proceedings.

Here, too, Defendants attempt to recast Plaintiffs' claim as one for money damages, arguing that "economic loss does not, in and of itself, constitute irreparable harm." Defs.' Br. at 34. But, as already discussed, *supra* pp. 5–6, Plaintiffs seek prospective injunctive relief rather than redress for past wrongs. No later remedy can undo the threat that the Mass Termination Decision presently poses to public health and public health works; the damage will have already been done. *See Colorado* PI Order at 48. These programs are needed now to avoid "worsening public health outcomes and placing . . . residents at risk." *Id.* at 54.

Nor would money damages abate the reputational harm caused by the labeling of the terminations at issue as "for cause." Because "for cause" termination requires grantee noncompliance, *see supra* pp. 16–17, it can trigger federal and state reporting requirements. *See, e.g.*, 45 C.F.R. § 75.372(b) ("the HHS awarding agency must report the termination to the OMB-designated integrity and performance system"); Maddox Decl., ¶ 17; Thompson Decl., ¶ 15 (Plaintiff Nashville must certify to Tennessee that it has not had a public transaction terminated for cause in the past three years). This reporting can make Plaintiff Local Governments less competitive for future grant awards. Thus, the Mass Termination Decision also threatens Plaintiff

Local Governments' business reputation and future grant prospects, as well as those of grantees that employ AFSCME members. *See Climate United Fund*, 2025 WL 1131412, at *19 & n.4.

IV. The remaining preliminary injunction factors favor relief.

The balance of equities and the public interest both strongly weigh in Plaintiffs' favor. As discussed in connection with irreparable harm, because of the Mass Termination Decision, grantees nationwide do not have the means to keep vital public health programs running and will need to terminate or significantly downsize programs that benefit the public—including programs that are vital to prevent the spread of infectious diseases.

Defendants do not bother to refute this in their brief. Instead, they argue, without any supporting evidence, that if grantees draw down funds "throughout the litigation, Defendants will be left with no meaningful recourse even if they prevail." Defs.' Br. at 34. This is simply not the case. Defendants' own regulations allow them to make administrative offsets or to withhold payments in order to recoup any money a grantee owes the federal government. 45 C.F.R. § 75.391. But even if Defendants were to face minimal complications recouping funds, this would not outweigh the serious ongoing harm to public health that the Mass Termination Decision continues to cause. *See Colorado* PI Order at 55 ("Congress's direction that the funds remain intact and the [Plaintiffs'] reliance on the continuation of the funding overshadows" Defendants' arguments that they may struggle to recover grant funds if they prevail in litigation).

Defendants also suggest that they suffer harm in "forced expenditure of money in support of causes that are inconsistent with Executive Branch policy objectives." Defs.' Br. at 35. But Defendants do not "have unfettered power to further a President's agenda, particularly when Congress appropriated this money to [Plaintiffs] to fund their public health systems and initiatives." *Colorado* PI Order at 57. In fact, "'[g]overnment actions in contravention of the

Constitution are 'always contrary to the public interest.'"' *ABA*, 2025 WL 1388891, at *8 (quoting *Turner v. U.S. Agency for Glob. Media*, 502 F. Supp. 3d 333, 386 (D.D.C. 2020)). When weighing "an agency's unreasoned, unsubstantiated, and likely unlawful determination that funding was 'no longer necessary,' against the [Plaintiffs'] interest and reliance on the funds to safeguard their public health outcomes, the balance of the equities and public interest are undeniably in the [Plaintiffs'] favor." *Colorado* PI Order at 57. For these reasons, the remaining public interest factors strongly favor the grant of an injunction.

V. The requested scope of relief is warranted.

The Mass Termination Decision is nationwide in scope and is currently impairing critical public health measures on a national scale. The broad sweep of Defendants' unlawful action militates in favor of a correspondingly broad preliminary injunction. Pls.' Br. at 41–42; Proposed Order, ECF No. 14-17; *see Massachusetts*, 2025 WL 702163, at *35 ("the broad impact" of the agency's unlawful action "warrants a broad response").

"[I]n drafting equitable relief, courts must consider 'what is necessary, what is fair, and what is workable.'" *Woonasquatucket River*, 2025 WL 1116157, at *25 (quoting *North Carolina v. Covington*, 581 U.S. 486, 488 (2017)). Nationwide injunctive relief is "not only appropriate, but necessary" in various cases, including when "the plaintiffs are dispersed throughout the United States," when there is a "need to protect similarly situated nonparties," or when more limited relief would not be practicable. *Woonasquatucket River*, 2025 WL 1116157, at *25 (cleaned up) (citing *Florida v. HHS*, 19 F.4th 1271, 1281–82 (11th Cir. 2021)).

In this case, nationwide relief is needed to provide complete relief to AFSCME's members, who are employed by public health departments across the United States, O'Brien Decl., ¶¶ 4, 6, including by state employers who would not gain the benefit of an injunction running in favor only

of the Local Government Plaintiffs, *id.* ¶ 3.[12] *See Nat'l Educ. Ass'n v. U.S. Dep't of Educ.*, No. 25-CV-091-LM, 2025 WL 1188160, at *32 (D.N.H. Apr. 24, 2025) (enjoining implementation of agency decision against national union, its members, and employers of those members).

Nationwide relief is also essential to ensure that the Local Government Plaintiffs are completely protected from irreparable harm caused by the Mass Termination Decision. A preliminary injunction limited to Local Government Plaintiffs will not provide them with complete relief because public health measures are inherently interdependent: the effectiveness of Local Government Plaintiffs' *own* efforts to protect the health of *their own* residents depends on whether *other* state and local jurisdictions take similar action to protect *their* residents. Congress recognized the interconnected nature of these efforts when it directed the use of funds to support broad, nationwide public health efforts—not small-scale measures limited to a few individual localities. *E.g.*, CRRSAA, 2021, Pub. L. No. 116-260, 134 Stat. 1184 at 1911 (2021) (directing Defendants to use funds "to ensure *broad-based* distribution, access, and vaccine coverage" (emphasis added)); ARPA, Pub. L. No. 117-2, 135 Stat. 4 at 37–41 (2021) (directing Defendants to spend funds to "strengthen vaccine confidence *in the United States*" and to "improve rates of vaccination *throughout the United States*" (emphasis added)). Not only are Local Government Plaintiffs geographically dispersed, but the public health threats they face—especially ongoing threats posed by highly contagious diseases like the measles—do not respect county lines, city limits, or state borders. *See* Maddox Decl., ¶ 19. If the Mass Termination Decision is allowed to remain in effect anywhere, then, Local Government Plaintiffs will not obtain complete relief for their injuries. *See Florida*, 19 F.4th at 1281–82.

[12] Defendants profess ignorance as to which of the terminated grants would be covered by an injunction in favor of AFSCME. Defs.' Br. at 39. But Defendants themselves have published a list of CDC's terminated grants, *see* HHS Grants Terminated, https://perma.cc/8YYL-69JW, so this information is readily ascertainable.

A nationwide injunction is also the only administratively feasible way to ensure that all Plaintiffs obtain full and prompt preliminary relief. Because Defendants allocated a significant portion of the public health funding though pass-through grant programs, many of the grants of Local Government Plaintiffs and other employers of AFSCME members are administered by state entities rather than by Defendants. *See* Pls.' Br. at 9–11. These state entities are responsible for allocating and distributing federal funds to various grant recipients—a process with which Defendants are not involved. *See* Paul G. Dembling & Malcolm S. Mason, ESSENTIALS OF GRANT LAW PRACTICE § 4.12 (1991); Legier Decl., ¶ 6. Defendants' lack of involvement with the administration of pass-through grants will pose no difficulties if the Court issues a nationwide preliminary injunction: the grant programs will simply resume functioning in the same manner as before the Mass Termination Decision. But a party-specific injunction would leave the pass-through grant recipients subject to inconsistent obligations, as they would likely receive only a partial restoration of their funding, and it is uncertain whether those partial funds could be readily directed only to Local Government Plaintiffs.

Nationwide relief is further necessary to ensure that similarly situated nonparties do not suffer irreparable harm as a result of Defendants' unlawful actions. Plaintiffs are likely to succeed on the merits of their challenge to Defendants' sweeping Mass Termination Decision, and there is no reason "why similarly situated nonparties should remain subject to" the Mass Termination Decision and be "forced to suffer the harms just because there was not enough time or resources for them to join th[is] suit" or file their own. *Woonasquatucket River*, 2025 WL 1116157, at *25; *accord Massachusetts*, 2025 WL 702163, at *33.

Finally, "the nature of th[is] action itself supports a nationwide injunction." *Woonasquatucket River*, 2025 WL 1116157, at *25. When a court determines that an agency has

acted unlawfully, the "ordinary result" is that the unlawful actions "are vacated—not that their application to the individual petitioners is proscribed." *Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (cleaned up); *see also* 5 U.S.C. § 706(2).

VI. The Court should neither require a bond nor stay its decision pending appeal.

The Court should not require a bond. This Court has the discretion to not require any bond at all. *P.J.E.S. ex rel. Escobar Francisco v. Wolf*, 502 F. Supp. 3d 492, 520 (D.D.C. 2020). It should exercise that discretion here, where Defendants are unlawfully withholding "previously committed funds," "will personally face no monetary injury from the injunction," and a bond would merely "hold Plaintiffs hostage" for the harm from the Government's unlawful actions. *Nat'l Council of Nonprofits v. OMB*, 2025 WL 597959, at *19 (D.D.C. Feb. 25, 2025). Plaintiffs seek a preliminary injunction to remedy the irreparable harm that they would otherwise suffer from the immediate loss of their grant funding. If Plaintiffs were required to pay back the same funding in the form of a bond, they would gain no relief at all. In these circumstances, the imposition of a bond would be tantamount to a denial of a preliminary injunction, effectively denying Plaintiffs their "right to judicial review of administrative action." *Nat. Res. Def. Council, Inc. v. Morton*, 337 F. Supp. 167, 168 (D.D.C. 1971) (collecting cases).

Nor should the Court stay its decision pending appeal. There is no basis—and Defendants cite none—to issue a preemptive stay of the Court's order in this case. Any such order would be issued only after finding that Plaintiffs suffer irreparable harm, negating the utility of a stay.

CONCLUSION

For these reasons and those detailed in their opening brief, Plaintiffs respectfully request a preliminary injunction.

Dated: May 19, 2025

Respectfully submitted,

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

STATE OF COLORADO; STATE OF RHODE ISLAND; STATE OF CALIFORNIA; STATE OF MINNESOTA; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF CONNECTICUT; STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF ILLINOIS; OFFICE OF THE GOVERNOR *EX REL.* ANDY BESHEAR, in his official capacity as Governor of the Commonwealth of Kentucky; STATE OF MAINE; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OREGON; STATE OF WISCONSIN; JOSH SHAPIRO, in his official capacity as Governor of the Commonwealth of Pennsylvania, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services, Defendants.	C.A. No. 1:25-cv-00121-MSM-LDA

MEMORANDUM AND ORDER

Mary S. McElroy, United States District Judge.

Bracing for the financial impact of an unprecedented public health crisis, Congress appropriated billions of dollars in spending across six appropriation acts starting in March 2020. The U.S. Department of Health and Human Services ("HHS") administered that money to all fifty States through grant programs aimed at responding to the ongoing health crisis. After the pandemic's official end in 2023, Congress reviewed its COVID-era spending and rescinded some appropriations it no longer saw as necessary, and left others in place. Since then, HHS has continued to administer the funding without issue.

On March 24, 2025, HHS suddenly terminated $11 billion of the public health grants appropriated by Congress to fund certain health programs and services, effective immediately ("Public Health Funding Decision). HHS began sending mass termination notices which contained the same boilerplate explanation that "[t]he end of the pandemic provides cause to terminate COVID-related grants. Now that the pandemic is over, the grants are no longer necessary." (ECF No. 4-40 Ex. A at 5.) Though Congress appropriated the funds during the pandemic, they did much more than address COVID-related public health concerns.

The terminations impact a wide range of the States' public health programs and services. The terminated funds addressed infectious disease outbreaks, including rising threats like measles and H5N1 (avian influenza). They ensured access to immunizations among vulnerable populations. They fortified emergency

preparedness for future public health threats. They provided mental health and substance abuse services. And they modernized critical public health infrastructure. Without the funds, these programs could not continue.

Challenging the Government's failure to comply with statutory and regulatory processes and fundamental Separation of Powers principles, a coalition of twenty-three States and the District of Columbia (the "States") sued in the District of Rhode Island.[1] The States now move for a preliminary injunction—a temporary court order requiring HHS to reinstate the funds, at least while their case is pending.

For the reasons discussed below, the Court GRANTS the States' Motion for a Preliminary Injunction (ECF No. 60). The Court DENIES the Defendants' Motion for Reconsideration and Request to Vacate the Temporary Restraining Order and Motion for a Stay Pending Appeal (ECF No. 56).

I. BACKGROUND

The Court begins with a preliminary statement of facts.

A. Congress's Appropriation of Public Health Funding

In March 2020, the world came to a screeching halt because of COVID-19. It sparked lockdowns across the globe, forced schools and businesses to shut their doors indefinitely, and quickly overwhelmed hospitals and healthcare providers.

[1] For ease of reading, the Court refers to the Defendants collectively as either "HHS" or "the Government." The Court refers to the Plaintiff-States collectively as "the States."

In response, Congress passed six appropriation acts to help people and businesses cope with the financial impact caused by the crisis. Congress enacted the laws to outline a path toward recovery, but also to better prepare the country for future public health threats. (ECF No. 60 at 3–4.) The funding was designed to strengthen healthcare outcomes and address gaps in the country's health system that were highlighted by the pandemic. *Id.*

Through these appropriations, Congress allocated large sums of money to HHS. HHS, in turn, was to distribute the money to the States by allocating certain amounts of the appropriated money to the Center for Disease Control ("CDC") and the Substance Abuse and Mental Health Services Administration ("SAMHSA"). (ECF No. 68 at 3-4.) As sub-agencies of HHS, both CDC and SAMHSA were responsible for allocating money to the States; they did so expeditiously through a variety of grant programs aimed at responding to the ongoing health crisis. *Id.* CDC and SAMHSA would either add the funds to existing awards to get the money to the States quickly or provide new grants to ensure the States could adequately respond to the pandemic. *Id.* at 4. The funds were largely used by the States, but in some cases, the agencies allowed for no-cost extensions of the grant awards if the funds could not be readily or timely used by the recipients. *Id.* As for CDC, some of the appropriations statutes direct a minimum amount of funding to be provided to state, tribal, local, and territorial entities, commonly referred to by HHS as "STLTs." (ECF No. 80-1 ¶ 7.)

Congress provided funds through six appropriation acts:

- Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, ("CPRSA") Pub. L. No. 116-123, 134 Stat. 146 (2020) ($8 billion);
- Families First Coronavirus Response Act, ("FFCRA") Pub. L. No. 116–127, 134 Stat. 178 (2020) ($15 billion);
- The Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020) ($2.1 trillion);
- The Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020) ($483 billion);
- The Coronavirus Response and Relief Supplemental Appropriations Act, (2021) Pub. L. No. 116-260, 134 Stat. 1182 (2020) ($900 billion); and
- The American Rescue Plan Act of 2021, Pub. L. No. 117-2, 135 Stat. 4 (2021) ($1.9 trillion).

Below, the Court describes with greater specificity what each act accomplished.

First, Congress passed CPRSA on March 6, 2020. Pub. L. No. 116-123, 134 Stat. 146 (2020). Title III of CPRSA specifically outlines the amount of money and purpose of the money being allocated to the CDC through HHS. *Id.* at 147–48. Congress specifically allocated $2,200,000,000 for "CDC-Wide Activities and Program Support" and further broke down that number into smaller allocations. For example, it required $950,000,000 be provided "for grants to or cooperative agreements with [STLTs] to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities[.]" *Id.* at 147.

Following the CPRSA, Congress passed the FFCRA on March 18, 2020. Pub. L. No. 116–127, 134 Stat. 178 (2020). FFCRA did not allocate any appropriations directly to CDC or SAMHSA; instead, the only allocations were $1,000,000,000, to

HHS, for the Public Health and Social Services Emergency Fund, "to remain available until expended." *Id.* at 182. It also gave $250,000,000 to HHS for Aging and Disability Services Programs. *Id.*

Next, Congress passed the CARES Act, which provided financial assistance to individuals, businesses, and local governments. CARES Act, Title VIII, 134 Stat. 281, 554–55 (2020). The Act includes provisions for direct payments to individuals, expanded unemployment benefits, and support for small businesses. *Id.* Additionally, it established the Coronavirus Relief Fund, which allocated $150,000,000,000 to help state and local governments manage the pandemic's impact. *Id.* at 554. The 2020 Supplemental Act further appropriated $950,000,000. 2020 Supplemental Act, Title III, 134 Stat. at 147. Together, these funds were for HHS to administer grant-in-aid programs with States and local jurisdictions to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. Specifically, Congress appropriated $4,300,000,000 to CDC, of which $1,500,000,000 was appropriated for awards to STLTs, to remain available until September 30, 2024.[2] 134 Stat. 281 at 554. As of April 14, 2025, CDC made available $2,108,388,501 to the STLTs, and the STLTs spent $1,812,715,188 of the awarded CARES Act funds. (ECF No. 80-1 ¶ 10.)

[2] Pursuant to 31 U.S.C. §§ 1552(a), 1553(a), the States have until the fifth fiscal year after the period of availability for obligation to spend the funds.

Next, on April 24, 2020, Congress passed the Paycheck Protection Program and Health Care Enhancement Act ("PPP"), Pub. L. No. 116-139, 134 Stat. 620 (2020). Through the PPP, Congress appropriated $11,000,000,000 to HHS for STLTs in total. (ECF No. 80-1 ¶ 11.) Congress specified that $750,000,000 be appropriated for the Indian Health Service, resulting in $10,250,000,000 billion appropriated for non-Indian Health Service STLTs. *Id.* HHS also transferred another $282,311,516 to CDC, and Congress separately appropriated another $1,000,000,000 directly to CDC under the PPP. *Id.* As of April 14, 2025, CDC made available $11,652,785,823 to the STLTs, and the STLTs spent $10,029,206,313 of the awarded PPP funds. *Id.*

With the Coronavirus Response and Relief Supplemental Appropriations Act ("CRRSAA"), Congress appropriated $8,750,000,000 to CDC, of which $4,290,000,000 was specifically appropriated for awards to STLTs, to remain available until September 30, 2024. Pub. L. No. 116-260, 134 Stat. 1182, 1911 (2021). As of April 14, 2025, $5,426,073,054 was made available to the STLTs from CRRSAA funds, and the STLTs spent $3,811,438,554 of the awarded CRRSAA funds. (ECF No. 80-1 ¶ 12.) Congress appropriated $1,650,000,000 for the Substance Abuse Prevention and Treatment Block Grant and $1,650,000,000 for the Community Mental Health Services Block Grant. 134 Stat. 1182 at 1913. The CRRSAA directed that SAMHSA award no less than 50 percent of the CMHS Block Grant appropriation to community mental health centers. *Id.*

Lastly, through the American Rescue Plan Act of 2021 ("ARPA"), Congress appropriated $1,000,000,000 to the CDC. Pub. L. No. 117-2, 135 Stat. 4, 38 (2021).

CDC received another $17,964,597,077 from HHS and CMS under ARPA. *Id.* As of April 14, 2025, $18,964,597,077 was made available to the STLTs, and the STLTs had spent $12,241,082,518 of the awarded ARPA funds. (ECF No. 80-1 ¶ 13.) As of April 14, 2025, HHS records show $6,723,514,559 of unspent ARPA funds that had been awarded to STLTs. *Id.* Congress appropriated $1,500,000,000 for the Substance Abuse Prevention and Treatment Block Grant and $1,500,000,000 for the Community Mental Health Services Block Grant. 135 Stat. 4 at 45–46.

B. Congress's June 2023 Review of COVID-Era Funding Laws

Around a month after health officials declared that the pandemic was over, Congress undertook a review of its COVID-era spending, rescinding some appropriations and indicating others were to remain available. In June 2023, Congress passed the Fiscal Responsibility of Act of 2023, which canceled $27,000,000,000 in appropriations that were no longer necessary due to the end of the public health emergency. Pub. L. 118–5, Div. B, Sec. 1-81 (June 3, 2023). The rescissions included funds that had been appropriated under the laws at issue here, the 2020 Supplemental Act, Pub. L. No. 116-123, the Families First Coronavirus Response Act, Pub. L. No. 116-127, the CARES Act, Pub. L. No. 116-136, the Paycheck Protection Act, Pub. L. No. 116-139, the 2021 Supplemental Act, Pub. L. No. 116-260, and ARPA, Pub. L. No. 117-2. *Id.* In undergoing its June 2023 review, Congress clarified that certain funds were unnecessary, while others were to remain intact, such as the funding impacted by HHS' 2025 Public Health Funding Decision.

C. HHS' Administration of Funds

As Congress was busy handling appropriations during and after the pandemic, HHS worked diligently with the States. The money, which remained after congressional review, was funding various public health programs and services including treatment to those struggling with substance abuse and mental health issues, improvements to infectious disease tracking and response capability, and efforts to modernize the States' and their local jurisdictions' public health infrastructure. *See* ECF Nos. 4-13 ¶ 10; 4-6 ¶¶ 40–50; 4-27 ¶ 18. HHS even granted extensions to the States to draw down the funds, in some cases through June 2027, and issued guidance on how to appropriately use the funds beyond COVID-related concerns. *See* ECF Nos. 4-3 ¶¶ 10, 13, 21–22, 48; 4-24 ¶¶ 11, 22; 4-32 ¶ 19.

D. The Public Health Terminations

All that changed on March 24, 2025. Starting that day, the States' local health agencies began receiving termination notices from HHS, CDC, and SAMHSA revealing that their funding was cut ("Public Health Terminations"). (ECF No. 60-1 at 12).

According to the States, HHS' termination notices, distributed across various local programs and agencies, include the same basic components. *See e.g.*, ECF No. 4-40 at 16, 22, 28, 33, 38; ECF No. 4-41 at 52, 54; ECF No. 4-27 at 82, 95, 107, 125. The notices were issued on March 24 and 25 and provided no advanced notice to recipients. *See id.* The recipients were advised that the funding was terminated "for cause" and HHS referred to the end of the COVID-19 pandemic as the reason. *See*

id. Rather than explaining why the grantee had failed to comply with the terms and conditions or what for cause meant, the notices simply explained that the "end of the pandemic provides cause" to terminate the funds. (ECF No. 4-27 at 125.) Finally, the terminations were effective immediately, giving recipients no warning that they stand to lose the money.

Separately, CDC began sending termination notices that stated the following:

> The termination of this award is for cause. HHS regulations permit termination if "the non-Federal entity fails to comply with the terms and conditions of the award", or separately, "for cause." The end of the pandemic provides cause to terminate COVID-related grants and cooperative agreements. These grants and cooperative agreements were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grants and cooperative agreements are no longer necessary as their limited purpose has run out. Termination of [this award] is effective as of the date set out in your Notice of Award.[3]

(ECF No. 4-40, Ex. A at 5.) Aside from this language, the notices executed by CDC did not provide any additional explanation to the recipients. (ECF No. 4-7 ¶ 59; 4-15 ¶ 15.) Prior to the termination, CDC did not notify the States that the grants were being administered in an unsatisfactory manner. *See, e.g.*, ECF No. 4-3 ¶¶ 19, 45; 4-7 ¶¶ 31, 43; 4-8 ¶ 18; 4-10 ¶ 36.

Although the CDC notices cited the end of the COVID-19 pandemic as cause for termination, many of the programs impacted by the Public Health Funding Decision were in place to advance health outcomes beyond the COVID-19 pandemic.

[3] The States note that while the terminations sent to their local programs and agencies do have minor, non-substantive variations, the gist of the language was the same. (ECF No. 60 at 10 n.2.)

These included funds to research labs investigating a listeria outbreak across multiple states (ECF No. 4-21 ¶ 27) and those preparing for future infectious disease threats such as avian influenza. (ECF No. 4-4 ¶¶ 7, 20; 4-7 ¶ 46; 4-8 ¶¶ 37, 43, 54; 4-24 ¶ 45.) And at times, CDC itself had extended the grants beyond the pandemic intentionally. *See, e.g.*, ECF No. 4-24 ¶¶ 11, 22; ECF No. 4-32 ¶ 19.

Similarly, SAMHSA implemented HHS' Public Health Funding Decision via notices that terminated block grants to the States and were effective immediately on March 24. (ECF Nos. 4-6 ¶ 11; 4-41 at 52.) The basis for the terminations was the same as the CDC notices—the end of the pandemic—and similarly, did not provide the recipients advanced notice or an opportunity for a hearing. *See id.* A few days later, SAMHSA issued superseding notices to recipients which stated:

> The termination of this award is for cause. The block grant provisions at 42 U.S.C. § 300x-55 permit termination if the state "has materially failed to comply with the agreements or other conditions required for the receipt of a grant under the program involved." The end of the pandemic provides cause to terminate COVID-related grants and cooperative agreements. These grants and cooperative agreements were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grants and cooperative agreements are no longer necessary as their limited purpose has run out.

(ECF No. 4-6 ¶ 12; ECF No. 4-41 Ex. D at 1.) Besides this explanation, the SAMHSA notices did not provide any additional detail. *See id.* Like the CDC terminations, SAMHSA did not notify the States that they were failing to administer the grants appropriately. And despite the rationale being the end of the pandemic, the terminated SAMHSA funding supported mental health and substance abuse treatment efforts far beyond pandemic-related care. For instance, the States were

using the funds to strengthen the 988 Suicide and Crisis Lifeline system; make Naloxone more widely available to prevent fatal overdoses; expand access to mental health treatment among rural communities; serve foster youth with mental health and substance related needs; provide crisis intervention training to law enforcement officials and first responders; and to train crisis counselors to serve those impacted by natural disasters. *See, e.g.*, ECF Nos. 4-6 ¶¶ 40, 41, 50; 4-26 ¶ 14; 4-28 ¶ 5; 4-41 ¶ 33.

E. This Case

On April 1, 2025, twenty-three States and the District of Columbia sued for declaratory and injunctive relief against HHS and Secretary Kennedy, initially that the terminations violate the Administrative Procedure Act ("APA"), 5 U.S.C. § 701. (ECF No. 1 ¶¶ 3.) The States simultaneously moved for a temporary restraining order ("TRO") to restrain HHS "from enforcing or implementing the public health terminations for Plaintiff States and their local health jurisdictions." (ECF No. 4 at 3.)

On April 3, the Court heard the parties on the TRO and, at the hearing's conclusion granted it.[4] A written order detailing the Court's reasoning soon followed. The Court found that "the States have established a strong likelihood of success on

[4] At the TRO hearing, the Court heard from the States and HHS, though counsel for HHS did not make any substantive arguments, instead objecting to the issuance of the TRO and requesting that the Court to impose a bond. The Court granted the TRO and asked the States to prepare a proposed order and to confer with the Defendants as to any objections. The parties promptly complied and submitted a proposed TRO on April 4.

the merits, irreparable harm, and that the balance of equities and public interest favor the States." (ECF No. 54 at 13.) The TRO made clear that the Government was "fully restrained from implementing or enforcing funding terminations that were issued to Plaintiff States . . . or from issuing new funding terminations to Plaintiff States." *Id.* at 14.

Meanwhile, on April 4, the Supreme Court granted an emergency stay application in *Department of Education v. California*, 145 S. Ct. 966 (2025) (per curiam). That case concerned a district court's TRO enjoining the Government from terminating two education-related grant programs. HHS quickly moved for reconsideration of the TRO, arguing that *California* divested this Court of jurisdiction. (ECF No. 56 at 2-3.)[5]

On April 8, the States filed an Amended Complaint, which asserted several additional constitutional claims, and a Motion for a Preliminary Injunction. (ECF Nos. 59, 60.) The States insist that this Court has jurisdiction over their claims, despite the Supreme Court's recent decision in *California*. *Id.* at 22. They also claim that they have established a likelihood of success on the merits because the Public Health Funding Decision was contrary to law, arbitrary and capricious, and violates the Separation of Powers. *Id.* at 2-3. Furthermore, the States submit that absent a preliminary injunction, they stand to suffer immediate, irreparable harm to their

[5] After hearing the parties' arguments during the preliminary injunction hearing, the Court determined that it would address the Defendants' Motion for Reconsideration along with the States' Motion for Preliminary Injunction.

local public health programs, services, and initiatives. *Id.* at 3. Lastly, the States claim that the public interest and balance of the equities strongly favor a preliminary injunction in their favor. *Id.* A preliminary injunction hearing was held on April 17.[6]

II. PRELIMINARY INJUNCTION STANDARD

"A request for a preliminary injunction is a request for extraordinary relief." *Cushing v. Packard*, 30 F.4th 27, 35 (1st Cir. 2022). "To secure a preliminary injunction, a plaintiff must show '(1) a substantial likelihood of success on the merits, (2) a significant risk of irreparable harm if the injunction is withheld, (3) a favorable balance of hardships, and (4) a fit (or lack of friction) between the injunction and the public interest.'" *NuVasive, Inc. v. Day*, 954 F.3d 439, 443 (1st Cir. 2020) (cleaned up). In evaluating whether the plaintiffs have met the most important requirement of likelihood of success on the merits, a court must keep in mind that the merits need not be "conclusively" determined; instead, at this stage, decisions "are to be understood as statements of probable outcomes only." *Akebia Therapeutics, Inc. v. Azar*, 976 F.3d 86, 93 (1st Cir. 2020) (cleaned up). "To demonstrate likelihood of success on the merits, plaintiffs must show more than mere possibility of success–rather, they must establish a strong likelihood that they will ultimately prevail."

[6] Because the Government did not brief the States' constitutional claims in its original briefing—due to the States' amended complaint amid a tight briefing schedule—the Court granted it leave to file additional briefing for the Court's benefit. It did so on April 24, and the States responded on April 29. *See* ECF No. 80, ECF No. 81.

Sindicato Puertorriqueño de Trabajadores, SEIU Loc. 1996 v. Fortuño, 699 F.3d 1, 10 (1st Cir. 2012) (per curiam) (cleaned up).

III. DISCUSSION

A. Jurisdiction

Before addressing the merits, the Court must assure itself of jurisdiction. The Government does not dispute in its papers that the States have established Article III standing to challenge the Public Health Funding Decision. *See* ECF No. 68, ECF No. 80. The Court is satisfied that the States have demonstrated standing to challenge HHS' actions. *See Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024).

To start, HHS argues that the Court of Federal Claims has exclusive jurisdiction here because the States' claims are essentially contract actions that fall under the Tucker Act, rather than claims for equitable relief brought under the APA. (ECF No. 68 at 9, 14.) Challenging HHS' actions as contrary to regulatory, statutory, and constitutional law, and asking purely for prospective equitable relief, the States maintain that their claims are properly before the Court. (ECF No. 60 at 21.)

Congress has waived the United States' sovereign immunity and permitted judicial review under the APA in suits challenging agency actions that seek "relief other than money damages." 5 U.S.C. § 702. So when a plaintiff sues the federal government for breach of contract—an action seeking money damages—that claim "falls outside of § 702's waiver of sovereign immunity." *Dep't of Army v. Blue Fox, Inc.*, 525 U.S. 255, 263 (1999). Instead, the Tucker Act "confers jurisdiction upon the

Court of Federal Claims" for contract claims against the United States. *Fisher v. United States*, 402 F.3d 1167, 1172 (Fed. Cir. 2005). It vests jurisdiction there for "any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1); *see Maine Cmty. Health Options v. United States*, 590 U.S. 296, 327 (2020). And in suits seeking more than $10,000 in damages, the Court of Federal Claims' jurisdiction is exclusive of the federal district courts. *See, e.g.*, *Burgos v. Milton*, 709 F.2d 1, 3 (1st Cir. 1983).

The "jurisdictional boundary" between the Tucker Act and the APA is well-traversed by litigants seeking relief against the federal government. *Suburban Mortg. Assocs., Inc. v. U.S. Dep't of Hous. & Urb. Dev.*, 480 F.3d 1116, 1117 (Fed. Cir. 2007). But the boundary's precise contours remain elusive. *See id.* at 1124 (listing cases treading the jurisdictional line); *Bublitz v. Brownlee*, 309 F. Supp. 2d 1, 6 (D.D.C. 2004) (noting that "[t]he bright-line rule" between monetary and equitable relief in the Tucker Act–APA context "turns out to be rather dim . . . ."). Plaintiffs at times try to "avoid Tucker Act jurisdiction by converting complaints which at their essence seek money damages from the government into complaints requesting injunctive relief or declaratory actions." *Martin v. Donley*, 886 F. Supp. 2d 1, 8 (D.D.C. 2012) (cleaned up).

But not every "failure to perform an obligation" by the federal government "creates a right to monetary relief" only under the Tucker Act. *United States v.*

Bormes, 568 U.S. 6, 16 (2012). Just because "a judicial remedy may require one party to pay money to another is not a sufficient reason to characterize the relief as 'money damages.'" *Bowen v. Massachusetts*, 487 U.S. 879, 893 (1988). The Supreme Court has "long recognized the distinction between an action at law for damages—which are intended to provide a victim with monetary compensation for an injury to his person, property, or reputation—and an equitable action for specific relief." *Id.* (explaining that "insofar as the complaints sought declaratory and injunctive relief, they were certainly not actions for money damages"). And "although the Tucker Act is not expressly limited to claims for money damages, it has long been construed as authorizing *only actions for money judgments* and not suits for equitable relief." *Id.* at 914 (Scalia, J., dissenting) (cleaned up) (emphasis added).

All that is to say: "when traversing the Tucker Act–APA jurisdictional boundary, courts must look beyond the form of the pleadings to the substance of the claim to determine whether the essence of the action is in contract." *Woonasquatucket River Watershed Council v. U.S. Dep't of Agric.*, No. 1:25-CV-00097-MSM-PAS, 2025 WL 1116157, at *12 (D.R.I. Apr. 15, 2025). And the "essence" of an action encompasses two components: the "source of the rights upon which the plaintiff bases its claim" and "the type of relief sought (or appropriate)." *Piñeiro v. United States*, No. 08-CV-2402, 2010 WL 11545698, at *5 (D.P.R. Jan. 26, 2010) (cleaned up).

The Court addresses the elements of this framework in turn below.[7]

1. Source of the Rights

First, the Court considers the source of the States' rights. After examining the Complaint, the Court finds that, like in *Woonasquatucket* and *Massachusetts v. NIH*, the "gravamen" of the States' allegations "does not turn on terms of a contract between the parties; it turns" largely "on federal statutes and regulations put in place by Congress" and HHS. *Woonasquatucket*, 2025 WL 1116157, at *13; *Massachusetts v. NIH*, 2025 WL 702163, at *6 (D. Mass. Mar. 5. 2025.). And this case is even clearer than either *Woonasquatucket* or *Massachusetts* because the States also assert constitutional claims alongside its APA claims.

To be more precise: the source of the States' claims do not arise in any contract, but the APA—particularly its provisions forbidding arbitrary and capricious action, action contrary to law, and action in excess of statutory authority and the Constitution's Spending Clause and underlying separation of powers principles.[8] These are precisely the type of claims that belong in district court. *See, e.g.*, *K-Mar*

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[7] While the First Circuit has not formally adopted the "rights and remedies" test that several other circuits have, district courts within it have used the test to determine whether the "essence" of an action is truly contractual. *See Woonasquatucket*, 2025 WL 1116175, at *12–15; *Massachusetts v. NIH*, No. 25-CV-10338, 2025 WL 702163, at *4–*8 (D. Mass. Mar. 5, 2025); *R.I. Hous. & Mortg. Fin. Corp.*, 618 F. Supp. 2d at 138; *Piñeiro*, 2010 WL 11545698, at *5.

[8] HHS goes on at length about the States' attempts to avoid jurisdiction by amending their complaint. (ECF No. 68 at 14–18.) But the States' motivation for exercising their right under the Federal Rules of Civil Procedure to amend is none of the Court's concern. Fed. R. Civ. P. 15 (a)(1). Before the Court are claims arising from violations of regulations, statutes, and the Constitution.

Indus., Inc. v. U.S. Dep't of Def., 752 F. Supp. 2d 1207, 1214 (W.D. Okla. 2010) ("The source of the rights alleged in this action is not contractual, it is the procedures put in place by the defendants.") To illustrate the point: throughout their briefing, the States have not pointed the Court to specific terms and conditions in their grant agreements. Instead, the States challenge the process HHS undertook in implementing the Public Health Funding Decision based on HHS' alleged violations of federal law. Ultimately, this case concerns the process the Government undertook when terminating the funding based on the end of the pandemic, meaning that the States have not put the specific terms and conditions of their agreements at issue.

To be clear, the fact that there are underlying contractual relationships between the States and HHS does not automatically "convert a claim asserting rights based on federal regulations into one which is, at its essence, a contract claim." *Normandy Apartments, Ltd. v. U.S. Dep't of Hous. & Urb. Dev.*, 554 F.3d 1290, 1299 (10th Cir. 2009) (cleaned up). As in *Massachusetts* and *Woonasquatucket*, the States "have not requested the Court to examine any contract or grant agreement created between the parties." *Massachusetts*, 2025 WL 702163, at *6; *Woonasquatucket*, 2025 WL 1116157, at *13. Instead, they "have asked this Court to review and interpret the governing federal statute and regulations." *Id.*

2. Type of Relief Sought

Having recognized that the source of the States' rights is based on federal law rather than on contract, the Court now turns to the relief sought. There is a "distinction between an action at law for damages," which provides monetary

compensation, and "an equitable action for specific relief," which might still require monetary relief. *Bowen*, 487 U.S. at 893; *see Great-W. Life & Annuity Ins. v. Knudson*, 534 U.S. 204, 213 (2002) ("Whether [restitution] is legal or equitable depends on the basis for [the plaintiff's] claim and the nature of the underlying remedies sought.") (cleaned up).

Simply because "a judicial remedy may require one party to pay money to another" does not necessarily "characterize the relief as money damages." *Bowen*, 487 U.S. at 893. A hallmark of such equitable actions is the existence of prospective relief in ongoing relationships. *Compare Bowen*, 487 U.S. at 905 (holding that the district court had jurisdiction because declaratory or injunctive relief was appropriate to clarify petitioner state's ongoing obligations under the Medicaid plan), *with Me. Cmty. Health Options v. United States*, 590 U.S. 296, 298 (2020) (holding that petitioners properly relied on the Tucker Act to sue for damages in the Court of Federal Claims because plaintiffs were strictly concerned with "specific sums already calculated, past due, and designed to compensate for completed labors").

The States dispel HHS' attempts to categorize their relief sought as "money damages," which would fall outside the APA's waiver of sovereign immunity under § 702, by highlighting that they have asked the Court for purely prospective, equitable relief. (ECF No. 60 at 22—23.) Rather than seeking compensation for past harm, the States ask the Court to enjoin HHS' likely unlawful termination of promised public health funding. Merely because their requested equitable relief would result in the

disbursement of money is not a sufficient reason to characterize the relief as money damages. *Bowen*, 487 U.S. at 893.

The Government's efforts to categorize the States' relief as money damages are to no avail when they have asked for a specific equitable remedy—an injunction to halt an agency's likely unlawful termination of critical public health funding. The States have asked this Court to vacate the unlawful terminations of grant money under the APA to access federal funds that were already appropriated. When a consequence of "a judicial remedy may require one party to pay money to another," it does not necessarily "characterize the relief as money damages." *Bowen*, 487 U.S. at 893. Absent equitable relief, the States stand to suffer devastating consequences to their public health systems and initiatives. It is clear that the States' primary purpose in bringing their claims is to secure an injunction, and not money damages arising out of a breach of contract claim.

The Court finds that this case does not concern contractual obligations or money damages for past harm. Rather, the States ask for a review of an agency's alleged unlawful action and seek prospective relief based on their ongoing relationship with the federal government to prevent harm to their local health jurisdictions.

3. *Department of Education v. California*

HHS argues that the U.S. Supreme Court's recent stay order in *Department of Education v. California*, 145 S. Ct. 996 (Apr. 4, 2025), makes its Tucker Act argument even clearer. The Court disagrees. True, the Supreme Court noted that noted the

APA's waiver of sovereign immunity does not apply to claims seeking money damages, but it also reaffirmed the general rule that "a district court's jurisdiction 'is not barred by the possibility' that an order setting aside an agency's action may result in the disbursement of funds." *Id.* at 968 (quoting *Bowen*, 487 U.S. at 910). The Government overreads the three-page stay order. *See Nken v. Holder*, 556 U.S. 418, 434 (2009) (explaining that the issuance of a stay "is dependent upon the circumstances of the particular case"). The Supreme Court's brief treatment of *Bowen* and *Great-West Life* in *California* and the cursory mention of potential jurisdictional issues do not appear to settle all jurisdictional issues here, despite HHS' arguments to the contrary.[9]

The Court recognizes the tension between *Bowen* and *California*. But the Court is not positioned to disregard *Bowen* and its progeny, even if it appears that it is now in tension with *California*. *See Mallory v. Norfolk S. Ry. Co.*, 600 U.S. 122, 136 (2023) (explaining that district courts "should follow the case which directly controls, leaving to [the Supreme] Court the prerogative of overruling its own decisions."). This holds true even when the lower court "thinks the precedent is in tension with some other line of decisions"—or here, rather than an entire competing

[9] Notably, the States point out that in *California*, the Supreme Court weighed the potential harm to the government because the grantees had not promised to return withdrawn funds if the terminations were reinstated and found that the recipients did not stand to suffer irreparable harm while the case played out because they could recover any wrongfully withheld funds in the proper forum. *See California*, 145 S. Ct. at 967. And the States maintain that is not the case here because unlike the plaintiffs in *California*, they do not have the financial wherewithal to keep their public health programs running in the meantime. (ECF No. 65 at 8.)

"line of decisions," a single three-page per curiam order granting a stay.[10] *See Merrill v. Milligan*, 142 S. Ct. 879, 879 (2022) (Kavanaugh, J., concurring) ("The Court's stay order is not a decision on the merits"). The case that "directly controls," and the one that the Court must follow, is *Bowen*.[11]

B. Likelihood of Success on the Merits

The Court now turns to the States' likelihood of success on the merits. They bring seven total claims.[12] The first four claims arise under the APA. Under Count I, the States argue that HHS' sudden termination of $10 billion in grants exceeds its statutory authority—in other words, a violation of the Major Questions Doctrine. (ECF No. 59 ¶¶ 101-102.) Under Counts II and III, the States allege that HHS' termination of two subsets of grants—those for SAMHSA and CDC—ran afoul of statutory and regulatory requirements. *Id.* ¶¶ 111, 126–127. In abruptly terminating the SAMHSA grants, HHS violated three provisions of § 300x-55: its provision

[10] In its supplemental briefing, HHS submits that the Court should treat the Supreme Court's decision in *California* as binding precedent on whether there is jurisdiction. (ECF No. 80 at 2 n.1.) Still, the Supreme Court's limited analysis in *California* is not a decision on the merits. And the source of the plaintiff-states' rights and their requested relief in *California* bears key differences from the States' claims here.

[11] District courts adjudicating similar claims agree that *California* did not divest them of jurisdiction. *See Woonasquatucket,* 2025 WL 1116157, at *14; *Maine v. United States Dep't of Agric.*, No. 1:25-CV-00131-JAW, 2025 WL 1088946, at *19 (D. Me. April 11, 2025); *New York v. Trump*, No. 25-cv-39-JJM-PAS, ECF No. 182 at 5–9 (D.R.I. Apr. 14, 2025); *State of Rhode Island, et al. v. Trump et al*, No. 25-cv-128-JJM-LDA, ECF No. 57 at 14—18.

[12] At this stage, the States need only show a substantial likelihood of success on one of their seven claims. *See, e.g.*, *Worthley v. Sch. Comm. of Gloucester*, 652 F. Supp. 3d 204, 215 (D. Mass. 2023) (collecting cases).

limiting funding terminations to cases where states, "materially failed to comply" with the grant agreements, as well as separate requirements for pre-termination investigation and hearing. *Id.* ¶ 111. And in abruptly canceling the CDC grants, HHS ran afoul of its own regulations, as laid out in 45 C.F.R. § 75.372(a)(2). *Id.* ¶¶ 126–27. Finally, under Count IV, the States allege that HHS' termination was arbitrary and capricious. *Id.* ¶¶ 134. They raise a host of arguments under this count, but their overarching point is that the decision was neither "reasonable" nor "reasonably explained," and each is independently fatal to its viability. *See id.*; *Ohio v. EPA*, 603 U.S. 279, 292 (2024).

The last three claims are constitutional. Under Count V, the States argue that the Executive's actions are an attempt to "unilaterally decline to spend funds," in violation of fundamental Separation of Powers principles and the Take Care Clause. *Id.* ¶ 149-150. Under Count VI, the States argue that the terminations violate the Spending Clause, because they improperly altered the relationship between the States and Congress. *Id.* ¶ 157. Finally, under Count VII, the States argue generally that HHS "lacked statutory or constitutional authority" to terminate the funds, so an injunction is necessary. *Id.* ¶ 164.

The States argue that they have shown a strong likelihood of success on the merits because HHS' Public Health Funding Decision and its implementation was contrary to law, arbitrary and capricious, and violates the Constitution. (ECF No. 60 at 23.) In turn, HHS reaffirms its position that this Court lacks jurisdiction over the States' claims, and that they cannot succeed on the merits. (ECF No. 68 at 21.) Even

aside from those "jurisdictional obstacles," HHS insists that the States have failed to show a likelihood of success on the merits because its actions "were not contrary to law or arbitrary and capricious, nor did they violate the Constitution." *Id.*

1. **Threshold APA Issues**

Before reaching the merits of the APA claims, though, the Court must determine two more threshold issues. First is whether HHS' actions constitute "final agency action," and second is whether, even if so, HHS' actions were of the narrow category "committed to agency discretion" and thus unreviewable under the APA.

A "final agency action" under 5 U.S.C. § 704 has two components: first, it "marks the consummation of the agency's decision-making process" and second, it is either an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 808 (2024) (cleaned up).

As to the first element, the States argue that HHS' actions "announce[d] the agency's final decision on the matter," and were effective as of the date set out in the Notice of Award, which was either March 24 or 25. (ECF No. 60 at 24, ECF No. 4-40, Ex. A at 1, 5.) As to the second prong, the States reason that there are "clear legal consequences" because the States immediately lost funding in the wake of HHS' Public Health Funding Decision. (ECF No. 60 at 24.) They also contend that the APA does not preclude bringing this challenge as a single action. *Id.*

Not directly contesting that its actions constituted final agency action, HHS instead argues that its "terminations were consistent with the applicable statutory

and regulatory provisions," meaning that "no further review under the APA is available." (ECF No. 68 at 18.) Even if these claims were reviewable under the APA, HHS says that the terminations were "quintessential agency actions" and "committed to agency discretion by law" under § 701(a)(2). *Id.* In response, the States explain that HHS' actions do not belong in the narrow class of agency actions which are "committed to agency discretion by law" and that "there are applicable statutory or regulatory standards that cabin agency discretion" and "meaningful standard[s] by which to judge the [agency]'s action." (ECF No. 60 at 24.) Thus, the States maintain that HHS' Public Health Terminations are reviewable by this Court. *Id.*

On both fronts, the States have the better of the argument. First, HHS' actions in terminating the public health funding at issue satisfy both prongs of the final agency test. The termination notices announced HHS' decision to cut the funding immediately. An immediate termination of funds surely marks the culmination of HHS' decision to cut the funding; there are no further steps HHS needs to take to determine whether it would cut the funding. As to the second prong, there are clear legal consequences of HHS' Public Health Terminations: the States cannot access previously available funds and consequently, will be forced to lay off highly trained specialists, disband infectious disease research teams, and eliminate public health programs that were created to vaccinate vulnerable populations and rural communities, and to treat those struggling with mental health or substance abuse related issues. *See, e.g.*, ECF Nos. 4-3 ¶ 48; 4-6 ¶¶ 4-7; 4-15 ¶ 17; 4-40 ¶ 11; 4-41 ¶ 3.

As to HHS' other argument: the Court disagrees that the Public Health Terminations were "committed to agency discretion by law" under § 701(a)(2) and thus unreviewable. To start, the APA "embodies a basic presumption of judicial review," and it "instructs reviewing courts to set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Dep't of Com. v. New York*, 588 U.S. 752, 771 (2019) (cleaned up) (citing 5 U.S.C. § 706(2)(A)). And the Supreme Court has read the "committed to agency discretion" exception to judicial review for actions committed to agency discretion "quite narrowly." *Id.* It is restricted to only "rare circumstances" where a court "would have no meaningful standard against which to judge the agency's exercise of discretion." *Id.* (cleaned up).

That is not the case here. There are applicable constitutional, statutory, and regulatory standards that cabin HHS' discretion as an agency. Whether HHS had the requisite authority to implement the Public Health Terminations is exactly the type of legal question district courts are well-equipped to handle. Whether HHS exceeded statutory authority or violated the Constitution by eliminating Congressionally appropriated funds cannot be committed to agency discretion. *See California v. U.S. Dep't of Educ.*, 132 F.4th 92, 97–98 (1st Cir. 2025) *opinion stayed on other grounds*, (explaining that "applicable regulations cabin the [agency's] discretion as to when it can terminate existing grants" which creates a meaningful standard for the court to judge the agency's action); *see also Pol'y & Rsch., LLC v. HHS*, 313 F. Supp. 3d 62, 75–78 (D.D.C. 2018) (concluding that agency's sudden halt on funding to a program was reviewable under the APA because applicable

regulations cabin its termination authority and consequently, provide a standard for judicial review).

While the Government relies on *Lincoln v. Vigil*, 508 U.S. 182 (1993), to support its position that "[a]n agency's determination of how to allot appropriated funds among competing priorities and recipients is classic discretionary agency action that is not susceptible to APA review," the States respond that this case does not concern the allocation of lump-sum appropriations. (ECF No. 68 at 19, ECF No. 69 at 11.) The determination of whether HHS had the authority to eliminate the Congressionally appropriated funds based on its own assessment that the appropriations were "no longer necessary" due to the end of the COVID-19 pandemic is certainly not a question about agency discretion. *See In re Aiken Cnty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013) (explaining that the Executive "does not have unilateral authority" to refuse to spend funds appropriated by Congress). Similarly, HHS' implementation of the terminations of public health grants already allocated and awarded concerns the application of statutory and regulatory "for cause" provisions, an analysis which district courts "routinely perform." *Pol'y & Rsch., LLC*, 313 F. at 83 (Jackson, J.).

The Supreme Court clarified in *Lincoln* that "an agency is not free simply to disregard statutory responsibilities: Congress may always circumscribe agency discretion to allocate resources by putting restrictions in the operative statutes." *Lincoln*, 508 U.S. at 193 (labeling an action unreviewable because Congress left the decision about how to spend the money up to the agency's discretion). With that in

mind, courts have held that § 701(a)(2) does not apply when the agency's actions contravene (1) appropriations laws and (2) other applicable regulatory and statutory authority. *California*, 132 F.4th at 97–98; *Pol'y & Rsch., LLC*, 313 F. at 75–78. The States claim that judicial review is proper under both grounds. (ECF No. 69 at 12.)

The Court agrees. First, Congress directed HHS to spend the appropriated funds on specific initiatives per the applicable statutes. Nor is this a case where Congress expressly delegated discretion to HHS. Notably, when reviewing the statutory authority for tribal grants under the CARES Act, the D.C. Circuit concluded that it was "nothing like the statutes at issue in *Lincoln*," and thus not entitled to a presumption of non-reviewability. *See Shawnee Tribe v. Mnuchin*, 984 F.3d 94, 100 (D.C. Cir. 2021) ("Congress has not left the Secretary any flexibility to shift funds within a particular appropriation account so that [he] can make necessary adjustments for unforeseen developments and changing requirements.") (internal quotation marks omitted). So too here.

Second, unlike the lump-sum appropriations in *Lincoln* which were left to agency discretion, HHS' decision to terminate is clearly reviewable when applicable statutory and regulatory language provide a clear standard for the Court's review. *See, e.g.*, 45 C.F.R. § 75.372(a)(2) ("[An] award may be terminated . . . for cause"); 42 U.S.C. § 300x-55(a) (A grant may be "terminated for cause" when "a State has materially failed to comply with the agreements or other conditions"). This is not one of "those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of

discretion." *Dep't of Com.*, 588 U.S. at 772. The Government's attempt to frame the Public Health Terminations as matters where it had discretion to choose how Congressionally appropriated funds are spent among competing priorities is without merit. *See Pol'y & Rsch., LLC*, 313 F. Supp. at 75–78.

Having held that the States are likely to establish that the Public Health Terminations constitute a "final agency action" under the APA and that they are not "committed to agency discretion by law," the Court moves to the merits.

2. Count I: Public Health Funding Decision

The States first argue that HHS' Public Health Funding Decision violated the APA in two ways. First, in determining that the congressionally appropriated funds were no longer necessary, the States argue that HHS overstepped its statutory authority. And second, the States maintain that HHS acted contrary to law in terminating the grants "for cause" for two reasons: (1) the States complied with the terms and conditions of their awards and HHS has not alleged otherwise and (2) HHS has not pointed to relevant authority which allows termination for cause based on the end of the pandemic, which was over two years ago. In turn, HHS insists that there is "no question" it had the express authority to terminate the public health grants for cause by applicable regulations. (ECF No. 68 at 23.)

Starting with the "excess of statutory authority" argument, the States say that HHS, in unilaterally terminating the programs despite Congress's decision not to, violated the major questions doctrine. Their argument goes like this: starting in 2020, Congress appropriated funds to grant-in-aid programs and provided specific

purposes and instructions on how to spend the money. In doing so, Congress expressly tied certain programs and funding to the end of the pandemic. And in 2023, Congress reviewed COVID-related appropriation statutes after the pandemic ended and rescinded $27 billion of appropriations. *See* Fiscal Responsibility Act, Pub. L. No. 118-5 137 Stat. 10 (2023) Div. B, § 2(3) (rescinding certain unobligated funds "with the exception of $2,127,000,000 and—(A) any funds that were transferred and merged with the Covered Countermeasure Process Fund"). Since then, Congress did not revoke any of the funding at issue here; it reviewed it and left it in place. As a result, the States insist that leaving the funding in place signaled Congress's determination that the end of the pandemic did not mean that certain programs and appropriated funds were no longer needed.

The Court presumes that "Congress intends to make major policy decisions itself" rather than leaving those decisions to agencies. *West Virginia v. EPA*, 597 U.S. 697, 723 (2022). Congress must "speak clearly" if it wishes to charge an agency with a decision of "vast economic and political significance." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764, (2021) (cleaned up). Thus, an agency "literally has no power to act—including under its regulations—unless and until Congress authorizes it to do so by statute." *FEC v. Cruz*, 596 U.S. 289, 301 (2022). And "where the statute at issue is one that confers authority upon an administrative agency, that inquiry must be shaped, at least in some measure, by the nature of the question presented—whether Congress in fact meant to confer the power the agency has asserted." *W. Virginia v. EPA*, 597 U.S. 697, 721 (2022).

The power that HHS has asserted here is a broad one: terminating $11 billion worth of funding based on its determination that the money is no longer necessary. The Court cannot see how it can claim that power based on the history of congressional action described above. *See Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014).

The Court recognizes that is not the typical "major questions doctrine" case, where the parties can point to—and argue about—one specific grant of power in one part of one statute. *Cf. Biden v. Nebraska*, 600 U.S. 477, 494 (2023) ("We hold today that the Act allows the Secretary to 'waive or modify' existing statutory or regulatory provisions applicable to financial assistance programs under the Education Act, not to rewrite that statute from the ground up."); *Alabama Ass'n of Realtors*, 594 U.S. at 763 ("The Government contends that the first sentence of § 361(a) gives the CDC broad authority to take whatever measures it deems necessary to control the spread of COVID–19, including issuing the moratorium.").

But that is a problem of HHS' making. In fact, it makes the States' case even clearer, given that no specific language satisfies the "speak clearly" test with regard to the $10 billion decision affecting funds across six statutes made here. And in any event, broader context including "background legal conventions," constitutional structure, and even "common sense," should inform the Court's analysis of an agency's assertion of power. *Biden v. Nebraska*, 600 U.S. at 510–513 (Barrett, J., concurring). That is true even without a single textual hook.

All three factors—background legal conventions, constitutional structure, and common sense—caution against accepting HHS' assertion of authority. Congress already considered the appropriations at issue here and clearly determined that some programs and services were still necessary, no matter when the pandemic ended. More importantly, when undertaking this review in June 2023, Congress did not grant HHS authority to rescind or reallocate the funds, nor did it authorize such drastic action. In the interpretation of statutes, the express mention of one thing is to the exclusion of others. *See, e.g.*, *N.L.R.B. v. SW Gen., Inc.*, 580 U.S. 288, 302 (2017) ("If a sign at the entrance to a zoo says, 'come see the elephant, lion, hippo, and giraffe,' and a temporary sign is added saying 'the giraffe is sick,' you would reasonably assume that the others are in good health.") Thus, Congress's express decision to eliminate some COVID-era public health funding, but leave alone the funding at issue here, signals its intent to continue that funding.

Consequently, HHS' Public Health Funding Decision usurped Congress's power to control these public health appropriations. If Congress intended to charge HHS with such a determination, it would have done so at some point—like in June 2023, when it went line-by-line and rescinded some COVID-era funding but left other funding in place. With that in mind, the Court holds that the States are likely to succeed on Count I.

3. Count II: SAMHSA Terminations

The States next assert that the SAMHSA terminations were contrary to law and in excess of statutory authority. Their argument is that HHS departed from

three key statutory requirements governing SAMHSA funding under § 300x-55. (ECF No. 60 at 27.) And in the States' view, each is sufficient to establish a successful claim. The Court lays out these three arguments below before addressing them.

First, under 42 U.S.C. § 300x-55(a), the Secretary may "terminate the grant for cause" only "if the Secretary determines that a State has materially failed to comply with the agreements or other conditions required for the receipt of a grant." Despite this requirement, the States claim that HHS "never asserted that any grantee materially failed to comply with agreements or other required conditions." *Id.*; *see, e.g.*, ECF. Nos. 4-6 ¶ 12., 4-41 ¶ 42. Rather, HHS merely stated that "[t]he end of the pandemic provides cause to terminate COVID-related grants. Now that the pandemic is over, the grants are no longer necessary." (ECF. No. 4-6, 4-41.)

Second, under § 300x-55(e), the Secretary shall provide to the State involved adequate notice and an opportunity for a hearing" "[b]efore taking action against a State . . . ." The States submit that HHS did not provide notice to the States or an opportunity for a hearing before taking action to terminate the grant funding, contrary to statutory requirements.

Finally, § 300x-55(g) bars HHS from withholding any funds without "an investigation concerning whether the State has expended payments under the program involved in accordance with the agreements required under the program." The States argue that HHS ignored this requirement. Just as there was no notice, in violation of § 300x55(e), there was also no investigation. HHS claims that it

terminated the SAMHSA funding "for cause" that is, the end of the pandemic, and consequently, the statutory requirements for non-compliance are inapplicable.

On this record, it is clear that HHS ignored multiple statutory requirements that govern the termination of block grant programs. HHS argues that Section 300x-55 does not apply to the terminations here because that section is only implicated upon a determination that a State has materially failed to comply with the grant terms or conditions. (ECF No. 68 at 27-28.) But that is a puzzling argument given that HHS relied on Section 300x-55 as its authority to terminate the funding when it issued the termination letters. *See* ECF No. 4-6 ¶ 12; 4-41 Ex. D at 1.

Because § 300x-55 applies, the Court struggles to see how the Government's decision to terminate the funds as "no longer necessary" satisfies the process laid out in the statute.[13]

The Government's argument that the States' material failure to comply is based on the notion that they were "not spending the money that had been allocated for COVID-19 relief purposes" is unavailing. (ECF No. 68 at 28.) Congress did not expressly limit the funds to COVID-19 related programs and services. *See* ARPA,

[13] To be sure, each State receives a block grant under SAMHSA based on a statutory formula. *See* 42 U.S.C. § 300x(a) (the Secretary "shall make an allotment each fiscal year for each State in an amount determined in accordance with section 300x–7"). With respect to block grants, agencies have no discretion and must distribute the funds based on the statutory formula. *See City of Providence v. Barr*, 954 F.3d 23, 27 (1st Cir. 2020). Regarding SAMHSA, Congress outlined specific circumstances in which HHS is not required to spend the funds. *See* § 300x-55(a) (A grant may be "terminated for cause" when "a State has materially failed to comply with the agreements or other conditions."). Accordingly, HHS lacked the requisite authority to refuse to spend the funds for any other reason.

Pub. L. No. 117-2, §§ 2701, 2702, 135 Stat. 4, 45-46 (2021) (appropriating $1.5 billion for services related to mental health and $1.5 billion for services related to substance abuse "to remain available until expended"); Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (Div. M of the Consolidated Appropriations Act, 2021), Pub. L. No. 116-260, 134 Stat. 1182 (2020) ("$1,650,000,000 shall be for grants for the substance abuse prevention and treatment block grant program" and "$1,650,000,000 shall be for grants for the community mental health services block grant program"). If Congress intended to tie these funds to the end of the pandemic, it would have done so.

And HHS' offering a hearing after terminating the funds only serves to strengthen the States' position that the Government acted contrary to law. Recall that under § 300x-55(e), the Secretary must provide the State involved adequate notice and an opportunity for a hearing "[b]efore taking action." Without that hearing prior to termination, HHS' Public Health Funding Decision and its implementation ran contrary to the States' statutory rights.

4. Count III: CDC Terminations

The States claim that HHS' termination of CDC grants "had no legal basis for its actions because of the end of the pandemic nearly two years ago. Defendants acted contrary to law and in excess of statutory authority." (ECF No. 60 at 28, 30.) According to the States, the CDC funding was terminated "for cause" based on "HHS regulations," presumably 45 C.F.R. § 75.372(a)(2). *Id.* at 28. The States say that the end of the pandemic, nearly two years ago, surely does not qualify when it has

previously construed "for cause" as a material failure to comply. *Id.* In turn, HHS says that the "for cause" provision is distinct from non-compliance, and that it was permitted to terminate the grants. (ECF No. 68 at 23.)

Again, the States have the better of the argument. The Court sees no reason to accept HHS' novel interpretation of the "for cause" termination requirement in its regulations, particularly in light of the Supreme Court's guidance on similar questions. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155–56 (explaining that "an agency's interpretation of its own ambiguous regulation" should not receive deference when the agency's interpretation "is nothing more than a convenient litigating position" or a "post hoc rationalization advanced by an agency seeking to defend past agency action against attack," or when it would cause an "unfair surprise" to the regulated parties).

When examining the "for cause" language in the past, HHS has generally construed it to involve a failure to comply with a grant's terms and conditions.[14] *Id.* Similarly, "for cause" has been construed as substantially the same as "failure to comply." *See* OMB, Guidance for Grants and Agreements, 85 Fed. Reg. 49506,49508 (Aug. 13, 2020). What's more, HHS has signaled its intent to adopt the OMB's

[14] *See R.I. Substance Abuse Task Force Ass'n*, DAB No. 1642 (1998), 1998 WL 42538, at *1 (H.H.S. January 15, 1998) ("When a grantee has materially failed to comply with the terms and conditions of the grant, [the Public Health Service] may . . . terminate the grant for cause."); *Child Care Ass'n of Wichita/Sedgwick Cnty.*, DAB No. 308 (1982), 1982 WL 189587 at *2 (H.H.S. June 8, 1982) ("'For cause' means a grantee has materially failed to comply with the terms of the grant."). This is consistent with the standard application of "for cause" terminations in statute and regulation. *See, e.g.*, 42 U.S.§ 300x-55(a); 10 C.F.R § 600.25 (allowing "for cause" award termination on the basis of noncompliance or debarment).

interpretation and eliminate the "for cause" provisions, illustrating how it has admitted that it sees the provision as an unnecessarily duplicative part of its regulatory scheme *See* HHS, Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 89 Fed. Reg. 80055, 80055 (Oct. 2, 2024) (effective October 2025) ("for cause" regulation substantially duplicative of "failure to comply regulation"). Nor would the end of the pandemic nearly two years ago seem to require termination when the appropriation statutes at issue extended the funding for purposes beyond the pandemic and Congress determined not to rescind the funds at issue in June 2023.

The States have thus shown a strong likelihood of success in proving that the CDC terminations were contrary to law.

5. Count IV: "Arbitrary and Capricious" Claim

Next, the States argue that the Public Health Funding Decision was arbitrary and capricious because the Government's termination of critical public health funding based on the end of the pandemic nearly two years ago is not substantively reasonable nor was it reasonably explained. (ECF No. 60 at 30.) In turn, HHS says that its conduct is not reviewable under the APA and even so, it did not act arbitrarily and capriciously because its decision to terminate the funds was lawful and agencies have discretion on how to allocate funds thus, the decision did not require any additional explanation. (ECF No. 60 at 31-32.)

The APA requires reviewing courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in

accordance with law." 5 U.S.C. § 706(2)(A). An agency action is arbitrary or capricious "if it is not reasonable and reasonably explained." *Ohio v. EPA*, 603 U.S. 279, 292 (2024). The Court cannot "substitute its judgment for that of the agency," but it must take care to "ensure" that the agency has "offered a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *Id.* (cleaned up). And "an agency cannot simply ignore an important aspect of the problem." *Id.* (cleaned up).

First, the States argue that HHS failed to provide a rational basis for the Public Health Funding Decision. Merely relying on a conclusory explanation that the funds are no longer necessary because the pandemic is over does not demonstrate a "rational connection between the facts found and the choice made." *Ohio*, 603 U.S. at 292. The Government's determination was unreasonable in light of Congress's direction that the appropriations at issue be used beyond the pandemic and to better prepare for future public health threats. *See, e.g.*, ARPA, §§ 2402, 2404, 2501, 135 Stat. at 41-42.

This holds particularly true when Congress expressly limited some appropriations to the end of the pandemic. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") Even so, in June 2023, Congress undertook a review of COVID-era spending and passed the Fiscal Responsibility Act of 2023 and rescinded $27 billion of

appropriations that were no longer necessary due to the end of the public health emergency. *See* Pub. L. No. 118-5 Div. B, Title I (2023). Given Congress's clear intent to keep the appropriations at issue intact, the Court cannot say HHS provided any rational basis to justify its decision to terminate the funds based on the end of the pandemic. That is sufficient to end the analysis, but to be thorough, the Court will address additional "arbitrary and capricious" arguments.

Next, the States claim that HHS' actions were arbitrary and capricious because it failed to undertake an individualized assessment or acknowledge the important public health initiatives supported by the grants, failing "to consider an important aspect of the problem." (ECF No. 60 at 32.) (quoting *State Farm*, 463 U.S. at 43)). In turn, HHS says that "it is not arbitrary and capricious for an agency to provide the same explanation across multiple decisions." (ECF No. 68 at 32.)

Still, the determination that funding appropriated by Congress is no longer necessary requires an assessment of the grantees' compliance with the agreements, which HHS declined to do. Recall that § 300x-55(g) bars HHS from withholding any SAMHSA funds without "an investigation concerning whether the State has expended payments under the program involved in accordance with the agreements required under the program." And based on its own interpretations, HHS may terminate awards "for cause" when a party has failed to comply with the terms and conditions of the grant under § 75.372(a). There is no evidence that happened here.

Third, the States allege that HHS failed to provide a reasoned explanation for its sudden change in position that appropriations Congress determined were needed

to fund public health initiatives beyond the pandemic were no longer necessary. Such a drastic change of course would require HHS to "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). While HHS acknowledged its change of position, it provided no explanation to the States as to why it did so suddenly and contrary to Congress's will that certain COVID-era spending was needed beyond the immediate public health emergency that ended in May 2023.

Fourth, HHS' Public Health Funding Decision was arbitrary and capricious because it failed to consider the States' reliance interests on the funds and the devastating consequences that would result from abruptly terminating critical public health appropriations. The Government asserts that is an "incorrect premise" because the States "failed to draw down over $160 million of the funds while they were available" and thus, cannot now claim they relied on the funds. (ECF No. 68 at 33.) That said, agencies must consider reliance interests when changing course because "longstanding policies may have engendered serious reliance interests that must be taken into account." *Dep't of Homeland Sec.*, 591 U.S. at 30 (cleaned up); *Fox Television Stations*, 556 U.S. at 515 (explaining that it is arbitrary and capricious to ignore reliance interests). The States and their local agencies and programs relied on this funding and had no reason to suspect that it would be abruptly canceled without process or explanation. The States were granted extensions in some cases through June 2027, and HHS issued guidance on how to appropriately use the funds beyond COVID-related initiatives. *See* ECF Nos. 4-3 ¶¶ 10, 13, 21–22, 48; 4-24 ¶¶

11, 22; 4-32 ¶ 19. Indeed, it appears HHS gave no consideration to the programs and services that would be impacted by these terminations when it decided the funds were no longer necessary based on the end of the pandemic.

HHS maintains that the Court should ignore the States' claimed reliance on these appropriations for two reasons: certain funds were not yet obligated or drawn down by the States and HHS allocated the funds that were statutorily required. (ECF No. 68 at 33.) Indeed, HHS says that it identified over $86 million in SAMHSA funding and nearly $79 million in CDC grants that had not yet been obligated or drawn down while available. *Id.* Still, Congress has already spoken. With respect to SAMHSA, the States had until September 2025 to spend the funds. Pub. L. 117-2, §§ 2701, 2702, 135 Stat. 4, 45-46. And with CDC, the funds were to be obligated by September 2024, but the States have an additional five years to spend those funds. *See* CARES Act Title VIII, 134 Stat. 281, 554; 31 U.S.C. §§ 1552(a), 1553(a).

The Government's decision to allocate, in some cases, more than it was statutorily required to does not alleviate HHS of its obligation to expend the appropriated funds under legislative directives. Notably, in the CARES Act, Congress even outlined specific purposes for the appropriated funds to be used beyond the pandemic including public health data surveillance, infrastructure modernization, disease detection, and emergency response, and surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. *See* CARES Act Title VIII, 134 Stat. 281, 554–555. Based on Congress's direction that the funds remain available, the

Government's argument that it met some of the statutory requirements in the appropriation acts is irrelevant; it is certainly not dispositive of any questions about its refusal to spend the remaining funds because it believes the money is no longer necessary.

Lastly, the States insist that the Government's conduct was arbitrary and capricious because it violated statutory and regulatory authority as HHS never alleged that the States failed to comply with the terms and conditions of the awards. *See* ECF No. 60 at 33. They also say that HHS did not explain its sudden departure from its longstanding position that the funds would extend beyond the pandemic and Congress's express decision to leave the funding in place. *Id.*

The Court agrees that HHS acted arbitrarily and capriciously when it applied "for cause" terminations here because contrary to statutory and regulatory authority, HHS never claimed any failure on part of the States to comply with their grant agreements. *See* § 300x-55(g); § 75.372(a). Instead, HHS merely relied on the end of the pandemic as "cause" to terminate the funds, despite this application being contrary to statutory and regulatory authority and inconsistent with Congress's directive that the funds remain available beyond the pandemic.

Once again, the States have demonstrated a strong likelihood of success on their claim that these terminations were arbitrary and capricious in violation of the APA.

6. Count V: Separation of Powers

Finally, the States are likely to succeed on the merits of their claim that HHS' Public Health Terminations and its implementation violate Separation of Powers. The States argue that, drawing analogies to cases directly about presidential power, HHS is operating at its "lowest ebb," because no constitutional or statutory provision authorizes HHS, as an agent of the Executive Branch, to unilaterally terminate funding appropriated by Congress. (ECF No. 60 at 34.) Rather, "the Executive has taken measures that are incompatible with the express will of Congress related to public health appropriations." *Id.* For their part, HHS insists that it had "inherent authority to spend the money that Congress allocates consistent with the limits Congress sets." (ECF No. 80 at 10.) As such, HHS says that its decision to exercise its discretion within those confines "is entirely consistent with separation-of-powers principles and is an action committed to agency discretion by law for which the APA does not provide an avenue for review. *Id.*

It is axiomatic that "[t]he United States Constitution exclusively grants the power of the purse to Congress, not the President." *City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018); U.S. Const. art. I, § 9, cl. 7 (Appropriations Clause)1; U.S. Const. art. I, § 8, cl. 1 (Spending Clause). It naturally follows that the same is true of the President's agents. "Congress may attach conditions on the receipt of federal funds, and has repeatedly employed the power 'to further broad policy objectives by conditioning receipt of federal moneys upon

compliance by the recipient with federal statutory and administrative directives.'" *Id.* at 1232 (quoting *South Dakota v. Dole*, 483 U.S. 203, 206–07 (1987)).

In contrast, "[t]here is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes." *Id.* (quoting *Clinton v. City of New York*, 524 U.S. 417, 438 (1998)). Simply put, "the President is without authority to thwart congressional will by canceling appropriations passed by Congress" and "does not have unilateral authority to refuse to spend the funds." *Id.* Nor may the President "decline to follow a statutory mandate or prohibition simply because of policy objections." *Id.* "No matter the context, the President's authority to act necessarily 'stem[s] either from an act of Congress or from the Constitution itself.'" *Trump v. United States*, 603 U.S. 593, 607 (2024) (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 634 (1952) (Jackson, J., concurring)). And again, the same is true of the Executive's agents. The Separation of Powers and these core principles are integral to our democracy. Meaning that, "liberty is threatened" when "the decision to spend [is] determined by the Executive alone." *Clinton*, 524 U.S. at 451 (Kennedy, J., concurring).

HHS' actions here clearly usurped Congress's authority to spend and allocate funds how it deems appropriate. *See City & Cnty. of S.F. v. Trump*, 897 F.3d 1225, 1235 (9th Cir. 2018) (explaining that without authorization from Congress, "the Administration may not redistribute or withhold properly appropriated funds in order to effectuate its own policy goals.") The power to spend lies solely with the Legislative branch. *See id.* at 1231-32; *see also* U.S. Const. art. I, § 9, cl. 7

(Appropriations Clause); U.S. Const. art. I, § 8, cl. 1 (Spending Clause). With this comes the "exclusive power" to impose conditions on appropriated funds. *Id.* at 1231. In contrast, the Executive's role is to "take care that the laws be faithfully executed," and agencies are there to serve that same end. U.S. Const. art. II, § 3.

As a federal agency, HHS "can spend, award, or suspend money based only on the power Congress has given to them—they have no other spending power." *New York v. Trump*, No. 25-CV-39-JJM-PAS, 2025 WL 715621, at *1 (D.R.I. Mar. 6, 2025), *denying stay pending appeal*, 2025 WL 914788 (1st Cir. Mar. 26, 2025). HHS' Public Health Funding Decision contradicts Congress's decision to appropriate funds to the States to address public health concerns. The Government had no statutory authority to decide that the funds were no longer necessary, particularly considering the Legislative's clear intent that the funds remain available beyond the pandemic. The Government's decision to allocate, in some cases, more than it was statutorily required to does not alleviate HHS of its obligation to expend the appropriated funds pursuant to Congress's intent. Indeed, the Legislature even outlined specific purposes for the appropriated funds to be used beyond the time of the pandemic to better prepare the country for future public health threats. Congress intended that the States have until September 30, 2025, to expend the SAMHSA funds and until 2029 with respect to the CDC grants. HHS even granted extensions to the States, in some cases through June 2027, and issued guidance on how to appropriately use the funds beyond COVID-related concerns. *See* ECF Nos. 4-3 ¶¶ 10, 13, 21–22, 48; 4-24

¶¶ 11, 22; 4-32 ¶ 19. As an agent of the Executive, HHS had "literally has no power to act" unless Congress authorized it to do so. *FEC,* 596 U.S. at 301.

In sum, the Government's unilateral determination that these funds were no longer needed based on the end of the pandemic violated core Separation-of-Powers principals because Congress made its directives clear in the appropriations statutes and once again when it chose not to rescind the funds in June 2023. The States have therefore demonstrated a strong likelihood of success on the merits of their claim that HHS' actions violated the Separation of Powers.

7. Count VI and Count VII

Having held that the States are likely to succeed on five of their seven claims, including a constitutional claim, the Court declines to address the sixth and seventh for purposes of resolving this motion for preliminary relief. *See Woonasquatucket*, 2025 WL 1116157, at *13; *Worthley*, 652 F. Supp. 3d at 215.

C. Irreparable Harm

While HHS insists that the States' motion "should be denied solely because they have failed to demonstrate irreparable harm," the Court disagrees. (ECF No. 68 at 35–36.) The States have submitted copious examples of irreparable harm flowing directly from HHS' decision to terminate this funding directly to their local health jurisdictions. *See* ECF Nos. 4-1—4-48.

Plaintiffs seeking preliminary injunctive relief face an uphill battle and must demonstrate "that irreparable injury is likely in the absence of an injunction." *Winter v. NRDC, Inc.*, 555 U.S. 7, 22 (2008) (emphasis omitted). True, "[p]reliminary

injunctions are strong medicine, and they should not issue merely to calm the imaginings of the movant." *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 73 (1st Cir. 2004). Harm that is "unlikely to materialize or purely theoretical will not do." *Id.* Rather, irreparable harm is based on "something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004).

Preliminary relief is appropriate when the alleged injuries cannot adequately be compensated "either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy." *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005); *see also Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 217 F.3d 8, 13 (1st Cir. 2000) (*Ross-Simons II*). "The necessary concomitant of irreparable harm is the inadequacy of traditional legal remedies. The two are flip sides of the same coin: if money damages will fully alleviate harm, then the harm cannot be said to be irreparable." *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 914 (1st Cir. 1989). District courts have "broad discretion to evaluate the irreparability of alleged harm." *Ross-Simons II*, 217 F.3d at 13 (cleaned up).

Before the Court is an extensive record from the States detailing the harm they stand to suffer in the wake of HHS' Public Health Funding Decision. The States divide these examples to three categories: protecting public health, the elimination of healthcare services, and impact on public health infrastructure. The Court discusses each below.

1. Protecting Public Health

The States assert that the termination in funding would impair their ability to protect public health because it will cause layoffs of essential staff. (ECF No. 60 at 38.) "Threats to public health and safety constitute irreparable harm that will support an injunction." *Cigar Masters Providence, Inc. v. Omni Rhode Island, LLC*, No. CV 16-471-WES, 2017 WL 4081899, at *14 (D.R.I. Sept. 14, 2017); *Sierra Club v. U.S. Dep't of Agric., Rural Utilities Serv.*, 841 F. Supp. 2d 349, 358 (D.D.C. 2012).

The Minnesota Department of Health ("MDH") will be required to layoff approximately 200 employees, or 12 percent of its staff. (ECF No. 4-24 ¶ 41.) These layoffs will include "epidemiologists, research scientists, and other highly skilled and trained workers." *Id.* There is a risk that MDH will not be able to hire back all staff who were separated, many of whom have subject matter expertise that would be difficult to replace. *Id.* Loss of funds and workforce has significant and immediate implications for programs fulfilling critical public health functions in Minnesota. *E.g.*, the ELC supplemental funds[15] impact MDH's ability to perform disease surveillance and monitoring work for COVID-19 variants, including wastewater surveillance. *Id.* ¶ 44.

Washington state stands to lose 200 employees, including 150 full-time employees that are responsible for planning and responding to communicable disease

[15] The CDC established the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases ("ELC") Cooperative Agreement to fund the country's ability to detect, prevent, and respond to infectious disease outbreaks. (ECF Nos. 4-4 ¶ 7; 4-13 ¶ 8; 4-21 ¶ 22.)

cases and outbreaks and related laboratory testing and disease surveillance. (ECF No. 4-40 ¶¶ 5, 8–9.) Without these employees, the state would be at greater risk for a variety of infectious diseases, some of which cause severe illness, disability, or death. *Id.* ¶ 17.

Colorado will lose all but one of the employees in its Immunization Program. (ECF No. 4-10 ¶ 53.) "The loss in staff will result in the loss of customer service for our vaccine providers through the immunization information system help desk, and the loss of the ability to provide notification to parents and patients regarding the need for both COVID-19 and routine vaccinations, including flue and the measles, mumps, and rubella (MMR) vaccine during a time of increased measles cases and outbreaks in the U.S." *Id.*

Termination of the funding will also reduce staffing and capacity and resources in programs that address gaps in vaccine access by supporting mobile and community-based clinics, particularly in communities that are underserved and experience barriers in access to care and can be deployed for emergency response such as testing and post-exposure prophylaxis during outbreaks. *Id.* ¶¶ 55–56. Decreased access to and education regarding routine vaccinations will increase cases and outbreaks, which result in lives lost and increased health care costs for those infected. *Id.* ¶ 57.

In Delaware, the termination of a community health worker grant will end support for "33.5 [Community Health Worker] positions across six organizations, including federally qualified health centers and community-based organizations."

(ECF No. 4-14.) And here in Rhode Island, health officials will have to dismantle the Project Firstline team, which would stop the state's Department of Health from providing infection control education to healthcare facilities to prevent outbreaks. (ECF No. 4-39 ¶ 34.) The loss of Epidemiology and Laboratory Capacity Enhancing Detection Expansion funds will also impact the staffing of nurses, epidemiologists, and disease intervention specialists, and the funding of equipment and support software. *Id.* ¶¶ 31–32, 38–39.

Absent an injunction, HHS' termination of this funding will leave the States no choice but to shutter their programs and begin layoffs of highly trained and specialized employees that will be difficult to hire back. *See, e.g.*, ECF Nos. 4-3 ¶ 38; 4-7 ¶¶ 12–13, 42, 46, 54; 4-8 ¶¶ 23, 26, 31–37, 44, 54; 4-9 ¶¶ 49–50, 53, 56, 59–60, 80–81, 108; 4-10 ¶ 20.

2. Elimination of Healthcare Services to States

Next, the States submit that the loss of critical funding will curtail their healthcare services to residents. This includes treatment to those struggling with mental health and substance use disorder, the funding of vaccines to vulnerable populations, and services to address infectious disease outbreaks.

a. Mental Health and Substance Abuse Services

In Connecticut, the termination of the Department of Mental Health and Addiction Services' SAMHSA grants will eliminate "housing and employment supports, regional suicide advisory boards, harm reduction, perinatal screening,

early-stage treatments, and increased access to medication assisted treatment." (ECF No. 4-12 ¶¶ 16, 29.)

In Illinois, the termination of mental health block grants means that providers will be unable to provide services through the state's "mobile crisis response units that assist people at risk of suicide." (ECF No. 4-17 ¶ 16.) And without that funding, "providers will simply be unable to help people in suicidal crisis." *Id.*

In New Mexico, the terminated mental health care block grants will cut funding to fifty-four providers who treat over 64,000 people for critical behavioral and mental health services. (ECF No. 4-28 ¶ 14.)

In California, the termination of the substance use disorder prevention and early intervention services for youth in at least eighteen of its counties risk increased substance use among young people. (ECF No. 4-6 ¶ 61).

New Jersey stands to lose funds that support forty-five direct care treatment programs which provide critical live saving services, including crisis intervention and behavioral health treatment services that allow intervention for individuals experiencing mental health and or substance use crises. (ECF No. 4-26 ¶ 7)

And in North Carolina, the termination of SAMHSA funds has halted the work of mental health professionals including therapists and substance use treatment specialists. (ECF No. 4-25 ¶ 7) The loss of funds has also led to termination of a program that helps address substance use recovery and mental health in local universities and colleges. *Id.* ¶ 8. And the termination of funding will also impact

programs designed to address the opioid epidemic by providing naloxone kits and support to opioid community clinics. *Id.*

b. States' Public Health Programs

Without the funding, California's Immunization and Vaccines for Children program will not be able to provide vaccines for measles, influenza, and COVID-19 to approximately 4.5 million children, roughly half of California's youth population. (ECF No. 4-3 ¶ 17.)

In Minnesota, the funding was being used to address "gaps in infection control practices, training, and resources, identified during the COVID-19 pandemic as a major concern of the operators of long-term care facilities serving older adults." (ECF No. 4-24 ¶ 48.) Because of the terminations, the Minnesota Department of Health had to cancel grants that would have provided infection prevention and control training to more than sixty skilled nursing facilities across the state, potentially exposing over 3,000 long-term care residents to a greater risk of infection. *Id.* Likewise, the terminations forced the cancelation of infection prevention and control training programs for 150 nursing and assisted living facilities, "potentially impacting 7,000 long-term care residents." *Id.*

In Rhode Island, the loss of the Health Disparities grant will curtail efforts to support "community education, mitigation, and response efforts in the state's hardest hit communities" including preparedness and response capacity to the state's designated rural community, Block Island. (ECF No. 4-38 ¶ 17(a).) The loss of COVID-19 vaccination supplemental funding will impact a planned vaccination clinic

for vulnerable populations in Rhode Island, including those living in nursing homes and assisted living communities. *Id.* ¶ 25.

Consequently, HHS' Public Health Funding Decision is not merely an economic loss when it threatens the "very existence" of key mental health, substance abuse, and other healthcare programs in the States, worsening public health outcomes and placing their residents at risk. *See Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986) (explaining that "economic loss does not, in and of itself, constitute irreparable harm . . . [r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the [programs]").

3. Impact on States' Public Health Infrastructure Projects

Lastly, while these funds were initially awarded to help with the COVID-19 pandemic, CDC recognized that most States lacked the necessary disease surveillance and laboratory infrastructure to respond to future health threats, so it encouraged and allowed States to invest these funds in strengthening these capacities. (ECF No. 60 at 17.) The States insist they have "long relied on the CDC's ELC support for infectious disease programs and projects." *Id.*

For instance, some of the funds supported data systems upgrades that facilitate better disease reporting and surveillance. (ECF No. 4-40 ¶ 13.) Washington DOH had planned to use the funding to bring a new system online over the next fourteen months after investing more than $12 million of CDC funding in its development. *Id.* Stopping now would be a loss of the benefits of that investment. *Id.* In Connecticut, the loss of funding impacts data system upgrades for infectious

disease and symptom surveillance. *See* ECF 4-13 ¶ 20 ("tens of millions of dollars spent to date [in updating data systems] will be wasted"). Similarly, Hawaii used the funds to make long overdue investments in its health department's efficiency, effectiveness, and capacity to effectively respond to current and future disease threats. (ECF No. 4-45 ¶¶ 15-17.) Abrupt termination of these funds will result in waste of government resources if the systems being developed cannot be implemented as planned. *Id.* Lastly, ELC funds were budgeted by New Jersey through July 2026 including the Communicable Disease Reporting and Surveillance System ("CDRSS"), an electronic web-enabled system where public health partners timely report and rack incidences of communicable diseases, which is critical for responding to current and future public health threats. (ECF No. 4-27 ¶ 24.) There are needed enhancements for security and improvement and with the loss of ELC funding, NJDOH will not be able to keep CDRSS operation. *Id.*

The Court could go on. The States have clearly demonstrated they are likely to suffer irreparable harm absent preliminary injunctive relief. Here, there is ample evidence to support the States' position that the Public Health Funding Decision is causing immediate damage to their healthcare programs and the safety of their residents. While the Court acknowledges HHS' position that it may be unable to recover the grant funds if it later prevails, Congress's direction that the funds remain intact and the States' reliance on the continuation of the funding overshadows that argument. (ECF No. 68 at 39.) And unlike in *California*, the States here cannot keep their critical public health programs and services running in the meantime, so much

that a later award for money damages would be wholly inappropriate. *See California*, 145 S. Ct. at 967; ECF No. 60 at 14; ECF No. 65 at 8.

D. Balance of the Equities and Public Interest

To conclude, the balance of the equities and public interest strongly favor preliminary relief for the States. Not only do the States have a substantial interest in the effective operation of their public health systems, but the States have also represented that HHS' Public Health Decision, and its implementation, would result in devastating consequences to their local jurisdictions. (ECF No. 60 at 39.) As discussed in the preceding sections, the healthcare funding terminations would constrain the States' infectious disease research, thwart treatment efforts to those struggling with mental health and addiction, and impact the availability of vaccines to children, the elderly, and those living in rural communities. *See, e.g.*, ECF Nos. 4-3 ¶ 48; 4-6 ¶¶ 4-7; 4-15 ¶ 17; 4-40 ¶ 11; 4-41 ¶ 3. Not to mention that the terminations were effective immediately, ignoring the States' reliance on the funds. As a result, the States submit that they will be forced to "take immediate action to curtail their public health programs and undergo massive layoffs of highly trained employees and contractors." (ECF No. 60 at 40.) In comparison, the Government's argument that it is the one who stands to suffer irreparable harm in the meantime is unavailing. (ECF. 68 at 40.)

The Court weighs the "balancing of the equities and analysis of the public interest together, as they 'merge when the [g]overnment is the opposing party.'" *Does 1-6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021) (quoting *Nken v. Holder*, 556 U.S. 418,

435, 129 S.Ct. 1749, 173 L.Ed.2d 550 (2009)). The States' interest in safeguarding its public health systems is clearly paramount.

While the Court acknowledges the Government's position that it may be forced to spend money inconsistent with the Executive's agenda, an injunction would strongly serve the public interest in maintaining the States' healthcare systems and initiatives. (ECF No. 68 at 40-41.) "[T]he wisdom" of the Executive's decisions "[are] none of our concern." *Dep't of Homeland Sec.*, 591 U.S. at 35 (cleaned up). Rather, this case is one "about the procedure" (or lack thereof) that HHS followed in trying to enact the Executive's policies. *Id.* Agencies do not have unfettered power to further a President's agenda, particularly when Congress appropriated this money to the States to fund their public health systems and initiatives. Thus, when the Court weighs an agency's unreasoned, unsubstantiated, and likely unlawful determination that funding was "no longer necessary," against the States' interest and reliance on the funds to safeguard their public health outcomes, the balance of the equities and public interest are undeniably in the States' favor.

E. Bond

Federal Rule of Civil Procedure 65(c) states that the court may issue a preliminary injunction "only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." The Government asks the Court to require the States to provide a bond. (ECF No. 68 at 45–46.) The Court declines.

Rule 65(c) "has been read to vest broad discretion in the district court to determine the appropriate amount of an injunction bond," *DSE, Inc. v. United States*, 169 F.3d 21, 33 (D.C. Cir. 1999), "including the discretion to require no bond at all," *P.J.E.S. ex rel. Escobar Francisco v. Wolf*, 502 F. Supp. 3d 492, 520 (D.D.C. 2020) (internal quotation omitted). A bond "is not necessary where requiring [one] would have the effect of denying the plaintiffs their right to judicial review of administrative action." *Nat. Res. Def. Council, Inc. v. Morton*, 337 F. Supp. 167, 168 (D.D.C. 1971) (collecting cases); *cf. Nat'l Ass'n of Diversity Officers in Higher Educ. v. Trump*, No. 25-CV-333, 2025 WL 573764, at *30 (D. Md. Feb. 21, 2025) (setting a nominal bond of zero dollars because granting the defendants' request "would essentially forestall [the] [p]laintiffs' access to judicial review"). In a case where HHS is alleged to have unlawfully terminated large sums of appropriated and committed funds to numerous recipients against Congress's will and in excess of HHS' statutory authority, it "would defy logic—and contravene the very basis of this opinion—to hold" the States "hostage for the resulting harm." *Woonasquatucket*, 2025 WL 1116157, at *24.

IV. PRELIMINARY INJUNCTION

Upon consideration of the States' Motion for a Preliminary Injunction (ECF No. 60), it is hereby ORDERED:

1) Defendants and all their respective officers, agents, servants, employees and attorneys, and any persons in active concert or participation with them who receive actual notice of this order (collectively "Enjoined Parties") are hereby preliminarily enjoined from implementing or enforcing through any

means the decision made on or about March 24, 2025 that numerous health programs and appropriations responsible for $11 billion of critical federal financial assistance were "no longer necessary" because the "COVID-19 pandemic is over" ("Public Health Funding Decision"), including any funding terminations, or from taking any action to reinstitute the Public Health Funding Decision for the same or similar reasons. This injunction is limited to funding for Plaintiff States, including their local health jurisdictions and any bona fide fiscal agents of Plaintiff States or their local health jurisdictions.

2) The Enjoined Parties shall immediately treat any actions taken to implement or enforce the Public Health Funding Decision, including any funding terminations, as null and void and rescinded. The Enjoined Parties must immediately take every step necessary to effectuate this order, including clearing any administrative, operational, or technical hurdles to implementation.

3) Defendants' counsel shall provide written notice of this order to all Defendants and agencies and their employees, contractors, and grantees by the end of the day on Tuesday, May 20, 2025.

4) By the end of the day on Tuesday, May 20, 2025, the Defendants SHALL FILE on the Court's electronic docket a Status Report documenting the actions that they have taken to comply with this Order, including a copy of the notice and an explanation as to whom the notice was sent.

5) For the reasons stated in the Court's Order, the Court finds that a bond is not mandatory under these circumstances and exercises its discretion not to require one.

IT IS SO ORDERED.

Mary S. McElroy,
United States District Judge

Date: May 16, 2025

EXHIBIT B

HHS Grants Policy Statement

Effective date: April 16, 2025

This HHS Grants Policy Statement (GPS) replaces all prior versions

Contact grantpolicyreq@hhs.gov with GPS feedback

Contents

Introduction and General Information

The Grants Policy Statement (GPS) is incorporated by reference in the official Notice of Award (NoA) as a standard term and condition.

The GPS provides information on HHS agencies that make awards, the award process, and where to find and apply for awards. The GPS also provides information about the legal and regulatory rules that apply to your award and will be used for enforcement purposes. The GPS will be updated to reflect changes in law and policy.

The latest version of the GPS is at www.hhs.gov/grants/grants/grants-policies-regulations/index.html and it includes:

- Introduction and General Information
- Pre-Award
- Post-Award
- Single Audit
- Appendices

    A. Awarding Agency Overview
    B. Abbreviations and Glossary
    C. Post-Award Considerations by Type of Program, Activity, or Recipient
    D. HHS Administrative and National Policy Requirements
    E. Financial Assistance General Certifications and Representations

Supersession

This GPS replaces the HHS Grants Policy Statement dated January 1, 2007.

This GPS reflects the current 45 CFR part 75 regulation and eight flexibilities from 2 CFR part 200 (effective October 1, 2024). It will be updated in 2025 to reflect the HHS adoption of 2 CFR part 200 in its entirety and the retention of certain HHS specific provisions in 2 CFR part 300. From this date on, HHS plans to update the GPS annually to make sure it reflects changes in statutes, regulations, and policies.

Applicability

The 2024 HHS GPS applies to awards and award modifications that add funding made on or after April 16, 2025. This includes supplements to award, competing and non-competing continuations. The GPS applies to all HHS recipients and the requirements flow down to subrecipients.

The HHS GPS does not apply to awards made by the National Institutes for Health (NIH). For NIH awards, please see the National Institutes of Health Grants Policy Statement (NIHGPS), which is the policy document describing the requirements that serve as the terms and conditions of NIH awards.

The HHS GPS does not apply to non-discretionary awards or to awards made to individuals. HHS agencies have the discretion to apply certain parts of the GPS to non-discretionary awards and other policies to your non-discretionary or individual award.

Agencies that administer HHS awards include:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

See Appendix A for more information.

Requirements

The following impose requirements on your award and are addressed in the GPS:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75)
- Eight provisions of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200):

    1. 2 CFR § 200.1 Modified Total Direct Cost Definition, Equipment Definition, Supplies Definition
    2. 2 CFR § 200.313(e) Equipment Disposition
    3. 2 CFR § 200.314(a) Supply Disposition
    4. 2 CFR § 200.320 Micro-purchase Threshold
    5. 2 CFR § 200.333 Fixed Amount Subawards Amount
    6. 2 CFR § 200.344 Closeout Provisions
    7. 2 CFR § 200.414(f) Indirect Cost Rate Provisions
    8. 2 CFR § 200.501 Audit Provisions

- The Notice of Award (NoA)
- The Notice of Funding Opportunity (NOFO), if stated in the NOA

Other regulations or statutes with more requirements might apply to your award. These include:

- Grants for Research Projects 42 CFR part 52
- Procedures of the Departmental Grant Appeals Board 45 CFR part 16
- Claims Collection 45 CFR part 30
- Equal Treatment for Faith-Based Organizations 45 CFR part 87
- Restrictions on Lobbying 45 CFR part 93
- Metric Conversion Policy for Federal Agencies 15 CFR part 273
- Public Health Service Policies on Research Misconduct 42 CFR part 93
- Protection of Human Subjects, 45 CFR part 46

See Appendix D for more information.

Terms and Conditions

HHS states the requirements of an award in the award terms and conditions:

- The GPS is incorporated by reference as a standard term and condition of awards.
- The NoA includes all terms and conditions of a specific award.
- Notice of Funding Opportunities (NOFOs) describe program requirements, which may be included as terms and conditions.

Types of HHS Awards

Awards fall into two main types:

- Discretionary: HHS chooses who gets the award and how much. Selection of these awards are generally competitive. The amount of an award can be competitive or by a set formula. Types of discretionary awards include research, training, services, construction, and conference support.
- Non-discretionary: A statute determines the recipients and amounts, either directly or by a formula (i.e., each State gets an award of a certain amount). This includes block grants and entitlement programs.

Award Instruments

Award instruments are legal agreements between an awarding agency and a recipient. The two kinds generally addressed in the GPS are:

- Grants: The awarding agency is not substantially involved in the project (31 USC 6302, 6304).
- Cooperative agreements: The awarding agency is substantially involved in the project (31 USC 6302, 6305).

Roles and Responsibilities

This section highlights roles and responsibilities. The GPS supplies more details throughout.

Recipient Roles and Responsibilities

Recipients manage performance and funds. Required roles are:

- Authorized Organizational Representative (AOR): The AOR has authority to act for the organization and is responsible for meeting award requirements, properly managing the award, and providing oversight. The AOR's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- Principal Investigator or Project Director (PI/PD): The PI/PD is the individual(s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.

Awarding Agency Roles and Responsibilities

HHS is responsible to Congress and U.S taxpayers for carrying out its mission in a cost-effective and compliant way. The HHS agencies that administer awards have grants offices and staff designated to conduct this work. The roles and responsibilities of HHS staff (at each awarding agency) include:

- Grants Management Officer (GMO): The GMO is the official who handles the non-program parts of an award for the HHS agency. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the HHS awarding agency to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
- Grants Management Specialist (GMS): Acts as the main grants administration contact for recipients. Handles administrative activities on behalf of the GMO. The GMS contact information can be found on the NoA.
- Project Officer or Program Official (PO): Responsible for the programmatic, scientific, and technical sides of award programs, including oversight and monitoring. The PO contact information can be found on the NoA.
- Review Administrator (RA): Provides oversight of the application review process, although not all agencies have this role.

Pre-Award

This section helps you find funding opportunities, prepare, and apply.

Locating Funding Opportunities

Agencies announce competitive funding opportunities. All discretionary Notice of Funding Opportunities are listed on Grants.gov**.** There are three other ways to find more information about HHS financial assistance.

Grants.gov, Forecasts, and the Notice of Funding Opportunity (NOFO)

HHS policy requires maximum competition for discretionary grants to the greatest extent possible. As such, HHS agencies promote the widest and earliest possible spread of information through forecasts of upcoming grant opportunities and NOFOs. Awarding agencies post discretionary or competitive NOFOs at Grants.gov.

Grants.gov forecasting is the direct way to find NOFOs. NOFOs are usually open for at least 60 days. Only rarely are they open for fewer than 30 days.

Because HHS aims for the widest and earliest possible spread of information, HHS agencies post future opportunities on Grants.gov through forecasts. Forecasts may be posted weeks or months before NOFOs. Forecasted NOFOs can be found in the Grants.gov search page by clicking the "forecasted" button. Forecasts include helpful information such as:

- expected number of awards
- estimated award amounts
- description of the program
- estimated NOFO posting date
- estimated application due date
- estimated project start date and period of performance

How to Subscribe to HHS Grants Forecast

When you create a Grants.gov account, you can customize the type of email notifications you receive. Log in and then go to the subscription page to sign up for news updates about system enhancements, notifications about saved searches, new funding opportunities, and more.

Awarding Agency Websites

Most awarding agencies have award web pages. See Appendix A.

SAM.gov and Assistance Listings

Assistance listings are public descriptions of federal assistance programs. All assistance listings are included on the System for Award Management (SAM.gov), a site run by the U.S. General Services Administration. Search assistance listings at SAM.gov.

Preparing to Apply

The first step is to read the entire NOFO and the links in it. Each part of the NOFO sets out basic information for that award.

To apply, you must:

- be an eligible entity
- address the NOFO requirements
- submit a complete and compliant application by the deadline(s)

General Eligibility Considerations

In general, HHS awards may be made to domestic public or private, non-profit or for-profit organizations. Foreign or international organizations are eligible for research awards, or if expressly authorized by law.

The NOFO includes specific eligibility criteria and any requirements to prove eligibility. Applicant eligibility criteria for all HHS NOFOs are almost always based on statute or program regulation.

HHS policy requires open competition to the greatest extent possible. Restricting eligibility, as compared to statute or program regulations, is only done with appropriate justification in rare cases.

Agencies review applications for eligibility when they receive them. The AOR signature generally serves as assurance of eligibility, unless additional proof of eligibility is required in the NOFO. If the applicant is not eligible, the application will not be reviewed.

Additional Eligibility Restrictions

Concurrent Applications

You cannot apply for funding for the same project or activities from multiple HHS Public Health Service (PHS) agencies at the same time. If you do, your applications will be returned. See Appendix A for a list of PHS agencies.

Suspension, Debarment, and Exclusion

Agencies are required to check SAM.gov for individuals and organizations that are debarred, suspended, declared ineligible, or voluntarily excluded from receiving HHS award funds. HHS will not give awards to or pay these individuals and entities, including recipients and subrecipients. If such an individual is involved in an award, costs like their salary are not allowed.

Applicants must disclose if any of the following conditions apply to their organization, planned staff or principals (as defined in 2 CFR § 180.995), including Principal Investigators (PIs), and other key personnel:

- Are currently excluded or disqualified;
- Were convicted within the previous three years of any offenses listed in 2 CFR § 180.800(a) or had a civil judgment for one of those offenses during that time;
- Are currently indicted for or otherwise facing criminal or civil charges by a governmental entity (federal, state, or local) for any of the offenses listed in 2 CFR § 180.800(a); or,
- Have had any public transactions (federal, state, or local) terminated within the previous three years for cause or default.

Recipients of HHS awards must also make subrecipient organizations and subrecipient participants follow federal Debarment and Suspension regulations (2 CFR part 376 and 2 CFR part 180). These participants can include:

- Consortiums
- Subcontracts
- Consultants
- Collaborators
- Contractors that require the provision of goods or services that will equal or exceed $25,000

These subrecipients must also make sure that anyone they hire with award funds follow the same rules. Before entering into an agreement, these participants should tell the award recipient if he, she, or any principals are excluded or disqualified at that time.

Ultimately, it is the job of the applicant or recipient to make sure none of the subrecipient and principals involved are excluded or disqualified. Award recipients cannot make a transaction with someone who is disqualified unless they get an exception under the disqualifying statute, Executive Order, or regulation from HHS.

For more information, see Suspension and Debarment at 45 CFR § 75.213, 2 CFR part 180 and 2 CFR part 376.

Delinquency on Federal Debt

If an entity or individual owes money to the U.S. with a lien, they cannot get an award. Applicants must state in their applications whether they are delinquent on any federal debts. Agencies may delay awards until federal debts are settled.

Do not include a person in the application if they have unpaid federal debts with a lien. Agencies will disallow costs for these individuals.

See 28 U.S.C. 3201(e).

Lobbying Prohibition

Applicants must certify they will not use federal funds to pay any person to influence agency staff, Congress members, and officers or employees of Congress about federal awards.

Applicants with total proposed costs of more than $100,000 must certify that they:

- have not made unallowable lobbying payments,
- will be responsible for reporting on non-federal funds used for lobbying,
- will include these requirements in consortium agreements, subawards, and contracts of more than $100,000 under their award.

See 2 CFR part 93, 2 CFR § 200.450, and the SF-424 for more about lobbying requirements.

HHS Application Process

Types of Applications

HHS uses these application types:

- New application: A request for funds for new activities. It can be competitive or not.
- Non-competing continuation application: A request for funds for the next budget period(s) within a period of performance. Agencies provide an NoA with new budget details.
- Competing continuation or renewal application: A request to continue a project that is ending with a new period of performance. This is competitive.
- Supplemental application: A request for more funds in the current budget period. This can be for changes in the project scope, expansion of already approved activities, or for unexpected costs.
- Revised application: A previously not funded application updated and submitted again for review.

Pre-applications and Letters of Intent

Before a full application, an agency might ask for:

- Pre-applications: Used to filter out applicants that will be unlikely to receive funding through an objective review. This saves time before writing a full application.
- Letters of Intent: Agencies might want notice that you plan to apply. This is usually optional and doesn't mean you have to apply. It's mostly to gauge interest and help the HHS agency estimate how many applications to expect.

Application Forms

Forms and instructions are on Grants.gov. You can find a NOFO's required forms in the application package in Grants.gov. The NOFO is your best source when completing forms. The NOFO agency contact, located on the NOFO, can answer any questions you may have.

Application Budgets

You will need to include a budget as part of your application. Some applications require a detailed budget. The NOFO will describe the budget requirements. For HHS budgets, applicants and recipients need to understand:

- The costs allowable under the program
- The relevant cost principles
- The difference between direct and indirect costs
- When you need an indirect cost rate or research patient care cost rate, and
- Any matching or cost sharing requirements

Project costs include allowable direct costs plus allocable indirect costs, minus applicable credits. See below Cost Principles, Direct Costs and Indirect Costs sections of the GPS.

Cost allowability is subject to the governing statute, program regulations, and award terms and conditions. There are situations when HHS will not reimburse indirect costs.

Cost Principles

Developing an application budget depends on understanding what costs are allowable under HHS financial assistance programs.

For more information about how cost principles apply to your organization, see 45 CFR § 75.401.

This section on cost principles interprets the regulations at 45 CFR part 75 and is not all-inclusive.

Cost principles:

- Establish general standards for the allowability of costs.
- Provide guidance on treating costs as direct or indirect.
- Provide principles for selected items of cost.

The cost principles apply to all recipients.

You can use your own accounting system to implement the cost principles if you meet the standards for financial management systems at 45 CFR § 75.302.

The federal-wide cost principles are in 45 CFR part 75, subpart E.

The cost principles for:

- Hospitals are at 45 CFR part 75 Appendix IX
- For-profit organizations are at 48 CFR § 31.2

If specifically identified, use the applicable cost principles for your type of organization. Cases where the cost principles do not apply are listed in 45 CFR § 75.401(a).

Is It Allowed?

As the HHS agency official for the non-program parts of awards, the Grants Management Officer (GMO) makes the final determination on allowability.

For all allowability requirements see 45 CFR § 75.403. Following is a summary.

A cost is allowable if all the following apply:

- It is necessary and reasonable for award performance.
- It complies with any limitations or exclusions in the cost principles or the federal award about types or amounts of cost items.
- It is consistent with policies and procedures across all recipient activities, regardless of source of funding.
- It is consistent across all activities in identifying direct and indirect costs.

- It follows generally accepted accounting principles (GAAP). See 45 CFR § 75.403(e) for exceptions.
- It is not used for cost-sharing requirements of another federally financed program, unless specifically allowed by law.
- You maintain required documentation.

Is It Reasonable?

For all reasonableness requirements see 45 CFR §75.404. Following is a summary.

Considerations for reasonableness include:

- If the cost is generally recognized as ordinary and necessary.
- The requirements of:
    - Sound business practices
    - Arm's-length bargaining
    - Federal, state, local, tribal, and other laws and regulations
    - Terms and conditions of the federal award
- If the cost aligns with market prices for comparable goods or services in the geographic area.
- The cost does not significantly deviate from your established practices and policies regarding such costs, regardless of source of funding.

Allocability

Allocability in grants means costs that can be applied to your award. For all allocability requirements see 45 CFR § 75.405. Following is a summary.

A cost is allocable if any of the following apply:

- It is spent only for the work under a federal award.
- It benefits both the federal award and other recipient work and can be distributed using reasonable methods.
- It is necessary to your overall operations and can be assigned to the federal award.

Direct and Indirect Costs

Costs can be direct or indirect:

- Direct costs: Directly related to the cost of the project or project activities. These costs are based on actual expenses or easily estimated accurately. Examples of direct costs are generally salaries, travel, equipment, and supplies directly for grant activities.
- Indirect costs: Not readily tied directly to the project or project activities. If a cost is indirect, it cannot also be listed as a direct cost for any federal award. Examples may be facilities operation and maintenance costs, depreciation, and administrative

expenses. You must have or negotiate an indirect cost rate to reimburse indirect costs.

See 45 CFR §§ 75.413-414, and 45 CFR § 200.414.

Indirect Cost Rates

As stated above, indirect costs are for common activities that cannot be specifically tied to a particular project. Examples include facilities operation and maintenance costs, depreciation, and administrative expenses. You must treat costs as direct or indirect consistently.

Indirect costs are allowable under most HHS awards and are charged as a rate. There are three ways indirect costs may work:

- Specified rate. The rate may be specified in statute, regulations, or policy. If this is so, the difference between the specified rate and the negotiated rate can satisfy match or cost sharing requirements. There are three HHS-specific specified rates to consider:
- Training grants, including career awards, are limited to 8%.
- Indirect costs to foreign organizations and foreign public entities when the awarded work is performed fully outside of the territorial limits of the U.S. are limited to 8%.
- Negotiated Indirect Cost Rate Agreement (NICRA). You can negotiate a rate with your cognizant federal agency. If the cognizant agency is HHS, a rate is negotiated by Program Support Center Cost Allocation Services (CAS) or the Division of Financial Advisory Services (DFAS) in the NIH Office of Acquisition Management and Policy (responsible for negotiating indirect cost rates for for-profit recipients). Indirect cost proposals must use the applicable cost principles and cognizant agency guidance.
    - See 45 CFR part 75, Appendix III for institutions of higher education.
    - See 45 CFR part 75, Appendix IV for non-profits.
    - See 45 CFR part 75, Appendix V for state and local government cost allocation plans.
    - See 45 CFR part 75, Appendix VI for public assistance.
    - See 45 CFR part 75, Appendix VII for state and local governments and Indian Tribe indirect cost plans.
- De minimis rate. If you do not have a NICRA, you can use the de minimis rate indefinitely. We are applying the newly revised rate, in 2 CFR § 200.414(f), of 15% of modified direct costs. Modified direct costs are salaries and wages, fringe benefits, materials and supplies, services, travel, and no more than $50,000 of each subaward, minus some exclusions. See 2 CFR § 200.2 for the full definition. See 2 CFR § 200.414 for more on the de minimis rate.

The de minimis rate is not applicable for some recipients. These recipients include governmental agencies that receive more than $35 million in direct funding and Indian tribal governments. See 2 CFR Appendix VII to § 200 D.1.b.

Exclusions

Some HHS awards and recipients are not eligible for indirect cost reimbursement. This will be described in the NOFO.

Indirect costs are not paid for:

- Grants to federal institutions, 45 CFR § 75.217(b)(3)
- Grants to individuals, including fellowships, scholarships, traineeships, or fixed amounts like educational allowances or tuition and fees, 45 CFR § 75.2 (Definition of Micro-Purchase Threshold).

Pass-through Entities

Pass-through entities must use their subrecipient's federal NICRA. A 15% de minimis rate may be used if there is no federally negotiated agreement. See 2 CFR § 200.414.

Salary Rate Limit (SRL)

Generally, the HHS Appropriations Act includes an SRL. This statutory requirement limits the amount of funds under a grant or other extramural mechanism that can be used to pay individual salaries (including executive salaries) at a rate above the Executive Level II. Recipients may pay salaries at a rate higher than the Executive Level II if the amount beyond the HHS SRL is paid with non-HHS funds. Since the Executive Level II rate and HHS Appropriations Act citation changes each year, HHS refers to the Office of Personnel Management (OPM) posting the most recent information at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/exec/html/EX.aspx.

The HHS SRL applies to:

- The majority of HHS awards.
- Both direct and indirect costs under applicable HHS awards.

Effective October 1, 2024, when HHS is the cognizant agency for indirect costs or when HHS is acting as the shared-service provider for another cognizant agency for indirect costs, the HHS component that reviews and negotiates indirect cost rate proposals and cost allocation plans will issue NICRAs that incorporate the HHS SRL, to comply with the HHS Appropriations Act requirement.

Beginning with HHS awards, including continuation and supplemental awards, made on or after October 1, 2024, HHS recipients that do not have an approved indirect cost rate that complies with the HHS SRL requirement must take and document the following actions.:

- Identify any HHS award where HHS funds are used to pay any salary that exceeds the SRL using the HHS award. This includes both direct and indirect costs, both in whole and any portion of a salary that at a full-time equivalent exceeds the SRL.
- Have written policies and procedures that ensure the recipient does not draw down HHS award funds, whether as direct or indirect costs, to pay for salaries above the HHS SRL.

This may occur because the NICRA was issued before October 1, 2024, and it is not yet up for renewal, OR because the NICRA was issued by another cognizant agency for indirect costs that does not have an identical SRL.

A recipient may request a companion rate on the NICRA from HHS that does not incorporate the HHS SRL if:

- HHS is their cognizant agency for indirect costs or HHS is the shared-service provider for their cognizant agency for indirect costs; and
- The recipient is applying for an award from another Federal agency or from a program not subject to the HHS SRL.

Cost Sharing

Cost sharing refers to project costs that are not funded by the HHS agency. It is also sometimes called "match."

Cost sharing can be voluntary or can be required by statute or regulation.

NOFOs include information about:

- Whether there is required or voluntary cost sharing
- The agency's approach to looking at cost sharing during the application review
- Any caps on the agency's portion of total award costs
- Any restrictions on the types of funding that are acceptable as cost-sharing (e.g., in-kind contributions)
- Required documents, like commitment letters

See more on cost-sharing requirements at 45 CFR § 75.306.

Program Income and Third-Party Reimbursement

Program income is money a recipient earns that is both:

- Earned during the period of performance
- Earned directly from an activity funded by the award or due to the award

This can include money earned from things like:

- Services performed under the award,
- Renting property bought with award funds,
- Selling items made with award funds,
- Third-party reimbursement, such as payments for health services, and fees based on ability to pay,
- Principal and interest on loans made with award funds, and
- Royalties from patents and copyrights.

It does not include:

- Interest earned on advances of Federal funds or things like rebates, credits, discounts, and interest earned on any of them unless stated otherwise in the NOFO or NoA.

The full definition for program income is found at 45 CFR § 75.2 "Program income"

NOFOs might ask for estimated program income in the budget. NOFOs explain how to use expected program income.

There are no requirements for what to do with income earned after the end of the award period of performance, unless the NOFO or NoA says otherwise.

See more on the treatment of program income at 45 CFR § 75.307.

Unique Entity Identifier (UEI) and Registering in SAM.gov

Every applicant needs a Unique Entity ID (UEI) from SAM.gov.

- For a new UEI, register on SAM.gov. You'll get an email when it's active. This can take time.
- If you already have a UEI, renew on SAM.gov yearly.
- Keep your SAM registration details current.
- Make sure that your SAM registration is accurate for both contracts and grants.

For more information, see Get Ready for Grants Management at HHS.gov.

State and Local Review Requirements

Federal rules allow state and local governments and health agencies to review and comment on applications. You will find the requirements in the NOFO. There are two types of reviews:

- Intergovernmental review. Executive Order 12372 and 45 CFR part 100 allow for intergovernmental review by state and local governments through the State Single Point of Contact (SPOC).
- Public health system reporting. This reporting provides state and local health agencies with information on applications by health care delivery programs. If a state or local health official wants to review a full application, the official contacts the SPOC.

Contact your SPOC to learn more. Find SPOCs at the Office of Management and Budget website. Not all states have this process.

Applying

In almost all cases, you will need to submit applications online. All HHS agencies are required to post their competitive NOFOs on Grants.gov and will also post there how to apply online.

Agencies will not review applications that are from ineligible applicants, incomplete, are not compliant, or are not responsive to program requirements.

Send your application by the NOFO's deadline. If you are late, it will almost always be deemed non-compliant and will not be reviewed.

The AOR's signature on an application certifies that:

- The information in it is truthful, complete, and accurate,
- The applicant will comply with all required certifications and assurances,
- The applicant will comply with terms and conditions when accepting an award, and
- The non-federal entity is aware that any false, fictitious, or fraudulent statements or claims may subject the applicant to criminal, civil, or administrative penalties.

Some agencies might allow paper or email submissions. The NOFO will explain exemption requests. These are rare.

> PLEASE NOTE: Applicants must register with Grants.gov. For how to register with Grants.gov, see Registering an Organization or contact the Grants.gov contact center at 1-800-518-4726 or support@grants.gov. Registering can take up to one month.

Application Receipt and Review

Initial Eligibility Review

The awarding agency screens applications for eligibility. Unless the NOFO requires specific proof of eligibility, the AOR's application certification is enough.

Use of Application Information

Agencies protect your application information during merit review and in accordance with laws like the Freedom of Information Act and Privacy Act of 1974. Once awarded, the government can only use or share data as federal law allows. To help safeguard your information:

- Avoid sharing personally identifiable information.
- Only add confidential information if necessary.

See the Access to Research Data section of the GPS.

Merit Review

Merit review is a review by those with expertise in the programmatic subject matter area for the submitted applications.

Applications for discretionary programs, whether received in response to a NOFO, requested from a single source (very rare), or received as an unsolicited request for grant funding, will go through a merit review.

The merit review provides recommendations to the individuals responsible for making award decisions. Merit review is necessary to make sure HHS choses applications that best meet the needs of

the program. These needs must be based on what the NOFO says about what makes a successful application.

Peer review is a form of merit review. Reviewers are peers with expert knowledge about how the program topic. Sometimes, the program statute may tell us which type of reviewers to pick or how a review should happen.

Award Risk and Business Review

Before award, agencies do pre-award risk and business reviews of applications. These can include:

- Cost analysis of the budget
- Assessment of management systems
- Final review of applicant eligibility
- Compliance with public policy requirements

During this review, the agency might request more details or actions from you.

Following review, officials make decisions about making the award, adding special conditions, and funding level.

Cost Analysis

HHS agencies careful review of the applicant budget includes:

- a review of the cost breakdowns
- a check to make sure the cost data in the application is correct
- an overall review of the costs for need for and the reasonableness and allowability of proposed costs

The review depth depends on project complexity, applicant prior experience, and other factors.

Management System Analysis

Applicants must have systems, policies, and procedures in place to manage award funds and activities. HHS agency staff take a close look at your financial and business management systems. This review includes property management and procurement systems and helps ensure:

- Applicant organizations apply policies and procedures consistently, regardless of funding source, and
- Systems meet the standards and requirements in 45 CFR § 75.302, Financial Management.

Civil Rights Assurance

Domestic recipients, subrecipients, and contractors must file Form HHS 690, Assurance of Compliance once with the HHS Office for Civil Rights (OCR). It is not needed for each application.

The recipient must ensure that subrecipients and contractors have filed the form.

Additionally, recipients must comply with all applicable Federal anti-discrimination laws material to the

government's payment decisions for purposes of 31 U.S.C. § 372(b)(4).

(1) Definitions. As used in this clause –

(a) DEI means "diversity, equity, and inclusion."

(b) DEIA means "diversity, equity, inclusion, and accessibility."

(c) Discriminatory equity ideology has the meaning set forth in Section 2(b) of Executive Order 14190 of January 29, 2025.

(d) Discriminatory prohibited boycott means refusing to deal, cutting commercial relations, or otherwise limiting commercial relations specifically with Israeli companies or with companies doing business in or with Israel or authorized by, licensed by, or organized under the laws of Israel to do business.

(e) Federal anti-discrimination laws means Federal civil rights law that protect individual Americans from discrimination on the basis of race, color, sex, religion, and national origin.

(2) Grant award certification.

(a) By accepting the grant award, recipients are certifying that:

(i) They do not, and will not during the term of this financial assistance award, operate any programs that advance or promote DEI, DEIA, or discriminatory equity ideology in violation of Federal anti-discrimination laws; and

(ii) They do not engage in, and will not during the term of this award engage in, a discriminatory prohibited boycott.

(3) HHS reserves the right to terminate financial assistance awards and claw back all funds if the recipients, during the term of this award, operate any program in violation of Federal anti-discriminatory laws or engages in prohibited boycott.

Human Subjects and Animal Welfare Assurance

If IRB review and approval is required but still pending at the time of award, agencies will restrict human subjects research until they get and approve the needed proof. Additional information is available on the Office of Human Research Protections website. This includes a series of decision charts to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

Before getting an award, if applicants plan to use vertebrate animals, they must send an Animal Welfare Assurance to HHS' Office of Laboratory Animal Welfare. This confirms that a committee has reviewed the parts of the application related to animals.

Communicating Decisions

Agencies inform applicants about their decisions in various ways:

- Award: If you are getting an award, you will receive a Notice of Award (NoA).
- Denial: If the agency decides not to fund your application, the AOR gets a letter.
- Approved unfunded: Sometimes, despite a good review, there's not enough funds.

The awarding agency could keep your application for future funding. The awarding agency will notify the AOR that your application is approved but unfunded.

- Revised application eligibility: If not successful, the NOFO might allow you to adjust and reapply later. However, some agencies cap the number of revisions and retries.

You cannot appeal a denial or the amount of funds awarded.

The Notice of Award

The Notice of Award is a legal instrument. See 45 CFR § 75.210 for the contents of an NoA.

Accepting the Award

Once accepted, the contents of NoAs are binding.

Applicants become recipients when the NoA is signed by the awarding agency's Chief Grants Management Officer (CGMO) or his/her delegate. The recipient accepts an award by drawing down funds. HHS expects recipients to draw down funds in the first 30 days of the period of performance.

Declining or Negotiating Awards

During the time between the NoA being signed and the drawing down of funds, if you can no longer accept an award or you need to negotiate any award parts, tell the awarding agency. If no agreement is reached, the agency will cancel the award. You cannot challenge the agency's decisions on the terms and conditions.

Periods of Performance

HHS uses the period of performance system for funding awards. Funding is provided in approved yearly increments called budget periods. The total period of performance includes the initial competitive

segment, any additional segments authorized by approved continuation applications, and any no-cost extensions.

A competitive segment usually will be no longer than five years, not including no-cost extensions. A single federal award for the entire period of support may be used if the project is only construction or modernization or if the total planned project will be less than 18 months.

The awarding agency will determine the length of the period of performance based on:

- Any statutory, regulatory, or administrative requirements,
- The length of time requested by the applicant,
- Any time limits on the period of performance recommended by merit review,
- The frequency of merit review, and
- The funding principles as specified in the NOFO.

The NoA generally approves a period of performance that goes beyond the current budget period, showing the HHS awarding agency's intention to continue providing support. Funding for future budget periods is not guaranteed at the level shown on the current NoA. There is no legal obligation for HHS awarding agencies to provide funding beyond the end date of the current budget period in the NoA.

Recipients must submit a continuation application or annual report to get approval and funding for each new budget period within the approved period of performance. The HHS agency will make its decision to fund the next budget period by issuing a NoA which shows the new budget period and amount of new funding. Funding is based on adequate performance, availability of funding, and the best interests of the federal government.

Budget periods usually last 12 months. However, they may be shorter or longer based on programmatic or administrative needs. The NoA will show the total approved budget for the applicable budget period. This includes direct costs, applicable indirect costs, and any required matching or cost sharing.

Costs in the NoA

The initial NoA and each subsequent NoA provide details of the award and the amount awarded. After the initial budget period, NoAs may reflect any authorized carryover and amounts previously awarded for the full period of performance. The amount awarded is shown either as total direct and indirect costs and as a categorical (line item) budget breakdown. This is based on the requirements in the NOFO.

Recipients have certain rebudgeting flexibility within the overall amount awarded. However, the total amount awarded is the maximum amount the awarding agency is obligated to pay under that award. Once an award is made, the HHS awarding agency is not required to provide any supplemental or additional funding.

Post-Award

As a recipient, you will manage HHS awards and activities including:

- Project performance, 45 CFR § 75.301 and 2 CFR § 200.202

- Use of award funds
- Compliance with award terms and conditions
- Issuing and monitoring subawards per 45 CFR § 75.352

Recipient internal controls and policies must meet 45 CFR § 75.303.

Awarding agency staff monitor recipients for compliance, performance, and need for technical assistance. Reviews include:

- Recipient reports
- Financial and progress reports
- Audit reports
- Correspondence,
- Onsite and remote site visits, and
- Other information.

The Notice of Award supplies HHS contact information and instructions for reporting.

Changes to Awards

Prior Approvals

At times, you may need to make changes to the program budget or activities. Some changes require prior written approval. To find out if a change needs prior approval:

- Carefully review your NoA.
- Review 45 CFR § 75.407 for actions needing prior approval.
- Review Appendix E of the GPS for prior approval requirements for certain types of awards.
- Ask your GMS if you are not sure.
- Ask your cognizant agency for indirect costs if you have questions about changes to indirect costs. The cognizant agency is the federal agency that approved your indirect cost proposal.

Seeking Prior Approval

Once you know that you need prior approval, you can request it from your GMS. Prior approval requests must include:

- Recipient name
- Principal investigator (PI) or project director (PD) and authorized organizational representative (AOR) name
- PI or PD and AOR telephone numbers and e-mail addresses

You must send your prior approval requests in writing, by mail, prior approval system, or email. It must:

- Be signed by the AOR (if sent in an email, attach the signed letter/memo)
- Include any necessary supporting documentation
- Get to the awarding agency in enough time for approval before making the change

Once received, the awarding agency GMO or his or her designee will review and approve or deny the request:

- If the GMO or GMS decides the change does not actually require prior approval, the awarding agency must promptly inform you.
- If prior approval is required, the GMS will send a decision to the AOR with a copy to the PI or PD within 30 calendar days of receipt.

Only the GMO or GMS, as the GMO's delegate, can issue written approval. Informal answers are not valid.

There is no appeal for denial of a prior approval request.

Subrecipient Prior Approvals

The recipient has the authority to give prior approval for changes to sub-award or contract activities or budget. This does not include any action inconsistent with the award purpose or terms and conditions. The awarding agency must approve any actions that will result in a change to project scope. Ask the GMS if you have questions about a proposed change.

Budget and Scope Changes

Minor Budget Changes

Within a budget period, you can adjust your budget without prior approval if:

- The change is within or between approved direct cost categories.
- Your award's federal share is below the simplified acquisition threshold, and your NoA doesn't include a prior approval need. Check the current threshold in the Federal Acquisition Regulation (FAR) at 2.101, Definitions.

Significant Budget Changes

Significant budget changes require prior approval when they constitute a change of scope or exceed 25 percent of total direct costs of the last approved budget period. When you are not clear if your budget change is beyond the scope, call your GMS.

Expanded Authority

If expanded authority is not granted in your NoA, you do not have it. To know if you have any expanded authorities:

- Review your NoA. Expanded authorities may be adopted by reference.
- Review your specific award conditions. These may include expanded authorities or limits on them.

When using expanded authorities as granted in the NoA, make sure you follow award requirements and the cost principles. All changes are subject to monitoring, audit, and related remedies for noncompliance. See the section below.

For a full understanding, see 45 CFR § 75.308(d)(1). Expanded authorities may include:

- Waiving the prior approval requirements in 45 CFR part 75, except for those listed in 45 CFR § 75.308(c)(1); and
- Three specific waivers in 45 CFR § 75.308(d), including:
    - Incurring project costs up to 90 calendar days before award. Doing so is at the recipient's risk.
    - Carrying forward unobligated balances to the next budget period unless the funds are currently restricted. You need prior approval to carry forward any unobligated balance to any budget period other than the next budget period.
    - Initiating a one-time extension of the period of performance by up to 12 months unless any of the following are true:
        - The extension requires additional federal funds
        - The extension involves any change in the approved project objectives or scope

Recipients may not use a one-time extension only to use unobligated balances.

Please Note: For awards that support research, unless your awarding agency provides other instructions in the NoA in general or because it is part of a regulation, the three specific waivers above (in 45 CFR § 75.308(d)) are automatic and noted in your NoA.

Several expanded authorities have specific deadlines for reports or notification. If a recipient consistently fails to meet them, the awarding agency may stop their ability to use them. Be sure to read your NoA carefully or ask your GMS if you have questions about expanded authorities under your award.

Extensions to Awards

The awarding agency may provide more time and funds after an award is made. The two types of extensions are:

- No-cost extensions: A time extension without more funds.
- Funding extension with funds: A time extension with added funds.

No-Cost Extensions

HHS agency prior approval is required for no-cost extensions, unless provided as an expanded authority.

When prior approval is required, the recipient must request the no-cost extension no less than 10 days prior to the end of the budget period.

In cases where there is expanded authority, the recipient must notify the HHS agency in writing with the supporting reasons and a recommendation for revised period of performance at least 30 calendar days before the end of the period of performance in the original NoA.

Regardless of whether approval is required, no-cost extensions are not meant to just spend unobligated funds. The purpose of a no cost extension is to:

- complete the project,
- provide for an orderly shutdown, or
- in some cases, provide a bridge to the next award.

If using expanded authority, and you do not need permission, you must tell the awarding agency.

Reminders for All Extensions

- You can't extend a period already lengthened by the awarding agency.
- Award terms and conditions still apply during the extended time.
- No matter the extension length, you must keep sending required reports as set out in your award.
- You must update all necessary certifications and assurances, including those about human subjects and animal welfare, following relevant rules and policies.
- A second extension longer than 12 months should be rare and will need special justification.
- If the agency denies an extension, you cannot appeal it.

Supplemental Funding Extension Without Change in Scope

A recipient may request supplemental funding with an extension of time without a change in scope that is under 25% of the total approved budget or $250,000, whichever is less, for the period of performance. These extensions are not competitive. Approving a request is at the discretion of the agency and depends on availability of funds.

Supplemental Funding Extension with Change in Scope

For supplemental funding and an extension of time with a change in scope, you must submit the request at least 30 days before the period of performance ends. The request must include the proposed revised ending date and justify both the extension and any additional funds. These extensions are not competitive. However, the HHS agency will conduct a merit review and will have to internally justify the award.

Transferring Major Work to A Subrecipient

Non-Pass-Through Programs

For these awards, you have a substantial project role and cannot just be a conduit for another party.

Before transferring major or substantive work to a subrecipient not in the approved application, you must get prior approval. This does not apply to buying or obtaining regular goods or services.

When asking for prior approval, include:

- What activities or tasks you want to transfer.
- Why a third party should do them.
- A detailed cost estimate and reasons, including any indirect costs and their reimbursement method.
- How you'll choose the subrecipient.
- The type of subaward planned.
- The types of organizations you'll solicit. If you've already chosen one, name it and explain why.

Pass-Through Recipient

A pass-through recipient means a non-Federal recipient that provides a subaward to a subrecipient to carry out part of a Federal program. In a pass-through program, the recipient:

- Chooses subrecipients to deliver services.
- Coordinates and oversees their activities
- Gives needed administrative support to meet awarding agency requirements.

For these programs, you don't need prior approval to give a subaward.

Change in Recipient or Recipient Status

The following section addresses policies for changes in recipient organization, scope, status of key personnel, and organizational status.

Change of Recipient Organization

To transfer the legal and management responsibility of an award to another organization, you must get prior approval.

The awarding agency must ensure the award's purpose and scope remain the same and the transfer aligns with federal appropriations laws and the statute or authority for the underlying award.

HHS allows transfer to a new recipient organization if:

- The award to be transferred has been terminated per 45 CFR § 75.372.
- There is a successor in interest or name change. Please contact your GMS for more information about the difference between these two.
- The awarding agency holds back a non-competing continuation award for reasons other than the project's performance. This can relate to the recipient's award management or not meeting terms and conditions.
- The original recipient agrees to give up the award before the period of performance ends. This can happen if a PI moves to a different organization. The project, with the same PI, can continue up to the current period of performance but not beyond. Costs cannot exceed the approved direct and applicable indirect costs.

Send your request as soon as possible before the end of the approved budget period within the period of performance.

If you want a change in organization, you must get prior approval from the GMS and sometimes, the Office of General Counsel. Contact the GMS if you believe the award needs to go to a new organization, ideally a few months ahead. Early requests enable important discussions, smooth review of the request, and avoid delays.

Supporting Documentation Needed for Requests

From the original organization:

- The PHS 3734, "Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant," or an equivalent form from the awarding agency.
- For research awards, include a "Final Invention Statement and Certification."
- A final Federal Financial Report within 120 days after the end of HHS support.

From the proposed new organization, the awarding agency will request an application and will provide instructions for completing the application.

Requirements for Review and Possible Approval

Transfer requests are only considered when:

- All benefits of the original award, including equipment purchased fully or partly with award funds, are transferrable;
- The awarding agency decides there is a continued need;
- There is no change in the project's scope. If there is, it may need a merit review and possibly a different procedure;
- The facilities and resources at the new organization will allow for successful performance; and,
- For transfers to or between foreign or international organizations, any special approval requirements are met. This might include approval by an advisory council or board.

Even if the requirements above are met, the HHS agency may reject the request or terminate the award.

To implement a recipient change, the HHS agency:

- Sends a revised NoA to the original recipient, updating the budget and end dates;
- Removes any support for future years;
- Deobligates any remaining funds, based on the expenses from the relinquishing statement; and,
- Issues an NoA to the new recipient, reflecting the balance from the relinquishing statement.

Change in Scope

The PI/PD may want to make changes in the methodology, approach, or other aspects of the project that do not change the scope. The GMS must give prior approval for a proposed change in scope.

A change in scope occurs when the recipient proposes to change the objectives, aims, or purposes identified in the approved application. This might include:

- Shifting the research emphasis from one disease area to another;
- Changing the service area;
- Eliminating a primary care delivery site; or,
- Making budget changes that cause a project to change substantially.

The HHS agency makes the determination of whether a proposed change is a change in scope.

Change in Status of Key Personnel

Key personnel include the PI or PD and any other key personnel named in the NoA.

Provide written request to the GMS if any key personnel:

- Withdraw from the project entirely;
- Are absent from the project for a period of three months or more; or,
- Reduce time devoted to the project by 25 percent or more from the approved level.

The awarding agency must approve replacement of key personnel, or any alternate arrangement proposed.

A request for approval to substitute key personnel includes:

- A justification for the change
- The proposed person’s biography
- Other sources of support, if applicable
- Any budget changes resulting from the proposed change

If your proposed arrangements are not acceptable to the awarding agency, they may suspend or terminate the award. If unable to make suitable arrangements, you may relinquish the award. To do so, notify the GMS in writing. The GMS will forward closeout instructions.

Change in Organizational Status

You must inform the awarding agency ahead of time about specific changes in your organizational status to ensure a smooth transition and maintain compliance with administrative requirements. The following are the situations that require prior notification:

- Successor-in-interest: This happens when the obligations and rights of an award are acquired as a part of the transfer of assets. Common causes include legislation or legal actions such as mergers or shifts in corporate structure.
- Name change: This occurs when an organization changes its name, but it doesn't affect the rights or obligations of the award recipient.

- Merger: This is when two or more entities legally unite. Handling of this scenario depends on its nature:
    - If the merger results in the transfer of awards, use the policies for a successor-in-interest.
    - If the merger doesn't involve award transfers, it's treated as a name change.

If the change would be considered a change of recipient organization as discussed above, then you must obtain prior approval.

For any change in organizational status, ask your GMS. This agency is usually the one that has granted you the most awards. The GMS can clarify whether the change will be treated as a name change or a successor-in-interest and guide you on the necessary steps to follow.

Financial Management

You must meet the standards and requirements for financial management systems in 45 CFR § 75.302. You must have adequate internal controls and a way to manage your award consistent with Department of the Treasury requirements. See the Payment section of GPS.

Financial management systems must:

- Provide accurate, current, and complete financial information about federal awards.
- Provide reasonable procedures to ensure that subaward recipients submit timely financial reports.
- Maintain records that:
    - Identify the sources of funds for award-assisted activities
    - Identify the award's purposes and uses, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income
    - Include accounting records supported by source documentation, such as canceled checks, paid bills, payrolls, and time and attendance records
    - Maintain effective control and accountability for all cash, property, and other assets under the award; adequately safeguard them; and ensure that they are used only for authorized purposes.
    - Compare actual expenditures with the approved budget amounts for the award.
    - Include written procedures to implement the requirements of 45 CFR § 75.305.
    - Include written procedures for determining the allowability of costs in accordance with 45 CFR part 75, subpart E.

Deficiencies in your financial management system may result in specific award conditions or increased monitoring.

States must expend and account for funds according to state laws and procedures for the state's own funds and ensure compliance with all the requirements above.

Payment

You accept an award and its terms and conditions by drawing down or requesting award funds from the designated HHS payment system or office.

HHS generally makes award payments through the Payment Management System (PMS). HHS grant payments are generally advance payments. You should draw down funds as often as needed.

In accordance with Department of Treasury regulations, you must draw federal cash only for your immediate needs. At time of draw down, you will certify you will not hold cash beyond three working days. You are responsible for knowing when funds are deposited into your bank account so that you can disburse them on time. You may end up with excess Federal cash on hand if you do not disburse or return funds on time. Do not request cash to cover unliquidated encumbrances, obligations, or accrued expenditures until payment is pending.

Refer to the Payment Management System (PMS) website and PMS User Guide | HHS PSC FMP Payment Management System for further guidance.

Types of Payment

As noted, HHS grant payments are generally advance payments. There are multiple ways to receive payments, including SMARTLINK II/ACH, CASHLINE/ACH, and cash request.

- SMARTLINK II/ACH: directly deposits funds to your bank account after you request them from PMS. You must have Internet access to submit a request for funds to PMS. This method makes funds available the day after the request using the Federal Reserve Bank's Automated Clearinghouse process.
- CASHLINE/ACH: directly deposits funds to your bank account using a telephone to call a "voice-response" computer at PMS. Makes funds available the day after the request with direct deposit using the Federal Reserve Bank's Automated Clearinghouse process.
- Cash request: provides payment if you are not eligible for unrestricted advance of funds. It will say in the NoA if you must use cash requests for payment. Cash requests may be an advance or reimbursement.

You may request funds monthly for advance payments. This request should be based on expected disbursements for following month and the amount of Federal funds already on hand.

A request for reimbursement may be submitted more often than monthly. You should submit requests to the awarding agency at least 2 weeks before the cash is needed. PMS makes payment electronically through the ACH process upon receipt of the approved payment request from the agency.

Refer to the Payment Management System (PMS) website and PMS User Guide | HHS PSC FMP Payment Management System for further guidance.

Interest Earned on Advances of Award Funds

You must keep advance payments in interest-bearing accounts, except as provided in 45 CFR § 75.305(b)(8). You can keep interest earned up to $500 per year for administrative expenses. Each year, you must remit any interest earned over $500 per year to the Payment Management System.

Indirect Costs

Indirect Cost Rate Negotiation and Salary Rate Limit (SRL) Policy

Please see Indirect Cost Rate Negotiation and SRL Policy in the Application Section.

New or Amended Indirect Costs

The GMO may permit new or increased indirect costs on an award when:

- A timely cost proposal was not received.
    - This can happen only if funds are available.
    - The amount is limited to the period after the effective date of the rate agreement.
- Rebudgeting changes a direct cost, which impacts an indirect cost.
    - The recipient may adjust the budget within the award ceiling and generally does need prior approval. See the Prior Approvals section of GPS.
- The indirect cost rate changes.
    - Generally, award amounts will not be adjusted based on a negotiated indirect cost rate different from that used at award.
    - However, if funds are available, a GMO may provide additional funds for indirect costs, only if:
        - An error was made in computing the award. This includes when a higher rate is negotiated after award and the date of the new rate agreement is within a month prior to the budget period start.
        - The awarding agency restores funds previously recaptured as part of an unobligated balance.
        - The recipient is eligible for additional indirect costs associated with additional direct costs awarded, such as a supplemental award.
        - A provisional rate was approved, and an approved indirect cost rate is now in effect.
    - The permanent rate will be used to determine indirect cost reimbursement, however:

- If the permanent rate is lower than the provisional rate, the award will not be adjusted downward, unless the indirect cost proposal included unallowable costs.
- The awarding agency is not required to provide new funds to accommodate a higher rate.

Applicable Credits

Applicable credits are funds saved or received that can reduce costs. Common examples include:

- Discounts
- Rebates
- Refunds for losses
- Corrections for overcharges

If you have any of these credits, you need to update the Federal Financial Report (FFR) to ensure that the proper amounts are charged to the award. If there are any extra steps, the awarding agency will let you know.

See 45 CFR § 75.406.

Allowable Costs and Activities

Allowable costs are either a direct cost or an indirect cost, and:

- Meet the applicable cost principles, including all the following:
  - Meet the factors affecting allowability. See 45 CFR § 75.403.
  - Are reasonable. See 45 CFR § 75.404.
  - Are allocable. See 45 CFR § 75.405.
  - Are allowable under the NOFO, program requirements, and NoA, including specific conditions and overall terms and conditions.
- Are specifically approved in the award, which means either:
  - The cost was included in the original award.
  - The cost is later approved by the awarding agency. See the Prior Approvals section of GPS.

Contact the GMS before incurring a cost if you have questions about allowability.

Subrecipients and contractors under the award must follow the requirements of their applicable cost principles.

Costs that Require Prior Approval

If you specifically describe a cost or activity that requires prior approval in your application budget, that cost is approved by the agency when you receive your award unless otherwise stated in the NoA. You do not need to get additional prior approval for that cost or activity.

You must get prior approval from the agency if you do not describe the cost or activity that requires prior approval in your application.

Profits and Fees

HHS will not provide profits or fees, except for the Small Innovation in Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.

You can't pay fees to subrecipients or consortium members, even if they are for-profit.

Contractors can make a profit for common goods or services in accordance with normal commercial practice. See 45 CFR § 75.351.

Expenditure Adjustments

Expenditure adjustments are used to correct accounting or bookkeeping errors. These adjustments move costs between two budget categories, with at least one related to the HHS award. Once the error is found, it must be corrected within 90 days. If after 90 days, you must ask the GMO for approval.

Don't use expenditure adjustments to cover cost overruns or for unallowable costs.

Documentation

The adjustment must be supported by documentation that fully explains how the error occurred. Documentation must:

- Explain how the error happened and have an official from your organization certify the correction.
- Show how the adjustment meets the cost principles of allowability, allocability, and reasonableness.
- Support why the adjustment is needed, considering the type of cost, the original charge, and when it was first recorded.

Unless the expenditure adjustment needs GMO approval, you don't need to send the documentation to the GMS. Keep records for monitoring or audits. See 45 CFR § 75.364.

Send a revised Federal Financial Report (FFR) if the adjustment changes your previous FFR.

Your financial system should catch errors quickly. Regular mistakes suggest you need to improve your accounting or internal controls. Agencies might ask for corrective actions or add terms and conditions to your award.

Rate of Expenditure and Drawdowns

Expenditure and drawdown rates give information about progress, financial management, and internal controls.

Expenditures

The GMS monitors spending rates within each budget period and throughout the period of performance.

The funds for each budget period are based on:

- the work planned for that time
- your budget, including any unobligated funds

HHS expects spending rates and types to match the approved plan and budget.

Drawdowns

The GMS checks drawdown patterns to see if money is taken out too early or too slowly. This can show:

- problems with your financial management system or internal controls
- risk of not finishing the project on time and within budget

If issues are found, the GMS will ask for more details and help you make corrections, which may include coordinating with the agency PO and GMS.

Cost Allocation

If a cost benefits more than one project or activity, divide the cost based on the benefit to each project.

If it is hard to determine the split because the projects are closely linked, distribute the costs on a reasonable basis with clear and documented explanations.

Treatment of Unobligated Balances

Unobligated balances are funds under an HHS award that you have not obligated. You calculate this by subtracting the cumulative amount of funds obligated from the cumulative amount of funds authorized.

Unliquidated obligations are commitments you have made, but not yet paid. Unliquidated obligations should not be reported as part of an unobligated balance.

If you have unobligated balances in your annual FFR, the awarding agency can:

- Carry Over: Revise the NoA to carry over to a following budget period.
- Offset: Move them to the next budget period but deduct the total from the award amount.
- A Mix: Use a mix of carry over and offset.

During an active budget period, if you have unobligated balances from a previous budget period, you can ask the awarding agency in writing to use them. If approved, the awarding agency will amend the NoA. If approved, funds carried over can be used for costs within scope of the project.

Program Income

Program income is gross income earned by an award recipient, subrecipient, or contractor and directly generated by an award-supported activity or earned as a result of the award.

Program income includes:

- fees for services
- charges for the use or rental of real property, equipment, or supplies bought with the award
- the sale of products made under an award
- charges for research resources
- license fees and royalties on patents and copyrights

The NoA governs the use of royalties and other income earned from a copyrighted work, patents, patent applications, trademarks, or inventions.

Accountability

Accountability refers to whether the awarding agency specifies how the program income is to be used, if the income needs to be reported to the awarding agency, and for what length of time. The following general policies apply:

- Unless otherwise specified in the award terms and conditions, you are not accountable for program income earned after the period of performance ends.
- Program income may be used only for allowable costs using the applicable cost principles and award terms and conditions.
- Subawards and contracts are subject to the same terms regarding generated income as the recipient. The following policies apply related to when the program income is earned:
    - Received and expended during the period of performance. Recipient is required to use program income as provided in the NoA.
    - Received and expended after the period of performance. Required to adjust the final FFR to reflect receipt and use of the income as directed by the GMO.
    - Received during the project period but expended after the period of performance. This may happen if you earn the income during the final budget period of the period of performance, please get GMO approval to use income post final budget period and adjust the final FFR accordingly.

Alternatives for Use

The NoA will tell you how to use program income. Here are the alternatives:

- Additive: Add it to the project's funds to further allowable objectives. Program income must be used for the purposes and under the conditions of the award.
- Deductive: Deduct it from the project's total costs and reduce federal funds and recipient cost-sharing contributions.
- Combination: Uses the additive alternative for program income up to $25,000 and the deductive alternative for any amount over $25,000.

- Matching: Use it as all or part of the non-federal (matching) part of an award.

See 45 CFR 75.307(e) for more information.

Generally:

- For non-research projects: If not specified in the NoA, use the deductive method.
- For research projects (except for awards to for-profit organizations other than the SBIR and STTR programs): If it is not specified, use the additive method.

Reporting of Program Income

Recipients must report the amount of net program income earned and expended on the FFR. This is the gross program income earned minus the costs associated with generating the income.

- Report program income using the additive alternative on line 10n, which will populate line 10o.
- Report program income using the deductive alternative on line 10m, which will populate line 10o.
- Report program income used to satisfy match on line 10j. Do not include it on line 10l.

Reporting requirements for accountable income earned after award support ends are in the NoA.

Cost Sharing

Cost sharing — or matching — is the portion of project costs not paid by federal funds, unless otherwise authorized by federal statute. This may include:

- The value of allowable third-party in-kind contributions.
- Non-award funded expenditures made by the recipient.

See 45 CFR § 75.306 for rules on cost sharing or matching.

The following policies apply:

- Cost sharing may be voluntary or required by the NoA.
- Required cost sharing is part of the total approved budget in the NoA. It is part of the award requirements and enforceable.
- Cost sharing must follow the same requirements as the federal portion of the budget. This includes applicable cost principles, prior approval requirements, and other rules for allowability.
- Recipients may apply program income toward cash match only when expressly permitted by the NoA with prior approval.
- All cost sharing contributions must be from allowable sources. See 45 CFR § 75.403, 45 CFR § 75.404 and 45 CFR § 75.405

- For research awards:
    - Voluntary cost sharing is not expected under research proposals.
    - Voluntary cost sharing cannot be used as a factor during merit review of research applications unless explicitly described in the NOFO review criteria.
    - Only mandatory cost sharing or cost sharing committed in the budget must be included in your research base for computing your indirect cost rate or reflected in allocating indirect costs.

The awarding agency will accept shared costs or matching funds, including cash and third-party in-kind contributions, when they meet all the following:

- follow 45 CFR § 75.306(e) for volunteer services
- are verified from the recipient records
- are necessary and reasonable to accomplish project objectives
- are provided for in the approved budget when required
- are not paid by the federal government under another federal award, unless specifically allowed by law. See 45 CFR § 75.306(b)(5)

The following policies apply:

- Sources of cost sharing or matching contributions must follow the applicable cost principles. See 45 CFR part 75, subpart E.
- If an awarding agency authorizes the recipient to donate buildings or land for construction or facility acquisition or long-term use, the value of the donated property for cost sharing or matching is generally the lesser of:
    - the value of the remaining life of the property recorded in the recipient's accounting records at the time of donation
    - the current fair market value

  See 45 CFR § 75.306(d).
- You must document in your records all costs and contributions used to satisfy a matching or cost-sharing requirement. These are subject to audit.
- You may use unrecovered indirect costs to satisfy cost sharing requirements with prior approval. These are the difference between the amount charged to the award and the amount that could have been charged to the award under the recipient's approved negotiated indirect cost rate.
- A third-party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing or matching requirement only if either:
    - it is an increase in the services or property provided under the contract without added cost to the recipient or subrecipient, or
    - it is a cost savings to the recipient or subrecipient.

If the NOFO specifies that matching or cost sharing is required, it will also say:

- Whether including matching or cost sharing in the application is an eligibility requirement or an evaluation criterion.
- The nature of the requirement. For example, whether it is a fixed percentage.
- Required documentation, like letters of commitment.

Valuation of Volunteer Services

Anyone offering skilled or manual work can volunteer for award-related activities. See 45 CFR § 75.306(e)-(f).

To value the services:

- For individuals:
  - Use the usual rates your organization pays or area market rates for similar work.
  - If you do not have a set rate, use the typical local rate for that work.
  - You can also add a fair amount for fringe benefits.
- For employees lent by other companies:
  - Use their regular rate if they are doing their typical job.
  - Use the method for individuals if they are doing something different.

Valuation of Donated Buildings and Land

If an awarding agency authorizes you to donate buildings or land for construction or facilities acquisition projects or long-term use, the value of the donated property for cost sharing must be the lesser of the following:

- the value of the remaining life of the property
- the current fair market value

See 45 CFR § 75.306(d), (h), and (i).

Enforcement

If you do not meet the specified level of cost sharing in the NoA, an awarding agency may do any or all of the following:

- reduce the award amount
- adjust down award funds during the budget period
- disallow costs post award

Procurement Management

You may acquire goods or services in support of award activities. The following policies apply when procuring property and services under an award:

- States must follow the same policies and procedures it uses for non-federal funds. Follow the requirements at 45 CFR § 75.326.
- All other recipients and subrecipients of a state must follow the procurement standards in 45 CFR §§ 75.327 through 75.335.

In order to procure goods and services, you must:

- Have written procurement procedures and standards of conduct that reflect applicable state, local, and tribal laws and regulations,
- Use a procurement method
- Do a cost or price analysis for all procurements above the simplified acquisition threshold
- Choose responsible contractors
- Follow all requirements in this section of the GPS

The HHS awarding agency has no direct relationship with your contractor.

Recipients other than federal institutions cannot use General Service Administration (GSA) supply sources except states who may acquire hardware and software from the GSA supply sources consistent with the terms and conditions of the GSA schedule.

Fixed Amount Subawards

With prior written approval from the GMO, you may provide subawards based on fixed amounts up to $500,000 (2 CFR § 200.333). Fixed amount subawards must meet the requirements for fixed amount awards in 45 CFR § 75.201.

Requirements for States

States may follow the same policies and procedures for procurements using non-federal funds. States will comply with 45 CFR § 75.331 and ensure that every purchase order or other contract includes any clauses required by 45 CFR § 75.335.

States may acquire hardware and software from Federal Supply Schedules consistent with the terms and conditions of the schedules.

State agencies or agencies that are political subdivisions of states must comply with section 6002 of the Solid Waste Disposal Act as amended by the Resource and Conservation Act. The requirements include:

- Procuring only items noted in guidelines of the Environmental Protection Agency (EPA) at 40 CFR § 247 that contain the highest practical percentage of recovered materials.
- Keeping an acceptable level of competition, where the purchase price of the item is more than $10,000 or the value of the amount acquired during the previous fiscal year was more than $10,000.
- Procuring solid waste management services to maximize energy and resource recovery.
- Establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

Requirements for Foreign Entities

The HHS awarding agency may require a review of all proposed procurements exceeding a certain dollar amount or for certain types of services. The HHS awarding agency may also add specific terms and conditions to its awards that address the procurement of such goods and services.

Selecting Responsible Contractors

You must avoid acquiring duplicate or unnecessary services or goods. You should use the most efficient strategy for acquisition. You should use federal excess and surplus property whenever possible to reduce project costs. You must award contracts based on factors like:

- Integrity
- Compliance with public policy
- Past performance
- Financial and technical resources

System for Award Management (SAM) Eligibility

You must check the System for Award Management (SAM.gov) to make sure that you do not make a subaward or contract to a debarred, suspended, or ineligible organization. SAM needs to be checked:

- By the recipient organization:
    - for all first tier subawards, regardless of the amount
    - for all first-tier procurement contracts of $25,000 or more
    - for all lower tiers of contracts under covered non-procurement transactions. See 2 CFR § 376.220.
- By the subaward recipient for all lower tier subaward recipients.

Written Agreements

You must execute a written agreement between your organization and the subrecipient, if applicable. The agreement must include all the following:

- the activities to be performed

- time schedule
- the provisions required by 45 CFR § 75.335 and found in 45 CFR part 75, Appendix II.
- policies and requirements that apply to the contractor, including 45 CFR § 75.327 and other relevant award terms and conditions
- maximum amount of funds to be awarded
- cost principles to be used in determining allowable costs for cost-type contracts

The following policy applies:

- The agreement must not affect your overall responsibility for the project or accountability to the federal government.

Subrecipient Periods of Performance - Contracts

If the term of the contract and the award budget period are not the same, you may charge the contract costs to the budget period in which the contract is executed even though some of the services will be performed in a later period. These conditions apply:

- You must notify the awarding agency.
- The expected contract performance period goes beyond the current budget period.
- You have a legal commitment to settle all contractual and administrative issues. See 45 CFR § 75.327(k).
- Only costs for services provided during the period of performance are allowable.
- For rental costs for facilities and equipment charge the applicable amount in each budget period as applicable. Contact the GMS before entering into leases that will result in direct charges to the award.

To limit liability, recipients should insert a clause in contracts less than $100,000 that states that payment after the end of the current budget period is contingent on continued federal funding.

Time and Materials Contracts

Time and materials contracts may only be used if:

- there is no other appropriate contract type
- the contract includes a ceiling price that the contractor exceeds at its own risk
- the direct hours are fixed and include wages, general and administrative expenses, and profit

Procurement Methods

You must use one of the following methods of procurement:

- Micro-purchases
- Small purchase procedures
- Sealed bids
- Competitive proposal

- Noncompetitive proposal

Micro-purchase procurements are the acquisition of supplies or services when the total dollar amount is less than the micro-purchase threshold ($50,000). To the extent possible, you must distribute micro-purchases equitably among qualified suppliers. Micro-purchases do not require soliciting competitive quotations if cost is reasonable.

Small purchase procurements involve simple procurement methods for securing services, supplies, or other property less than the Simplified Acquisition Threshold ($250,000). Non-federal entities must obtain price or rate quotes from sufficient qualified sources.

Sealed bid procurements require public solicitation for bids, leading to a firm fixed price contract (lump sum or unit price) given to the bidder whose bid is the lowest in price and complies with all material terms and conditions.

Competitive proposals usually involve more than one source sending an offer. A fixed price or cost-reimbursement type contract is awarded. It is generally used when sealed bids are not appropriate. You must adhere to the following requirements when using this procurement method:

- Requests for proposals must be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals must be considered to the maximum extent practical.
- Proposals must be solicited from an adequate number of qualified sources.
- You must have a written method for technical evaluations of the proposals and for selecting bids.
- Contracts must be awarded to the responsible firm whose proposal is best for the program.

You can also use the competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services. Applicant qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation.

Non-competitive proposals solicit a proposal from a single source. You may only use this method when the item is only available from a single source or in the event of a public emergency to expedite the acquisition, or when there is inadequate competition for a product, material, or service. You can get approval for non-competitive proposals from the GMO or his/her delegate.

Upon request, you are required to undergo a pre-procurement review and submit procurement documents to the HHS awarding agency or pass-through entity when:

- Your procurement procedures or operations do not comply with the procurement standards required by those regulations.
- The procurement is expected to exceed the Simplified Acquisition Threshold and is to be awarded without competition, or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the Simplified Acquisition Threshold specifies a “brand name” product.

- A proposed award over the Simplified Acquisition Threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.
- When prior written approval is required, the non-federal entity must make available sufficient information to enable review. This may include, at discretion, pre-solicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the non-federal entity or may be conditioned on the receipt of additional information. Any resulting approval does not constitute a legal endorsement of the business arrangement by the federal government nor does such approval establish the HHS awarding agency as a party to the contract or any of its provisions.

Written Standards of Conduct and Conflict of Interest

Recipients must maintain written standards of conduct covering conflicts of interest. Individuals affiliated with a recipient organization cannot participate in the selection, award, or administration of a contract supported by a federal award if they have a real or apparent conflict of interest with:

- Employees
- Officers
- Agents
- Immediate family members, spouses, or partners
- Potential employer

These individuals are prohibited from soliciting gratuities, favors, or anything of monetary value from subrecipients. However, recipients may set standards for situations where financial interest is not

agency for utilization using the SF-428-B (final) or SF-428-C (disposition). The recipient will receive disposal instructions from the HHS awarding agency.

Revocable License

In some cases, federally owned property may be made available to a recipient under what is called a "revocable license agreement." This agreement means the HHS awarding agency allows the recipient to use the property for the period of the award under the following conditions:

- The title to the property remains belongs to the federal government;
- The HHS awarding agency reserves the right to require the property to be returned to the should it be determined to be in the best interests of the federal government to do so;
- The use to which the non-federal entity puts the property does not permanently damage it for federal government use; and,
- The property is controlled and maintained in accordance with the requirements of the NoA.

Equipment

Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit purchase cost which equals or exceeds the lesser of the capitalization level established by the recipient for financial statement purposes, or $10,000.

Please see the general requirements under 45 CFR § 75.320 and 45 CFR § 75.439 for how to manage and track equipment. Unless a statute specifically says the recipient should own the title for equipment without further obligation to the HHS awarding agency, the title must be a conditional title. Under this conditional title, the recipient must:

- Use the equipment for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project; and,
- Not restrict the use of the equipment without approval of the HHS awarding agency.
- Subject to disposition instructions provided by the HHS awarding agency, use the equipment in the project it was acquired in as long as needed, whether or not the project continues to be supported by the federal award.

Important Property Reminders

- You must classify equipment that will be permanently attached or fixed to the land as real property.
- States must use, manage, and dispose of equipment acquired under a federal award by the state in accordance with state laws and procedures.
- Real property constructed or renovated with award support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by the awarding agency.

- If you default on a mortgage, you must immediately notify the GMS by telephone and in writing. If the mortgage holder intends to foreclose, you must notify the GMS in writing at least 30 days before the foreclosure action is initiated.
- The mortgage agreement must specifically allow, in the case of default, that HHS or its designee may assume the role of mortgagor (borrower) and continue to make payments.

Insurance

You must insure property and equipment acquired or improved under an award. The following policies apply:

- You must provide the same insurance coverage for property under an award as you do for other such property.
- You don't need to insure federally owned property unless required by the award terms and conditions.
- If your organization is a government agency, you may follow your own insurance requirements.
- If title to real property bought with award funds vests with your organization, you must provide the following minimum insurance coverage:
    - Title insurance policy covering the fee interest in the real property for an amount not less than the full appraised value of the property, even if federal support is partial.
    - Physical destruction insurance policy covering the full appraised value of the facility from risk of partial and total physical destruction, even if federal support is partial.
    - You must maintain the insurance policy for the duration of the federal interest in the property.

Within five days of completion or beneficial occupancy, you must submit a written statement signed by the AOR to the GMS. This statement must assure that you have purchased the required insurance policies and will maintain the insurance coverage as required above.

Self-Insurance

The awarding agency may waive one or both of the requirements above if you are effectively self-insured. If you claim self-insurance, you must provide the awarding agency an assurance that includes:

- A statement that you meet the definition of effectively self-insured. This means that you have sufficient funds to pay for any damage to the facility, including total replacement, or to satisfy any liens placed against the facility.
- The source of the funds, such as the organization's endowment or other special funds set aside for this purpose.

See 45 CFR § 75.447.

Notice of Federal Interest for Construction, Acquisition, and Modernization

A Notice of Federal Interest (NFI) is required for construction, acquisition, and modernization, except for Minor A&R. The non-federal entity (or owner, if other than the non-federal entity) must file an NFI prior to initiating construction or modernization, or when an existing facility or land is acquired with federal funds. The non-federal entity must:

- Record the NFI by the owner in the appropriate public records of the jurisdiction where the property is located. Associated fees are allowable costs.
- Provide a copy of the NFI to the HHS awarding agency.
- Accurately indicate that the property was constructed, acquired, or modernized with HHS awarding agency funds and, that during its useful life of the facility, as defined in the NFI, the HHS awarding agency's use and disposition requirements apply.
- Seek review by the HHS awarding agency to make sure it is acceptable.

The federal interest may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a non-federal entity unless approved by the HHS awarding agency.

Property and Equipment Disposition

According to 45 CFR § 75.318(c), you must request disposition instructions from the awarding agency when:

- Property under the award is no longer needed for the intended purpose or you will not be using the property for other activities currently or previously supported by an awarding agency.
- Federal statutes, regulations, or awarding agency disposition instructions in the NoA do not say otherwise.

Equipment

Unless the NoA or HHS awarding agency instructions say otherwise, you must dispose of the property as follows, in accordance with awarding agency disposition instructions:

- Retain, sell, or dispose of equipment items with a current fair market value of $10,000 or less, with no further responsibility to the government. See 2 CFR § 200.313(e)(1). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- Retain or sell equipment items with a current fair market value over $10,000. The following apply:
    - You pay the awarding agency the current fair market value according to the percentage of the federal share in its original cost.

    - If sold, the awarding agency may allow you to deduct the lesser of $500 or ten percent of the proceeds from the federal share.
    - If you organization is a non-profit institution of higher education or non-profit organization with a principal purpose of scientific research, you are exempt from any requirement to account for proceeds from a sale.

- Transfer property title to the federal government or an eligible third party. You are entitled to compensation for its share of the current fair market value.

Supplies

Your organization is assigned the title to supplies when you acquire them. If you have more than $10,000 in supplies after the award is terminated or project is completed, you must retain the supplies for use on other activities, or sell them, and then compensate the federal government for its share. See 2 CFR §200.314.

Modernization of Real Property

Modernization includes both major and minor alterations and renovations (A&R) unless otherwise stated. Modernization is not an allowable cost under the following:

- Federal awards to individuals
- Conference awards

You may not perform major A&R using federal funds or required matching or cost sharing unless

- There is specific statutory authority, and
- The NoA explicitly allows it.

Minor A&R is an allowable cost under all types of awards with prior approval under the following criteria, unless restricted in the NOFO or NoA:

- The governing statute or program regulations do not exclude it.
- The work is required to use the space more effectively to meet the program needs.
- The building has a useful life consistent with the project and is architecturally and structurally suitable for conversion.
    - If you own the property, it has a useful life consistent with the project.
    - If you lease the property, the terms and length of your lease are consistent with the project.
- Work and costs to get an initial occupancy permit is not an allowable cost. Costs must be for purposes other than human occupancy (e.g., storage).
- If the building is under construction or the A&R will take place in an incomplete structure, the costs are only allowable if:
    - It is cost-effective to perform the A&R while the building is under construction or being completed, and

  - Minor A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting it for the federal award supported purpose.

- The space involved will be occupied by the project.
- National Environmental Policy Act (NEPA) and the National Historic Preservation Act (NHPA) requirements are followed, as applicable.

The following are not considered minor A&R:

- Costs associated with routine maintenance, painting, and repair of facilities or equipment that are normal business costs and generally charged as indirect.
- Certain costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, unless the non-federal entity's accounting system considers these modernization costs rather than equipment costs.
- Costs of furnishings and movable equipment.

Federal Interest Involving Construction and Modernization of Leased Property

You must make sure any leased property that you propose construction or modernization costs for has a long enough lease for the full value of the federal award supported improvements to benefit the award activity and support the expected useful life of the facility. You must submit additional documentation to the HHS awarding agency in these cases:

- You must submit lease language to the HHS awarding agency prior to drawing down funds or being reimbursed.
- The property owner must consent to the proposed work, acknowledge federal interest in the property, and file a Notice of Federal Interest (NFI), if required. The lease must include, or be amended to include:

  - Your full use of and access to the leased property during the term of the lease.
  - Your agreement not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-federal award-related purpose(s) without the written approval of the HHS awarding agency (at any time during the term of the lease, whether or not federal award support has ended).
  - That the lessor will inform the HHS awarding agency of any default by the non-federal entity under the lease.
  - The HHS awarding agency has 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period.

- The HHS awarding agency intervening to ensure that the default is eliminated by the non-federal entity or another non-federal entity named by the HHS awarding agency.
- The lessor accepting payment of money or performance of any other obligation by the HHS awarding agency's designee, for the non-federal entity, as if such payment of money or performance had been made by the non-federal entity.
- If the non-federal entity defaults, the federal award is terminated, or the non-federal entity vacates the leasehold before the end of the lease term, the HHS awarding agency has the right to designate a replacement for the non-federal entity for the balance of the lease term, subject to approval by the lessor in a separate agreement with HHS, which will not be withheld except for good reason.
- Documentation of a NFI for the leased property (if required).

Intangible Property

Intangible property is property having no physical existence. These may include:

- trademarks, copyrights, patents, and patent applications
- property, such as loans, notes, and other debt instruments; lease agreements; stock; and other instruments of property ownership

Intellectual Property

HHS expects you and your PIs and PDs to make your award results and accomplishments available to the research community and the public. If the research results in inventions, the Bayh-Dole Act of 1980 and 37 CFR part 401 apply. If you follow these requirements, you have the right to retain title to any invention conceived or first actually reduced to practice.

The law and regulation promote:

- commercialization of federally funded inventions.
- free competition and enterprise without restricting future research and discovery.

The law and regulation require recipients to:

- Make efforts to develop and commercialize the technology to advance to industry for development.
- Make unpatented research products or resources available through licensing to vendors or other investigators.
- Share copyright-protected research outcomes in journal articles or other publications.

Irrevocable and Royalty-Free License

Except as otherwise provided in the NoA, you may assert copyright in any publications, data, or other copyright-protected work developed under an award. Doing so does not require awarding agency approval.

Rights in data also extend to students, fellows, or trainees under awards with an educational purpose. In this case, authors are free to assert copyright in works.

The federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use material resulting from a supported project or program. This applies whether HHS funded all or part of the project. You are responsible for ensuring that any necessary copyrights obtained from your subrecipients also allow the material to be used by the federal government.

HHS may also extend this license to others for federal purposes. For example, to make it available in government-sponsored databases for use by other researchers. The NoA addresses the specific scope of awarding agency rights. See 45 CFR § 75.322(d), 45 CFR § 75.365.

Access to Research Data

A federal agency may use award-related research data in developing an agency action that has the force and effect of law. If so, 45 CFR § 75.322(e)(1) requires recipients to release the research data to the awarding agency to support a FOIA request. See 45 CFR § 75.322(e). See also:

- the definition of research data at 45 CFR § 75.322(e)(3).
- the definition of records, which includes research data at 45 CFR § 5.3.

Excluded are:

- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects (e.g., laboratory samples, audio or video tapes)
- trade secrets
- commercial information
- materials necessary to be held confidential by a researcher until publications in a peer-reviewed journal
- information that is protected under the law such as intellectual property
- personnel, medical files, and similar files, if disclosure would constitute an unwarranted invasion of personal privacy
- information that could be used to identify a particular person in a research study

If the data are publicly available, HHS directs the requester to the public source. Otherwise, the awarding agency FOIA coordinator handles the request, consulting with the recipient and the PI. The recipient may charge a reasonable fee to cover their costs to respond. HHS may do the same.

This requirement to release research data does not apply to for-profit organizations or to research data produced by state or local governments. However, if a state or local government recipient contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to disclosure.

Patents and Inventions

Inventions conceived or first actually reduced to practice under awards are governed by the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR part 401.

The regulations at 37 CFR § 401 apply if both the following are true:

- Inventions result from federally funded research.
- Your organization or your subrecipient or contractor is a university, non-profit entity, governmental entity, or small or large business.

See iEdison for more information.

Royalties and Licensing Fees from Copyrights, Inventions, and Patents

You may commercially apply intellectual property and require payments for its use.

Unless the NoA says otherwise, you do not have to report program income earned from license fees and royalties. This includes copyright-protected material, patents, patent applications, trademarks, and inventions made under an award.

You may pay royalties to others as an allowable direct cost.

See 45 CFR § 75.448.

Invention Reporting

For information, see Invention Reports at iEdison. See also 37 CFR part 401.

Seek the advice of the GMS about:

- Whether an invention made under a career development award is a subject invention
- The extramural technology transfer policy
- Reporting of inventions

Publications and Acknowledgement of Support

Publications

HHS encourages you to publish the results and accomplishments of awards. You can publish your results without prior approval. These policies apply, unless otherwise specifically addressed in your NoA:

- You may assert copyright in scientific and technical articles based on data produced under the award.

- You may transfer copyright to the publisher or others for journal publication or other professional activities.
- All copyrights, including transfers, are subject to a royalty-free, non-exclusive and irrevocable license to the federal government, and any agreement must include that the assignment is subject to the government license.
- You must account for royalties and income earned from a copyrighted work as specified by the awarding agency.
- You must submit one copy of each publication resulting from work under an award with the annual or final progress report.
- If you plan to issue a press release about award-supported activities, you must notify the awarding agency in advance to allow for coordination.

Stevens Amendment

HHS will include the following information in your NoA and NOFO. When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as toolkits, resource guides, websites, and presentations – describing the projects or programs funded in whole or in part with HHS funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

The NoA may provide further instructions and language to use.

Acknowledgement of Support

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as tool-kits, resource guides, websites, and presentations (hereafter "statements") – describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

- If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources: This [project/publication/program/website, etc.] [is/was] supported by the [full name of the OPDIV/STAFFDIV] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX

with 100 percent funded by [OPDIV/STAFFDIV]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Name of the Awarding Agency]/HHS], or the U.S. Government. For more information, please visit [Award Agency Stevens Amendment website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

- This [project/publication/program/website, etc.] [is/was] supported by the [full name of the HHS Awarding Agency] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with XX percentage funded by [full name of the HHS Awarding Agency]/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Awarding Agency]/HHS, or the U.S. Government. For more information, please visit [Award Agency's Stevens Amendment website, if available].

Oversight and Monitoring

Subrecipient Flow-Down Requirements

The GPS applies to subrecipients and contractors. This includes consortium agreements where the recipient collaborates with other organizations.

The terms and conditions of awards flow down to subawards and subrecipients unless a particular GPS policy or award term and condition specifically says otherwise.

You have to have a formal written agreement with each subaward recipient. You must include applicable GPS requirements in your subaward agreements. Agreements must meet programmatic, administrative, financial, and reporting requirements. At a minimum, the subaward agreement must include:

- the PI or PD and subrecipient staff responsible for the program activity, including roles and responsibilities
- program administration and monitoring procedures
- policies and process for subrecipient funding, such as allowable costs, expenditure approval, funding caps, payment method and schedule, required documentation
- travel, salaries, and fringe benefit policies and procedures
- applicable public policy requirements and applicable assurances and certifications and provisions indicating the intent of the subrecipient to comply, including submission of applicable assurances and certifications
- conflict of interest requirement
- provisions regarding property, program income, publications, reporting, record retention, and audit

Reporting

You must submit financial, performance, and other reports. Not meeting reporting requirements could result in enforcement actions. These actions include those in the Remedies for Noncompliance section of the GPS including 45 CFR §§ 75.371-.380, and reporting to Responsibility/Qualification in SAM.gov (formerly FAPIIS).

Federal Financial Reports

You submit Federal Financial Reports (FFRs) through the Payment Management System (PMS).

How often you need to submit an FFR is in the NoA. This can range from quarterly to annually. Higher risk recipients may report more often.

Updated information on FFRs is at the Program Support Center for PMS.

You may need to revise your FFR in some cases. You must submit a revised FFR to HHS immediately for overcharges. You also must submit revised FFRs as soon as possible for expenditures that you did not report before. You must explain why the revision is necessary and how you will prevent this in the future. For annual FFRs, revisions are due no later than 9 months from the end date. For final FFRs, revisions are due no later than 6 months after the end date. The agency will tell you how your award will be updated if revised FFRs are accepted.

PLEASE NOTE: The GMS may not accept a revised interim FFR submitted by the recipient that claims additional expenditures after one year from the end of the reporting period (regardless of when the original report was actually submitted).

Progress Reports

You submit progress reports through GrantSolutions or NIH eRA.

The reporting schedule and requirements are in the NoA. Schedules can range from quarterly to annually. Higher risk recipients may report more often.

See 45 CFR § 75.342(b)(1).

Other Reporting

Intellectual Property Reporting

If you have a research award, you must report on patents and inventions through iEdison (iEdison | NIST).

Each competing continuation application and progress report (when used in lieu of a non-competing continuation application) must indicate whether or not any subject inventions were made during the preceding budget period.

Invention Reporting

You must report on inventions. The iEdison website includes information on invention reports. See also 37 CFR part 401.

You must also submit an annual invention use report for:

- all inventions to which title has been elected, and
- inventions that have been licensed but not patented (research tools).

The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

Contact the GMS for questions, including:

- if inventions under a career development award is a subject invention
- the extramural technology transfer policy
- reporting and use of inventions

Real Property Reporting

Construction awards must report the status of real property each year for as long as the federal government retains an interest, up to 15 years. If the federal interest lasts beyond 15 years, the awarding agency or pass-through entity may require the recipient to report at various multi-year frequencies.

Non-Compliance

Failure to Submit Reports

When you fail to submit required reports within the time allowed, the awarding agency may take enforcement actions including those in the Remedies for Noncompliance section of the GPS.

Overdue Reports

An awarding agency may give a waiver, if permitted by law, or extension if a report is overdue and the reason is beyond your control.

Failure to meet a new date may result in the awarding agency taking enforcement actions.

Submission of a required report does not necessarily fulfill your obligation. Reports must meet content requirements. You must provide the revised report by the indicated due date to avoid enforcement actions.

Fraud, Waste, and Abuse

Fraud, waste, or abuse related to HHS awards or use of award funds should be reported to HHS. Fraud, waste, and abuse may be reported:

- By telephone at 1-800- HHS-TIPS (1-800-447-8477) or TTY at 1-800-377-4950
- Fax at 1-800-223-8164. Forms for use are available at the OIG website.
- E-mail at HHSTips@oig.hhs.gov
- USPS mail at U.S. Department of Health and Human Services, Office of Inspector General, Attn: OIG Hotline Operations, P.O. Box 23489, Washington, DC 20026.

If you report, you are not required to give your name, but if you do, your identity is kept confidential.

Fraud, waste, and abuse includes embezzlement, misuse or misappropriation of award funds or property, and false statements or claims. Examples include:

- theft of award funds for personal use
- using funds for non-award-related purposes
- theft of federally owned property or property acquired or leased under an award
- charging inflated building rental fees for a building owned by the recipient
- submitting false financial report
- submitting false financial data in bids submitted to the recipient

The federal government may pursue administrative, civil, or criminal action under a variety of statutes that relate to fraud and false statements or claims. Even if no award is made, you may be subject to penalties if information submitted as part of an application is found to be false, fictitious, or fraudulent. See the statutes referenced in Appendix D and Appendix E for statutes related to fraud, waste, and abuse.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 USC 35, as implemented by 5 CFR part 1320, is designed to:

- Reduce, minimize, and control burdens
- Maximize the practical use and public benefit of the information created, collected, disclosed, maintained, used, shared, and disseminated by or for the federal government

OMB clearance is required for awarding agency collection of information. This includes all application or reporting forms, whether paper or electronic. Below is information about how the PRA is implemented.

Federally Sponsored Surveys

Recipients may use award funds to collect information through surveys or questionnaires:

- When the collection of information is not a primary objective of the award but is incidental to, or is an integral part of, an award-supported activity
- When the collection of information is a primary objective of the award, but such information is not intended primarily for use by the federal government, or a party designated by the federal government

When information is collected, according to either of the two conditions above, you may not represent what the information is being collected for, or in association with, unless:

- You receive awarding agency approval, and
- You follow OMB report clearance procedures, when required. When OMB approval is required, the awarding agency, rather than the recipient, will obtain the necessary clearance.

OMB clearance is required whenever the HHS awarding agency sponsors the use of a reporting form or plans to collect identical kinds of information or data from 10 or more people.

Information collection is considered HHS awarding agency-sponsored when any of the following circumstances exist:

- The awarding agency allows you to state that the information is being collected for, or in association with, the awarding agency.
- You use the report form or collect information that an awarding agency has requested for the planning, operation, or evaluation of its program.
- The award terms and conditions provide awarding agency approval of the study design, questionnaire content, or data collection procedure.
- The award terms and conditions provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the awarding agency.

HHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted privacy invasion.

Collection of the following types of information is not subject to the clearance requirements at 5 CFR § 1320:

- health professions data as described in Section 708 of the Public Health Service (PHS) Act
- tests or examinations of individuals for determining knowledge, abilities, or aptitudes, and the collection of information for identification or classification in connection with such tests
- information from patients to be used exclusively for research of or direct treatment of a clinical disorder; for the interpretation of biological analyses of body fluids, tissues, or other specimens; or for identification or classification of such specimens

See 5 CFR § 1320 for additional clearance requirement exemptions.

Remedies for Noncompliance

If you do not comply with award terms and conditions, the awarding agency or pass-through entity may take enforcement actions, in accordance with applicable statutes, regulations and policy.

You usually have an opportunity to correct the deficiencies unless there is a serious threat to public health or welfare concerns. The awarding agency may take necessary proactive steps to protect the federal government's interests. Awarding agencies may take any action allowed by law, including those below. See 45 CFR §§ 75.371-.380.

Implementation of Specific Award Conditions

An awarding agency or pass-through entity may place specific conditions on an award. The purpose is corrective. This remedy may be used if you:

- fail to comply with the terms and conditions of an award
- fail to meet expected performance goals

- are not otherwise responsible

When the awarding agency or pass-through entity imposes specific award conditions, they will notify you of:

- the nature of the conditions
- the reason why
- the type of corrective action needed
- the time allowed for completing corrective actions
- the method for requesting reconsideration of the conditions

Examples of specific award conditions are removing a PD/PI, converting your award from advance payment to reimbursement, and adding reporting requirements.

See 45 CFR § 75.207.

Disallowed Costs

HHS may disallow all or part of the cost of an activity or action determined not in compliance. This can happen at any time during the award or after closeout.

You must repay disallowed costs with non-federal funds or an offset from future year funds. You may appeal disallowed costs.

Other Remedies

Depending on the nature of the deficiency, an awarding agency also may:

- temporarily withhold payment
- withhold further awards for the project or program

Suspending Award Activities or Termination

Consistent with 45 CFR § 75.372(a), an awarding agency or pass-through entity may suspend, pending corrective action, or terminate all or part of your award activities pending your corrective action if you fail to materially comply with the award terms and conditions. See 45 CFR part 75 D – Remedies for Noncompliance.

The HHS awarding agency generally will suspend, rather than immediately terminate, a federal award. This allows you an opportunity to take appropriate corrective action before making the decision to terminate. The HHS awarding agency may decide to terminate the federal award if you do not take appropriate corrective action during the period of suspension.

Under a suspension, the HHS awarding agency will provide you:

- What project activities, if any, will take place during the period of suspension.
- What costs the HHS awarding agency will reimburse if the enforcement action is ultimately lifted and the award resumed.
- What corrective actions must occur during the enforcement action.

- The HHS awarding agency's intent to terminate the award if the non-federal entity does not meet the conditions of the enforcement action.

The HHS awarding agency may terminate without first suspending the federal award if the problem is serious enough or if public health or welfare concerns require immediate action. Termination for cause may be appealed under the HHS awarding agency and HHS's federal award appeals procedures.

A federal award also may be terminated, in whole or partially, by the recipient or by the HHS awarding agency with the consent of the recipient. If you decide to terminate a portion of a federal award, the HHS awarding agency may determine that the remaining portion will not accomplish the original purpose. In this case, you will be advised of the possibility of termination of the entire federal award and will be allowed to withdraw your termination request. If you do not withdraw your request for partial termination, the HHS awarding agency may terminate the entire federal award for cause. See 45 CFR § 75.372.

When an HHS awarding agency terminates a federal award prior to the end of the period of performance due to the non-federal entity's material failure to comply with the federal award terms and conditions, the HHS awarding agency must report the termination to the OMB-designated integrity and performance system accessible through the Responsibility/Qualification System in Sam.gov. This information will be reported after the non-federal entity has exhausted its opportunities to object or challenge the decision or has not within 30 calendar days after being notified of the termination informed the HHS awarding agency that it intends to appeal the decision to terminate. For full information on reporting termination in FAPIIS, see 45 CFR § 75.372(b).

HHS applies appeal rights in line with 45 CFR § 75.374. Appeals rights exist for termination actions that are a remedy for non-compliance.

Suspension or Debarment

An awarding agency may initiate suspension or debarment proceedings under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376. A pass-through entity may recommend that the awarding agency do so for a subaward.

Closeout

To close an award, you do several steps to include submitting a final report. Ask your GMS and review the closeout provisions HHS now follows at 2 CFR § 200.344. The awarding agency will resolve any amounts due to them or to you.

Upon the completion date of an award, you have 120 days to liquidate all financial obligations and submit all required reports, including a final FFR, final progress report, tangible and real property reports (if needed), and Final Invention Statement and Certification (if needed). The GMO or their delegate may give an extension upon a written request. Not submitting timely and accurate reports can affect future funding. HHS may close out your award on its own if you fail to provide your reports on time.

HHS may still disallow costs or recover funds based on an audit or review after your award is closed out. After closeout, you still have to return any funds due to HHS because of refunds, corrections, indirect cost rate adjustments, or other transactions.

You still need to account for property acquired on your award and follow disposition and record retention requirements after close out. HHS adopted two 2 CFR § 200 provisions about equipment and salary disposition:

- 2 CFR § 200.313(e) - Equipment: Increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency." The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- 2 CFR § 200.314(a) - Unused Supplies: Increases from $5,000 to $10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items.

See 45 CFR §§ 75.317-323 for other disposition requirements. See 45 CFR §§ 75.361-75.365 for record retention requirements. Keep in mind the above changes in equipment and supply costs adopted by HHS in 2 CFR § 200.

Final Federal Financial Report (FFR)

A final FFR is required for all of the following:

- terminated awards
- awards transferred to new recipients
- awards at the end of a period of performance

Final FFRs must:

- account for all funds awarded during the period of performance
- have no unliquidated obligations
- say the exact unobligated balance

In some cases, you may need to submit a revised FFR. When a revised final FFR results in additional recipient claims, the awarding agency will consider approval if:

- You show why the revision is needed, explains, and implements internal controls to avoid similar future situations
- The charge is allowable under the award
- There is an unobligated balance for the budget period that can cover the claim
- The funds are still available

- The awarding agency receives the revised FSR within 6 months of its original due date

Final Progress Report

A final progress report is required for all of the following:

- terminated awards
- awards at the end of the performance period

Submit final progress reports as directed in your NoA.

Use the awarding agency instructions. At a minimum, they include:

- a summary of progress towards achieving the stated aims
- significant results, positive or negative
- publications

If you submit a competing continuation application, the final progress report requirement may be met by the information included in that application.

Final Invention Statement

For research awards, you must submit a Final Invention Statement and Certification (HHS 568). HHS requires this statement even if the award does not result in any inventions. The HHS 568 is at the iEdison Web site at iEdison | NIST.

The HHS 568 lists all inventions conceived or initially reduced to practice under the award. The form must be signed by the PI or PD and AOR. The form covers the period from the original award start date through the award end date. If there were no inventions, the form should indicate “None.”

Post-Closeout

After award closeout, you still have obligations for record retention, property accountability, and financial accountability. See 45 CFR §§ 75.317-.323 and 75.343.)

Record Retention and Access

You must keep financial, supporting, and statistical records, and all other records considered pertinent to an award.

The retention periods are three years after sending:

- the final FFR for closed awards
- quarterly or annual reports for awards renewed quarterly or annually

These periods are extended until the conclusion of any litigation matters, claims, or audits and audit findings are fully resolved.

You must allow records access to the:

- HHS Awarding Agency
- Inspector General
- Comptroller General
- Pass-through Agency

See:

- Retention requirements for records (45 CFR § 75.361)
- Access to records (45 CFR § 75.364)
- Restrictions on public access to records (45 CFR § 75.365)

Debt Collection

During or after closeout, HHS may find that you received more than the correct amount or that you misspent funds. This may result from disallowed costs, recovery of funds, unobligated balances, or other situations. In these cases, HHS will send you a request for repayment. Debts to HHS agencies are considered delinquent 30 days after you are notified. You have 90 calendar days to repay the amount.

If you do not pay back the funds in 90 calendar days, the HHS awarding agency may reduce your debt by:

- making an administrative offset against payments on other HHS awards
- withholding advance payments
- taking other action allowed by law

HHS must, by law, collect debts due to the federal government. Unless prohibited by law, HHS is also required to charge interest on delinquent debts.

See Collection of Amounts Due (45 CFR § 75.391) for more.

You may appeal a request for repayment. If appealed, HHS suspends the collection pending a final appeal decision. If denied, in whole or in part, HHS will charge interest on the debt starting with the date of the original request for repayment.

Refer to the HHS Claims Collection (45 CFR part 30) and the Program Support Center's Debt Management Collection System at https://pms.psc.gov/ for more on collection of debts.

Appeals

Awarding agencies may have their own appeals procedures. See also the procedures of the Departmental Appeals Board (45 CFR part 16).

Awarding agencies and recipients may use alternative dispute resolution (ADR). ADR can reduce the cost, time, and level of dispute involved in appeals.

For more information on appeals, see Opportunities to Object, Hearings, and Appeals (45 CFR § 75.374) and the Departmental Appeals Board website.

Single Audit

An audit is a review to verify if accounting and control systems reasonably assure:

- proper financial operations
- timely, fair, and correct financial reports
- compliance with applicable laws, regulations, and terms and conditions of award
- resources are managed and used economically and efficiently
- desired results and objectives are being achieved effective
- recipients and subrecipients follow the audit requirements of 45 CFR part 75, subpart F.

Audit Requirements

As of October 1, 2024, you and your subrecipients must have an audit if either spends $1,000,000 or more in federal awards during its fiscal year (see 2 CFR § 200.501). Even if an audit is not required, keep records available for review by federal officials.

You must use an independent auditor who must follow the Government Auditing Standards and the audit requirements in 45 CFR 75, subpart F. Audit costs are allowable and often covered by the indirect cost rate.

Pass-through entities are responsible for establishing audit requirements, to ensure compliance by subrecipients.

HHS may request more audits, if necessary.

Types of Audits

Program Specific Audit**:** test a single program. Refer to 45 CFR § 75.507.

- Single Audit: The auditor uses a risk-based approach to identify major programs which the auditor tests and provides an opinion on compliance. See 45 CFR part 75, subpart F.
- Financial Related Audit: Specific to for-profit organizations. Must be conducted in accordance with the Government Auditing Standards.

Audit Options

If an audit is required, the following options are available:

For Governments, Indian Tribes, Institutions of Higher Education, and Non-Profits

- Only one program: If federal awards are expended in only one program, the program-specific audit is an option.
- Multiple programs: If federal awards are expended from more than one program, a single audit is required.

For-Profit Organizations

- Only one program: If federal awards are in only one program, then they may opt for a program-specific audit or financial related audit of the award.
- Multiple programs: If federal awards are in more than one program, then they must have a single audit or financial related audit of all awards.

Contractors

Audit requirements for federal awards do not apply to contractors with annual HHS awards less than $1,000,000. See 2 CFR § 200.501.

Foreign Entities

Audit requirements and processes for foreign entities will be addressed in your NOFO and NoA.

Recipient Responsibilities

- Procure or otherwise arrange for the required audit and make sure it is performed properly. See 45 CFR § 75.509.
- Provide the auditor with access to needed personnel, accounts, books, records, supporting documentation, and other information.
- Prepare financial statements, including the schedule of federal award expenditures. See 45 CFR § 75.510.
- Make sure the audit is submitted within 9 months after your fiscal year end. See 45 CFR § 75.512.
- Promptly follow up and take corrective action on audit findings.

See 45 CFR § 75.508 for a listing of auditee responsibilities.

Audit Findings and Resolution

Non-Federal entities and their subrecipients must follow up and take corrective action on all audit findings. This includes preparing:

- a summary schedule of prior audit findings. See 45 CFR § 75.511(b).
- a corrective action plan. See 45 CFR § 75.511(c).

Requirements

The summary schedule and the corrective action plan must include:

- reference numbers the auditor assigns to audit findings under 45 CFR § 75.516(c)
- the fiscal year in which the finding initially happened
- findings relating to the financial statements required to be reported under Government Auditing Standards

See 45 CFR § 75.511.

Report Submission

Reports for non-profit recipients are submitted to the Federal Audit Clearinghouse (FAC). For-profit and foreign recipients submit reports to ARD or the Centers for Disease Control (CDC) (if CDC is the awarding agency).

The HHS assignment system receives single audit reports from the FAC and assigns audit findings to the awarding agencies for resolution.

Both you and your auditors must complete and submit your portions of the reporting package to FAC. They are due within 30 calendar days after receipt of the auditor's report or nine months after the end of the auditee's fiscal year.

See 45 CFR § 75.512.

Delinquent Audits

HHS will follow up to obtain audit reports that are delinquent.

If required audits are not completed or do not follow 2 CFR part 200 and 45 CFR part 75, audit costs may be disallowed or other sanctions may be taken.

HHS Office of Inspector General

The HHS Office of Inspector General (OIG) audits programs and their recipients to ensure funds are used correctly and guard against fraud and waste. The OIG:

- can freely access records and information
- can request information and documents through subpoenas
- acts as the National Single Audit Coordinator, giving audit guidance to HHS agencies and recipients

You need to have strong internal controls and guidelines must be in place to ensure proper use of federal funds.

Documentation

Ensure that the basis for valuing services, materials, equipment, buildings, and land can be verified. Make sure your records, including those from your subrecipients, can support the value. If using volunteer services, document their time and attendance as you would for regular employees.

Additional Information

Cooperative Audit Resolution and Management Decisions

Cooperative audit resolution is a structured approach that brings the appropriate stakeholders together to address audit findings and proposed corrective actions. Non-federal entities must follow this approach to ensuring timely and appropriate resolution of audit findings and recommendations. The non-federal entity must initiate and proceed with corrective action as quickly as possible and corrective action should begin no later than upon receipt of the audit report.

The HHS awarding agency will coordinate with the non-federal entity during the cooperative audit resolution process. The HHS awarding agency will:

- Follow-up on audit findings to ensure the non-federal entity takes appropriate and timely corrective action.
- Issue a management decision, on all assigned reporting packages with audit findings within six months of the date the FAC accepts the reporting package.
- Issue sanctions when the non-federal entity fails to correct conditions identified by audits that are likely to cause improper payments, fraud, waste or abuse.

The HHS awarding agency or pass-through entity responsible for issuing a management decision must do so within 6 months of acceptance of the audit report by the FAC. The management decision provides timely information to the non-federal entity regarding where the HHS awarding agency is in evaluating findings and related corrective actions. The HHS awarding agency management decision will include:

- whether or not the audit finding is sustained
- the reasons for the decision
- the expected action the non-federal entity must take to repay disallowed costs, make financial adjustments, or take other action
- a timetable for follow-up if then non-federal entity has not completed corrective action
- a description of the appeal process available to the non-federal entity

Appendix A: Awarding Agencies Overview

Below is an overview of HHS awarding agencies. Visit HHS Organization Chart | HHS.gov for more.

GPS refers to "Public Health Service (PHS) agencies." We have marked them below.

Agency	Overview	Support
Administration for Children and Families (ACF) www.acf.hhs.gov	Promotes economic and social well-being of children, families, and communities.	• childcare for low-income families • foster care and adoption • child abuse and domestic violence prevention
Administration for Community Living (ACL) www.acl.gov	Advocates for older adults, people with disabilities, families, and caregivers to help all people live independently and participate in their communities.	• health, wellness, and nutrition • self-advocacy • connecting people to services • retirement planning • American Indian, Alaska Native, and Native Hawaiian nutrition and older adult support
Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov PHS agency	Improves quality, safety, accessibility, equitability, and affordability of US health care.	• digital healthcare research • PSNet (Patient Safety Network) • quality indicators
Administration for Strategic Preparedness and Response (ASPR) www.aspr.hhs.gov	Assists the country in preparing for, responding to, and recovering from public health emergencies and disasters.	• development and stockpiling of medical countermeasures • pandemic preparedness
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) www.healthit.gov	Administers health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve health care.	• advance development and use of health IT capabilities • establish expectations for data sharing
Centers for Disease Control and Prevention (CDC) www.cdc.gov PHS Agency	Protects against health and public health, safety, and security threats. Their focus is both foreign and domestic.	• immunization services • monitoring and preventing disease outbreaks • disease prevention strategies • workplace safety

Centers for Medicare & Medicaid Services (CMS) www.cms.gov	Advances health equity, expanding coverage, and improving health outcomes.	• clinical standards and quality • minority health equity • meaningful measures
Food and Drug Administration (FDA) www.fda.gov FDA Grants and Cooperative Agreements Page PHS Agency	Protects public health by ensuring the safety of human and veterinary drugs, biological products, medical devices, cosmetics, and food.	• food safety • animal feed safety • laboratory systems • scientific conferences
Health Resources and Services Administration (HRSA) www.hrsa.gov PHS Agency	Provides access to essential health care services for people who are low-income, uninsured, or live in areas with limited access.	• rural health • maternal and child health • opioid response • health workforce training • telehealth
Indian Health Service (IHS) www.ihs.gov PHS Agency	Ensures comprehensive, culturally appropriate personal and public health services are available to American Indians and Alaska Native people.	• community health • behavioral health • environmental stability • school health
National Institutes of Health (NIH) grants.nih.gov PHS Agency	Seeks knowledge about the nature and behavior of living systems. Applies it to enhance health, lengthen life, and reduce illness and disability.	• biomedical and behavioral research • research training • research infrastructure and communications
Office of the Assistant Secretary (OASH) www.hhs.gov/ash PHS Agency	Seeks to serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures.	• minority health • family planning • adolescent health • women's health • infectious disease and HIV/AIDS policy • research integrity
Office of the Inspector General (OIG) www.oig.hhs.gov	At the forefront of the Nation's efforts to fight waste, fraud and abuse and to improving the efficiency of Medicare, Medicaid and more than 100 other Department of Health & Human Services (HHS) programs.	• Medicare/Medicaid oversight • improved efficiency • fraud, waste, abuse detection

Substance Abuse and Mental Health Services Administration (SAMHSA) www.samhsa.gov PHS Agency	Improves the quality and availability of substance abuse prevention, addiction treatment, and mental health services.	• substance abuse and mental health services.

For awarding agency staff and recipient roles and responsibilities, see the Introduction and General Information section.

Appendix B: Abbreviations and Glossary

Abbreviations

Please see abbreviations listed in 45 CFR part 75. The abbreviations are used by the HHS Financial Assistance Community. Although not all of the terms are in the GPS, they may be useful to applicants and recipients.

Glossary

This glossary defines terms commonly used in the HHS GPS. These definitions are for purposes of clarity and do not replace controlling definitions in applicable statutes and regulations.

acquisition cost	The total invoice price of items, counting costs for changes or accessories or additions to make them work for their intended use. Costs like setup, shipping, taxes, and insurance can be included or excluded based on the recipient's usual accounting methods. The term doesn't cover rental or property modification costs.45 CFR § 75.2 Acquisition cost
accrual basis	Accrual accounting records revenue and expenses when the transaction happens, not when money is paid.
administrative requirements	Common practices in managing awards like financial accountability, reporting, equipment management, and records retention.
advance payment	A payment made to a recipient before they spend the money or based on set payment schedules. 45 CFR § 75.2 Advance payment
allocable cost	An allocable cost relates to a specific project or activity based on the relative benefits it provides. It's allocable to a federal award if: • It's specifically for the award. • It benefits both the award and other tasks, and can be distributed based on those benefits. • It's needed for the organization's overall functioning. 45 CFR § 75.405 Allocable costs
allowable cost	Allowable costs are: • Reasonable for the award's purpose. • Allocable. • Within the federal cost principles or NoA guidelines. • In line with the recipient's consistent policies, covering both federal and non-federal activities. • Consistently treated as either a direct or indirect cost. • Based on standard accounting principles. • Not used in another federal award, unless statute says otherwise. 45 CFR § 75.403 Factors affecting allowability of costs

alteration and renovation (A&R)	Alteration and renovation involve changing the inside or features of a facility or installed equipment to enhance its current use or adapt it for a new purpose. It can include improvements, remodeling, or modernization but is different from construction or major permanent upgrades.
alternative dispute resolution (ADR)	A method to solve disagreements without going to court. It aims to resolve issues faster, cheaper, and in a less confrontational way, preventing them from becoming bigger problems that need formal legal action.
applicable credit	Receipts that offset or reduce direct or indirect costs. Typical examples include purchase discounts, rebates, or allowances; recoveries or indemnities on losses; insurance refunds; and adjustments of overpayments or erroneous charges. 45 CFR § 75.406 Applicable credits
application	A request for financial support of a project or activity submitted on specified forms and in accordance with awarding agency instructions. See Types of Applications.
approved budget	The spending plan for a project funded by an award. This budget has both federal funds and, if applicable, non-federal funds like cost-sharing. If both types of funds are in the budget, the recipient must spend them in the same ratio as they appear in the total budget. See also 45 CFR § 75.2 Budget
assurance	A written statement by an applicant, normally included with the application, that it will follow a particular requirement if there is an award.
audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings like questioned costs. See also 45 § CFR 75.2 Cooperative audit resolution.
award	The document that provides the awarding agency funds to a recipient to carry out an approved project, based on an approved application. In the GPS, award means both grants and cooperative agreements. 45 CFR 75.2 Federal award
awarding agency	The agency responsible for making, monitoring, and overseeing awards. For changes in award terms or for approval requests, the reference may be to the GMS. See also 45 § CFR 75.2 Federal agency.
award-supported project	Activities described in an application or in a subsequent submission that are approved by an awarding agency for funding, even if federal money isn't the sole financial support for them.
award terms and conditions	The legal requirements set by the awarding agency for the award. These can come from laws, regulations, policies, or the NoA. The NoA might also add specific conditions to ensure the award's goals are met, enable post-award management, save funds, or protect federal interests.
budget periods	The period of time (usually 12 months each) into which a period of performance is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as “incremental funding.”

carryover	Unspent federal funds from a particular budget period that can be transferred and used in the next budget period used to cover allowable expenses in that subsequent period. Funds that have been committed but not yet spent (obligated but unliquidated) are not classified under carryover.
cash basis	An accounting method in which revenue and expenses are recorded on the books of account when received and paid, respectively, without regard to the period in which they are earned or incurred. It is different than accrual basis.
change of recipient	Transfer of the legal and administrative responsibility for an award from one legal entity to another before the end of the period of performance.
closeout	The process used by an awarding agency to determine whether all administrative actions and work required under the award have been completed by the recipient and the awarding agency. 2 CFR § 200.344
cognizant agency	The federal agency that, on behalf of all federal agencies, reviews, negotiates, and approves cost allocation plans, indirect cost rates, and similar rates. They monitor non-federal audit reports; conduct federal audits as necessary; and resolve cross-cutting audit findings. The cognizant agency under applicable cost principles and under 45 CFR part 75, subpart F may be different for a given recipient. 45 CFR § 75.2 Cognizant agency for indirect costs
competition	A process in which applications undergo a merit review and are evaluated against established evaluation criteria in the NOFO.
completion date	The date on which all work under an award is completed or the date in the NoA (as amended) on which federal sponsorship ends (i.e., the end of a period of performance).
consortium agreement	A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards.
contract under an award	A written agreement between a recipient and a third party to acquire commercial goods or services. 45 CFR § 75.2 Contract
construction	A project to support the initial building or major alteration and renovation like large-scale modernization or permanent improvement of a facility.
consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. Also includes a firm that provides paid professional advice or services.
cooperative agreement	A financial assistance support mechanism used when there will be substantial federal programmatic involvement. Substantial involvement means that the awarding agency's program staff will collaborate or participate in project or program activities as specified in the NoA. 45 CFR § 75.2 Cooperative agreement

copyright	Protection provided by statute (Title 17, U.S. Code) to the authors of "original works of authorship," including literary, dramatic, musical, artistic, and certain other intellectual works, including computer programs. This protection applies to both published and unpublished works.
cost analysis	The systematic review of a budget proposal to: • Detail and assess cost components. • Ensure costs are necessary, reasonable, and allocable. • Confirm alignment with federal guidelines, ensuring no unallowable expenses.
cost sharing	See "matching or cost sharing."
Departmental Appeals Board	The DAB is a board within HHS that impartially addresses disputes from HHS assistance programs. It offers a fair hearing process for challenges to certain grants management decisions, with its role and rules outlined in 45 CFR part 16. 45 CFR § 75.2 Departmental Appeals Board
direct costs	Costs directly linked to a specific project, instructional activity, or other institutional activities, which can be accurately and easily allocated to those activities. 45 CFR § 75.413 Direct costs
domestic organization	A U.S.-based public or private entity, subject to U.S. laws, responsible for the legal and financial management of awarded funds and the execution of the supported activities.
Entity Identification Number (EIN)	A 12-character code in PMS comprising three parts: the first character indicates if the recipient is an organization or individual; the following 9 characters represent the TIN for organizations or the SSN for individuals; the final 2 characters differentiate between organizational entities with the same or multiple EINs, denoting subsidiaries, branches, or other subdivisions.
equipment	A tangible item with a lifespan exceeding 1 year and a cost of $5,000 or more per unit, or below the recipient's capitalization threshold, whichever is lower. 2 CFR § 200.1 Equipment
excess property	Property that, as decided by the head of the awarding agency or its representative, is no longer needed for the agency's functions or responsibilities. 45 CFR § 75.2 Excess property
exempt property	Tangible personal property bought either entirely or partly with federal funds, where the awarding agency has the legal authority to vest title to the recipient without additional obligations to the federal government. 45 CFR § 75.319 Federally owned and exempt property
expanded authorities	Permissions granted to recipients that eliminate the need for prior approval from the awarding agency for certain activities.
expiration date	The specified date in the NoA marking the conclusion of the current budget period, beyond which the recipient is not authorized to obligate award funds.

facilities and administrative costs (F&A)	See indirect costs
federal institution	A Cabinet-level department or independent agency within the executive branch of the federal government, or any of its sub-entities.
federal share	The proportion, usually expressed as a percentage of the total project costs, that represents the financial and other direct contributions provided by the awarding agency, as detailed in the NoA. 45 CFR § 75.2 Federal share
fee	A sum paid beyond the actual allowable costs to an entity delivering goods or services in line with standard commercial practice, often referred to as "profit."
financial assistance	The provision of funds, property in place of funds, or other direct aid to a qualified recipient to encourage or further a public purpose authorized by law.
foreign component	The execution of a major part or component of a project outside the United States by the recipient or by a researcher affiliated with a foreign institution, regardless of whether award funds are used.
foreign organization	An entity situated in a country outside of the United States and its territories, governed by the laws of that nation, regardless of the nationality of the proposed Principal Investigator/Project Director. 45 CFR § 75.2 Foreign organization
for-profit organization	A legal entity formed for the purpose of generating profit for its shareholders or owners. This type of organization is also known as a "commercial organization." See also 45 § CFR 75.2 Commercial organization.
grant	A funding mechanism given to an eligible entity to support a public-purpose project or activity without significant involvement from the awarding agency. Unlike direct benefits for the government, a grant provides financial assistance or other resources to accomplish approved objectives. See also 45 § CFR 75.2 Grant agreement.
high risk	A recipient with a history of subpar performance, financial instability, or inadequate management, placing them at risk of financial or operational failure.
human subject	An individual from whom an investigator collects data via intervention, interaction, or acquisition of identifiable private information, including organs, tissues, body fluids, or any related graphic or recorded details. Regulations govern the use of human subjects.
Indian tribal government	The governing body overseeing an Indian tribe, group, or community, including Alaska Native villages per the Alaska Native Claims Settlement Act of 1971. This body is recognized by the Secretary of the Interior for access to specific programs and services via the Bureau of Indian Affairs and the Indian Health Service. See also 45 CFR § 75.2 Indian tribe.

indirect costs	Costs incurred by a recipient for shared purposes and not tied to a specific project or program. They are also referred to as "facilities and administrative costs." 45 CFR § 75.2 Indirect (Facilities and Administration or F&A) costs
institutional review board (IRB)	A committee that safeguards the rights and well-being of human subjects in research. The IRB can approve, modify, or disapprove research activities under its jurisdiction.
intangible property	Property without physical form, such as copyrights, patents, and other intellectual property rights acquired under awards. It also encompasses loans, notes, leases, stocks, and other ownership instruments. However, intellectual property created, rather than purchased, under awards is excluded.45 CFR § 75.2 Intangible property
international organization	An organization with members from multiple countries, representing their interests, regardless of whether its headquarters or activities are located within or outside of the US.
invention	A potentially patentable or protectable discovery or invention made by an awardee during work funded by a contract, grant, or cooperative agreement. The term "subject invention" refers to inventions specifically conceived or first reduced to practice as part of the funded work.
key personnel	The PI/PD and other individuals who contribute to the programmatic development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award.
local government	A local government entity such as a county, city, town, township, school district, or council of governments, among others. This includes regional or interstate government entities and local public authorities, but excludes institutions of higher education and hospitals. 45 CFR § 75.2 Local government
matching or cost sharing	The value of non-federal contributions to a federally assisted project, including third-party in-kind donations. These costs must adhere to the same allowability policies as other costs in the approved budget. 45 CFR § 75.2 Cost sharing or matching
merit review	An unbiased evaluation of discretionary applications by experts in the relevant field. Also known as objective review. See also 45 CFR § 75.204 HHS funding agency review of merit of proposals.
monitoring	A method of evaluating an award's programmatic and business management performance using data from reports, audits, site visits, and other sources.
non-competing extension	An additional timeframe beyond the original period of performance, granted by the awarding agency or recipient (under expanded authority), to finalize project activities.
non-federal share	The portion of allowable project costs not borne by the Federal government.
notice of funding opportunity (NOFO)	An official announcement from the awarding agency that outlines the availability of federal funds for a specific program. This announcement invites applications and provides essential details such as eligibility requirements, evaluation criteria, and guidelines for application preparation and submission.
objective review	See merit review.

obligations	The value of commitments made by a recipient during a budget period for orders, contracts, subawards, and received goods and services, that will need payment within the current or later budget periods. 45 CFR § 75.2 Obligations
outlays or expenditures	The charges made to the federally sponsored project or program. They may be reported on a cash or accrual basis. 45 CFR § 75.2 Expenditures
patent	A property right awarded by the federal government that grants the right to exclude others from making, using, or selling the invention for a period of years.
peer review	A method of evaluating the merit of applications based on assessment by individuals of equal scientific or technical expertise (peers). This review ensures that applications meet high scientific or technical standards, as determined by experts in the relevant field.
period of performance	The total time for which support of a project has been programmatically approved. 45 CFR § 75.2 Period of performance
pre-award costs	Costs incurred before the official start date of an award, expected to be covered by the award but undertaken at the applicant's own risk, given there's no guarantee of reimbursement unless later approved. 45 CFR § 75.209 Pre-award costs
prior approval	Written approval from the awarding agency's CGMO, or their delegate, granted in response to a recipient's request, to incur a specific cost or action requiring such approval. If these costs/actions are detailed in an application, the award's issuance based on that application serves as the authorization. For indirect cost components, prior approval must come from the relevant agency or as per the associated cost principles. 45 CFR § 75.2 Prior approval
profit	See fee
program income	Income directly produced by a project, program, or activity funded by the award, or earned due to the award. 45 CFR § 75.2 Program income
progress report	Regularly submitted reports, typically annually, from the recipient to the awarding agency to evaluate progress and determine funding for the next budget period, excluding the final report.
real property	Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment. 45 CFR § 75.2 Real property
recipient	The entity or individual awarded a grant or cooperative agreement by the awarding agency. They are accountable for the funds and the execution of the project or activity. Even if a specific component is mentioned in the NoA, the recipient refers to the complete legal entity. 45 CFR § 75.2 Recipient
reimbursement	A payment made to a recipient upon its request after it makes cash disbursements.

research	A comprehensive study aimed at expanding knowledge or addressing a specific need. It involves the application of knowledge to produce materials, devices, systems, or methods, including the design and enhancement of prototypes and processes. Often referred to as "research and development." 45 CFR § 75.2 Research 45 CFR § 75.2 Research and Development (R&D)
research patient care	Standard and supplementary hospital services given to research participants. The expenses for these services are typically allocated to individual research projects using established research patient care rates.
subaward	Financial assistance given as money or property under an award by a recipient to a qualified subrecipient (or by a subrecipient to a lower-tier subrecipient). This aid can be provided through any legal agreement, even if termed a contract, but excludes procurement of goods/services or any assistance other than grants and cooperative agreements. Consortium agreements are included. 45 CFR § 75.2 Subaward
subrecipient	An entity that receives a subaward from a recipient or another subrecipient under a financial assistance award and is responsible to that recipient or subrecipient for the proper use of the federal funds provided by the subaward. 45 CFR § 75.2 Subrecipient
substantive programmatic work	The primary project activities for which award support is provided.
supplies	Tangible items that are not classified as equipment, intangible property, or debt instruments. While some items in the "supplies" category might resemble equipment, they don't meet the specific criteria or cost threshold to be categorized as such. 2 CFR § 200.2 Supplies
suspending award activities	A temporary halt on a recipient's ability to use award funds until they take corrective action as directed by the awarding agency or until the agency decides to end the award. This definition of "suspension" is distinct from its use in the context of debarment and suspension procedures. 45 CFR § 75.2 Suspension of award activities
tangible personal property	Tangible assets including equipment and supplies, excluding intangible property like intellectual property.
termination	The awarding agency's permanent removal of a recipient's right to commit previously granted funds before the initial authority ends, which can include the recipient willingly giving up that right. 45 CFR § 75.2 Termination
total project costs	The total allowable costs (both direct and indirect) that the recipient incurs to carry out a project supported by the award. This includes costs billed to the award itself and costs that the recipient covers as part of a matching or cost-sharing agreement. 45 CFR § 75.2 Total Costs

unallowable cost	A cost specified by law or regulation, federal cost principles, or term and condition of award that may not be reimbursed under a grant or cooperative agreement.
unliquidated financial obligations	If using a cash basis, the amount of obligations made by the recipient that have yet to be paid. If using an accrual basis, the sum of obligations made by the recipient for which a disbursement or expense hasn't been recorded. 45 CFR § 75.2 Unliquidated obligations
unobligated balance	The amount of the funds authorized by the federal agency that the recipient has not obligated. 45 CFR § 75.2 Unobligated balance
vertebrate animal	Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or related purposes.
withholding cash payment	The awarding agency, after following necessary steps, limits a recipient's access to funds until they make the needed corrections.

Appendix C: Post-Award Considerations by Type of Program, Activity, or Recipient

Services Provided by Affiliated Organizations

Universities and other organizations (parent organizations) sometimes create affiliated organizations.

The parent organization often provides considerable support services. These include administration, facilities, equipment, accounting, and other services. The affiliated organization includes the costs of these services in its indirect cost proposal.

In some cases, the awarding agency may reimburse these costs. This happens only when the affiliated organization satisfies any of the following:

- It is charged for, and must legally pay for, the costs.
- It is subject to state or local law that sets out how to spend the federal reimbursement and a state or local official approves the expenditures.
- A formal agreement allows the affiliated organization to keep the related federal reimbursement. The parent organization may direct the expenditure of the funds or allow the affiliated organization to decide.

If these conditions don't apply, the awarding agency cannot reimburse the costs. However, the services may be acceptable for cost-sharing purposes.

Data Sharing for Research and Demonstration Projects Considerations

Expectations

Sharing data and research tools is important to quickly turn research into useful products and knowledge to improve human health. This includes things like cell lines and software. Also sharing information about demonstration projects helps others use and duplicate projects. If you are an NIH recipient, reminder to please go to the NIH GPS at:
https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

HHS encourages researchers to share their findings promptly.

If you enter into subawards, including consortium agreements, and you want access to third-party data or research tools, include a provision in the third-party agreement. There may be times the HHS awarding agency requires you to do so They can also access third-party data or tools. Please check the NoA.

You must also share copies or samples of materials developed under the award. You can charge a small fee for shipping and handling these items. Any income earned from this is considered program income.

If you think you can't meet these expectations, talk to the GMS before getting an award.

Timely Release of Research Data and Tools

Investigators should share their final research data and tools either when their main findings are accepted for publication or when they submit findings to the awarding agency. This ensures timely sharing.

Protection of Certain Data

HHS knows data sharing can be complicated due to various rules and laws, including the HIPAA Privacy Rule, Human Research Protections, and others. We must always protect the privacy of project participants and their data.

For wider use, data must not include any indicators that could reveal the identity of individual participants. Researchers need to ensure that data from human cells or tissues also can't reveal the identity of the original donors.

Researchers can share materials through their lab or organization or submit them to a repository. They should send unique biological data, like DNA sequences, to the appropriate data banks. When sharing unique resources, investigators must provide details about the nature, quality, or characterization of the materials.

Conference Awards

If you have questions about conference awards or what's allowed under your award, ask your GMS.

Here are definitions and details about costs related to conference awards:

- Conference: Events like meetings, retreats, or seminars that share technical information. They must be necessary and reasonable for the award's success.
- International conference: A meeting open to attendees from at least two countries other than the U.S. or Canada. It can be anywhere, even in the U.S. But, if it's outside the U.S. or Canada, award funds can't cover general support. They can cover specific parts, like a workshop or panel.
- Domestic conference: A meeting in the U.S. or Canada mainly for attendees from these two countries. Award funds can support these conferences, whether they're domestic or international.

Equity in Representation

For HHS-supported meetings, ensure diverse participation. Recipients of HHS financial assistance awards must make sure all those eligible for the HHS funded project are able to participate and receive the benefits from the project. When administering HHS-funded meetings, programs, activities, projects, assistance, and services, the recipient must make sure no one able to participate is discriminated against, to the extent doing so is prohibited by Federal statute. Please see 45 CFR § 75.300 and Advancing Equity at HHS for more information.

Funding Requirements

The NoA will include any specific requirements. A change in conference focus is a change in scope and needs prior approval.

Acknowledgment of Support and Disclaimer

All conference materials, like agendas or media promotions, must mention HHS support, whether in whole or in part. Refer to Appendix D for the exact wording of this acknowledgment.

If you're releasing a press statement about activities supported by an HHS award, inform the awarding agency beforehand to coordinate, which may include a review of mate

Allowable and Unallowable Costs and Activities

Please refer to 45 CFR part 75, subpart E, your NOFO/NoA, and the HHS awarding agency.

Other Cost Considerations

If you don't have a written travel policy, follow the Federal Travel Regulation. Always adhere to the U.S. foreign travel restrictions in place at the time, which may include restrictions on countries or limits on funds for travel.

When attending a conference:

- Only claim per diem for days you attend and the actual travel time, taking the most direct route.
- Local travel costs can be covered for local attendees only.
- If meals or lodging cost are nominal or free, like within a registration fee, adjust your per diem accordingly.
- Travel costs shouldn't exceed coach fares. Always choose U.S. carriers when possible.

Intellectual Property: Publications, Copyright, and Public Disclosure

If you publish something using HHS funds, you can distribute it for free. If you sell it, the money earned is considered program income and should be reported as directed in your NoA and on the FFR. More details can be found in the Program Income section of the GPS Program section After the Award.

You can seek copyright for publications from an HHS-supported conference unless your award says otherwise. However, HHS still has rights to the materials, as mentioned in the Irrevocable and the Royalty-Free License GPS section After the Award.

Construction and Modernization of Facilities Awards

Applicability and Definitions

Note that construction and modernization activities must be allowed by law; that law may provide more specifics about allowable construction and modernization activities. However, as a general matter, this section applies to the following HHS award-supported activities:

- Construction: constructing a new building, structure, or facility that provides new space. It also includes installing fixed equipment in such space. It excludes purchasing land and ancillary improvements like parking lots, roads, or fencing. Constructing shell space is not allowed as a construction activity as it does not provide usable space.
- Modernization: altering, renovating, remodeling, improving, expanding, or repairing an existing building. Also includes completing existing shell space. Activities must make the building suitable for the purposes of a particular program. This can include space used for storage or by people. It can range from updating flooring to replacing everything except for the existing frame and foundations. If the main award purpose is modernizing a biomedical research facility, the award can't also support research.
- Alteration and renovation (A&R) activities: These are modernization activities and can be under research awards where the primary purpose of the award is other than construction or modernization.

Refer to the NoA for additional related requirements.

Allowable and Unallowable Costs and Activities

This section outlines costs and activities generally allowable and unallowable under construction awards. (The final decision is based on the decision of the HHS awarding agency and the program.)

These policies apply to the use of federal funds and cost sharing or matching funds. The lists are not all-inclusive. Consult program guidelines and award terms and conditions for specific costs allowable under a program or award.

Allowable Costs and Activities

- Acquisition and installation of fixed equipment.
- Architectural and engineering services.
- Bid advertising.
- Bid guarantees and performance and payment bonds as provided in 45 CFR § 75.334.
- Contingency funds for unanticipated charges included in the initial cost estimates for construction contracts. Before you receive bids, the budgeted amount can't exceed five percent of expected construction costs. You must reduce it to not more than two percent after you award a construction contract.
- Filing fees for recording the Notice of Federal Interest (NFI).
- Force accounts to provide funding for your own construction and maintenance staff used in carrying out modernization activities. These are allowable if you can document that a force account is less expensive than if you were to competitively bid the work. You must substantiate costs with receipts for the materials and certified labor pay records. Use of a force account requires awarding agency prior approval.

- Compliance with the National Historic Preservation Act. This can include:
- hiring special consultants to research and document the historic value of proposed performance sites
- costs to prepare and present required materials to inform the public and others.
- Incentive costs for contractors consistent with contract type as specified in the solicitation of bids or proposals and in the contract. Incentive costs must be reasonable and documented, including that conditions to earn the incentive were met. Incentive-type contracts may also contain a penalty provision. Other types of bonus payments are not allowable.
- Inspection fees.
- Insurance costs of title insurance, physical-destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs. However, you can treat it as a direct cost if your established policy does so and you consistently do so. You may charge title insurance, if required, to the award in proportion to the amount of awarding agency participation in the property. See Real Property —Insurance.
- Legal fees related to obtaining a legal opinion about title to a site.
- Relocation expenses.
- Sidewalks necessary for use of facility.
- Site clearance costs are allowable if reflected in the bid.
- Site survey and soil investigation costs.
- NEPA analysis costs to evaluate the environmental effects and produce the Environmental Impact Statement (EIS).
- Pre-award costs for architect and consultant fees needed for planning and design are allowable if the project is later approved and funded.
- Project management costs.
- Threat-risk assessment costs for a site-specific or project-specific assessment of security risk by a qualified professional. The threat-risk assessment identifies and quantifies potential threats, both internal and external to the building, its contents, the personnel working in it, and the general public. The analysis also includes examination and evaluation of the physical aspects of the proposed facility, along with operational issues.

Unallowable Costs and Activities

- Bonus payments other than earned incentive payments to contractors under formal incentive arrangements.
- Construction of shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract.

- Indirect/F&A costs.
- Fund-raising expenses.
- Land acquisition.
- Legal services not related to site acquisition.
- Movable equipment.
- Off-site improvements such as parking lots.

Prior-Approval Requirements

You must get awarding agency prior approval for the following types of project or budget changes:

- Any applicable changes as specified in the Prior Approvals section of the GPS.
- Change in the use of the facility. See Use of Facility and Disposition in this section.

You must provide enough details in your approval request to explain why you need the change. Once approved, you can make the changes. For smaller changes to construction contracts, you don't need prior approval. But keep copies of all changes as part of your award records.

Procurement Requirements

Construction activity usually is conducted through one or more contracts. All such procurement must use the methods described in 45 CFR §§ 75.327 through 75.335, as applicable.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

You must provide equal employment opportunity and labor standards requirements for federally assisted construction and modernization to potential bidders/offerors and include them in the resulting contract. See 45 CFR part 75, Appendix II (C) and 41 CFR chapter 60. The Davis-Bacon Act or the Copeland "Anti- Kickback" Act apply only if specifically required by the program's authorizing statute. The NoA will show if they apply.

Equal Employment Opportunity Requirements

Construction contracts (and subcontracts) awarded under HHS awards must follow the requirements of EO 11246 and implemented in 41 CFR § 60-1. Recipients must:

- Include the "Equal Opportunity Clause" at 41 CFR § 60-1.4(b) in any construction contract under the award. You must direct the contractor to include this clause in any applicable subcontracts.
- Follow solicitation and contract requirements for affirmative action specified in 41 CFR § 60-4 for contracts in specified geographical areas that will exceed $10,000. These requirements are specified in EO 11246.
- Notify the Office of Federal Contract Compliance Programs regional, area, or field office when you expect to award a construction contract over $10,000.

Labor Standards Requirements

- Under EO 13202, as amended by EO 13208, you must ensure that bid specifications, project agreements, or other controlling documents for construction services contracts:
- Ensure that bidders, offerors, contractors, or subcontractors are able and willing to enter into or adhere to agreements with one or more labor organizations on the same or other related construction projects.
- Refrain from discrimination against bidders, offerors, contractors, or subcontractors for initiating, refusing to initiate, or adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Under 41 CFR § 60-1.8, segregated facilities are not permitted for any contract for construction services that will exceed $10,000. The recipient must require each prospective contractor to submit a certification that the contractor:

- Maintains all facilities provided to employees in a non-segregated manner
- Prohibits its employees to perform services at any location, under the contractor's control, that maintains segregated facilities
- Obtains a similar certification before awarding any covered subcontract

Awards, contractors, and subcontractors with construction contracts or subcontracts over $100,000 must follow the Contract Work Hours and Safety Standards Act, 40 USC 3701–3708. Among other provisions, the statute covers standards listed below. Consult the statute for proper interpretation and guidance.

- Work hours
- Report of violations and withholding of amounts for unpaid wages and liquidated damages
- Health and safety standards in building trades and construction industry
- Safety programs
- Limitations, variations, tolerances, and exemptions
- Contractor certification or contract clause in acquisition of commercial items not required
- Criminal penalties

Other Requirements

Liquidated Damages

Invitations for bids must supply a date or timeframe to complete the project for each prime contract. You may include a liquidated damages provision in the contract. It allows you to assess damages when the contractor does not complete the construction or modernization by the specified date. Liquidated damages must be real, justified, and approved by the awarding agency before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

Disposition of Unclaimed Wages

If an employee doesn't claim wages from an HHS-supported construction contract, the recipient might need to pay HHS back. Here's the process:

- Check that the contractor tried to find the employee. This might include forwarding mail or contacting their union.
- If the contractor's search fails but seems incomplete, try to find the employee.
- Open an escrow account in the employee's name. Keep it for two years after the contract ends, or longer if local laws say so. Tell the GMS about this account.
- If you pay wages from the account to the employee or their representative, report to the GMS when you close the account.
- If money is still unclaimed after two years, refund the awarding agency based on the award's contribution to those wages.

Use of Facility and Disposition

Unless a statute or instructions from your awarding agency say otherwise, here's how to manage real property:

- Keep using the property for its intended purpose. Don't sell or encumber the title without approval.
- If you don't need it for the initial purpose, get written approval from the awarding agency to use it for a similar federally funded project.
- If you no longer need the property, follow the rules in 45 CFR 75.318. Your options include:
- Keep it and pay the awarding agency their fair share based on their contribution and the property's market value.
- Replace it. If buying new property under the same award, use any sales money to reduce the new property's cost.
- Sell it and pay the awarding agency based on a formula in 45 CFR 75.318(c)(2).
- Transfer it to the awarding agency or their approved third party. They'll pay you your fair share based on your contribution and the property's current market value.

Foreign Organizations, International Organizations, and Domestic Recipients with Foreign Components

The GPS generally applies to awards to foreign organizations and international organizations. You can find the definitions of these terms in Appendix B of the GPS. In this section, we refer to them as foreign awards.

The AOR must contact the GMS if their organization can’t follow these requirements. This section includes:

- Exceptions and modifications to GPS requirements for foreign awards
- Highlights of other related policies
- Policies that apply to awards with a foreign component

Public Policy Requirements and Objectives

Requirements in Appendix D apply to foreign awards, unless otherwise noted here, the NoA, or in awarding agency policies. Exceptions include:

- Civil rights: The civil rights requirements do not apply to foreign awards.
- Debarment and suspension: These rules and the certification requirement do not apply to:
- foreign governments and foreign recipients
- public international organizations
- entities that are foreign-government-owned or controlled, in whole or in part

All other foreign organizations and international organizations are subject to these rules.

- Drug-Free workplace: The awarding agency may exempt foreign awards from these requirements. To do so, they must find that the requirements are not consistent with U.S. international obligations or the laws and regulations of a foreign government.
- Environmental requirements: A foreign award isn't subject to environmental requirements that would not otherwise apply to it.

Funding and Payment

These policies apply:

- All application budgets, fund requests, and financial reports must be in U.S. dollars.
- If exchange rates change, extra costs might be covered, depending on the awarding agency's available funds.
- You only need prior approval for rate changes if they lead to needing more federal funds or if they will reduce project scope significantly.
- Review local currency gains to determine if you will need additional federal funding before the award ends.
- Adjustments for currency increases may be allowable only when you provide the awarding agency with adequate source documentation from a commonly used source in effect at the time you made the expense.

Allowable and Unallowable Costs

The cost principles that apply to foreign organizations depend on the type of organization. See Cost Principles. There are some exceptions:

- Major A&R are unallowable under foreign awards and domestic awards with foreign components, except where allowed by the governing statute and as indicated in the NoA.
- Minor A&R are generally allowable on awards made to foreign organizations or to a foreign component of a domestic award, unless prohibited by the governing statute or implementing program regulations. You may include and justify minor A&R costs in the detailed application budget. Rebudgeting to accommodate minor A&R requires prior approval.
- F&A Costs under foreign awards, including foreign recipients with a domestic component, are at a fixed rate of eight percent of modified total direct costs. These are direct costs minus tuition and related fees, equipment, and subawards in excess of $25,000. See 45 CFR 75.414(c)(1)(ii). These funds are to support the costs of compliance with federal requirements.
- Capital expenses (facilities) are not allowable, except where allowed by the governing statute and as indicated in the NoA. The awarding agency will not support the acquisition cost or provide for depreciation.
- Equipment is an allowable direct cost.
- Patient care costs are provided only in exceptional circumstances or where allowed by the statue setting up the award program.
- Travel Visas (including short-term) are generally allowable:
    - As a direct cost as part of recruiting costs if the institution has an employee-employer relationship with the individual
    - When identified in specific NOFOs
    - If within the scope of an approved research project

Administrative Requirements

Expanded authorities generally apply to foreign awards. Review the NoA to determine the specific award requirements. See the Prior Approvals and Expanded Authority sections of the GPS. These requirements also apply to subawards to foreign entities under financial assistance arrangements, rather than acquisition of goods or services.

If you make a subaward to a foreign entity, to comply with audit requirements, you must include oversight methods. These may include reviewing reports, on-site reviews, or alternatives to a single audit, if one will not be available during the period of the subaward.

Federal Institutions and Payments to or on Behalf of Federal Employees Under Awards

Most policies contained in the GPS apply to awards made to federal institutions. This section includes specific exceptions and modifications of general GPS requirements for federal recipients. It also highlights other related policies.

Eligibility

Specific eligibility is in each NOFO. An awarding agency may not issue an award to any component of its own organization.

PHS organizational segments, other than IHS hospitals, may receive award support under exceptional circumstances only. Such circumstances may include when the work cannot be supported within the mission of the PHS agency and cannot be performed elsewhere.

The federal agency or department is the official applicant, regardless of where within it the work is to be performed. A federal institution must ensure that its own authorizing legislation allows it to receive awards and to be able to comply with the award terms and conditions.

A document that assures both the assumption of responsibility and authority to receive an award must accompany each new and competing continuation application. The assurance must be signed by the head of the responsible federal department or independent agency or a designee who reports directly to the department or agency head. This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

For-Profit Organizations

General

Terms and conditions for for-profit organizations vary from standard ones. Also, terms and conditions for SBIR and STTR programs vary from those usually applied to for-profit organizations.

Cost Principles

Usual cost principles do not specifically apply to for-profit organizations. As a result, use:

- For for-profit organizations: FAR, 48 CFR § 31.2.
- For private hospitals: 45 CFR part 75, appendix IX.

Allowable and Unallowable Costs

Allowable Costs

- Indirect costs
- Travel that does not exceed costs established by the Federal Travel Regulation (FTR).

Unallowable Costs

- Independent research and development costs, as provided in 45 CFR § 75.476.
- Profits or fees, except for awards under the SBIR and STTR programs and funds paid to a contractor for routine goods or services.

Consult the GMS for questions on costs.

Administrative Requirements

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management.

- Equipment: For-profit groups must track equipment. You can't use award-funded equipment to compete unfairly by offering paid services. Any fees charged for using the equipment count as program income and you must report it on the FFR.
- Intellectual property: All for-profit groups, regardless of size, follow the intellectual property rules in 37 CFR § 401. For-profit organizations have different invention reporting rules than non-profits. For-profit organizations can assign invention rights to others without agency approval, but they must still report each invention. The federal government will keep information about federally supported inventions confidential, as allowed by law.
- Program income: See Program Income.
- Operating authorities: Standard award terms apply to for-profit organizations. However, some policies do not allow automatic carryover of unobligated fund balances. The NoA specifies the disposition of the reported unobligated balance.
- Audit: Requirements for non-federal audits of for-profit organizations are in 45 CFR § 75.501. For-profit organizations are subject to requirements for non-federal audits. See Audit Requirements.
- Labor distribution requirements: Salary and wage amounts charged to awards for personal services must:
    - Be based on an adequate labor distribution system that distributes payroll costs in line with generally accepted practices of like organizations.
    - Align to industry standards.
    - Track time spent on award activities. The time and-effort reporting system used must:
    - Be for both professional and other staff
    - Reflect daily reporting
    - Track time by individual projects and indirect activities
    - Record both hours worked, and hours absent
    - Enable the AOR to meet the requirement to certify time entries at least every pay period.
    - The GMS must approve any alternative system.

Small Business Innovation Research and Small Business Technology Transfer Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have three stages. Some projects might not be eligible for all three.

Phase I

Before providing Phase II support, this phase assesses:

- The technical merit and feasibility of proposed research or R&D
- The quality of the applicant's performance

Phase II

This phase advances efforts started in Phase I. These policies apply:

- Funding is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.
- Only Phase I recipients can apply for Phase II funding.
- You can only submit Phase II applications before a Phase I award if using the Fast-Track application process (see below).
- You must submit non-Fast-Track Phase II applications within the first six receipt dates after the end of your Phase I budget period. This is typically two years.

Phase III

The SBIR and STTR programs do not fund Phase III. This phase is for the SBC to work to commercialize the results of the research or R&D done in Phases I and II. In some cases, a federal agency may:

- Use non-SBIR and STTR funds to continue the work.
- Contract for items for federal use.

SBIR and STTR

STTR

The STTR program focuses on teaming a Small Business Concern (SBC) with a non-profit research body for a project that might be turned into a product.

The program requires:

- The SBC collaborates with a single non-profit research institution.
- The SBC must do at least 40% of the research. A domestic non-profit organization does at least 30%. This rule is the same for both Phase I and Phase II.
- Eligible research partners include universities, non-profit hospitals, other non-profits research organizations, and federally funded Research and Development Centers.
- The award goes to the SBC. It disperses funds to the research institution.
- The PI must spend at least 10% of their time on the STTR project.

SBIR

The SBIR program requires that SBC employ the PI at least half-time at the time of award and during the project.

Fast-Track Process

The Fast-Track process speeds up decisions and funding for SBIR and STTR Phase II applications. Policies include:

- To be eligible, the project must be scientifically meritorious with a high potential for commercialization.
- Not every agency lets SBCs use Fast-Track. Talk to the agency first before applying.
- If you aren't approved for Fast-Track, your application might go through the regular review.
- With Fast-Track, Phase I and Phase II applications are handled together and usually get one overall score.

For more details, check the SBIR and STTR NOFOs.

Place of Performance and Sources of Materials

All project activities for Phase I and Phase II of SBIR and STTR must be done in the United States. Using a foreign site for research is rare and needs a solid scientific reason. An example includes testing specific patient groups only available abroad. You must attempt to get alternate funding for the part of the work to be done abroad.

If you must buy materials from another country, you must have a good reason and clearly explain it. Approval of such a waiver is rare. The awarding agency reviews each request individually. If you'll need to do this, talk to the GMS before you apply.

GMSs decide waiver requests. The NoA will clearly state if it is approved.

Change in Organization Status & Change of Recipient Institution Actions

The awarding agency makes eligibility decisions at the initial award time.

A later event like a merger or successor-in-interest could alter the organization's status. If the change makes the organization ineligible for the SBIR or STTR program:

- Any current awards can still proceed unless the small business concern makes a material misstatement that the agency decides poses a risk to national security; or there is a change in ownership, change to entity structure, or other substantial change in circumstances of the small business concern that the Federal agency decides poses a risk to national security
- After that, the organization will not qualify for new SBIR or STTR awards

If an SBIR or STTR award needs to be transferred to a different institution or organization, this new entity must also fulfill the eligibility requirements of the SBIR or STTR program.

Contact the awarding agency to discuss options when considering a move to a new organization.

Minimum Level of Effort

Congress requires minimum levels of effort for these programs.

SBIR required levels of effort:

Program and Phase:	SBC level of effort:	Aggregate payments to others may not exceed:
SBIR Phase I	67%	33%
SBIR Phase II	50%	50%

STTR minimum levels of effort:

Program and Phase:	SBC minimum level of effort:	Single, non-profit research institution minimum LOE:
STTR Phase I	40%	30%
STTR Phase II	40%	30%

Policies include:

- Waivers are not allowed.
- The basis for establishing the percentage of work to be done by each participant is the entire cost (including direct, indirect costs, and fee) related to each party. However, if described and justified under the "Consortium/Contractual Arrangements" section of the application, a different basis might be used.

Multiple Program Director or Principal Investigator Applications and Awards

Team science efforts may use a multiple program director or principal investigator (Multi PD/PI) option. The following policies apply:

- The SBC is always the applicant or recipient organization. Other participants are subcontractors.
- Each PD or PI must commit at least 1.2 calendar months (10% effort) to the project.
- SBIR Phase I and II projects: The contact PD or PI must meet the primary employment requirement. Other PDs or PIs do not have to meet the requirement.
- STTR Phase I and II projects: The PI listed must have a formal appointment with, or commitment to, the SBC. This must be an official relationship but does not require pay.
- Phase IIB Multi PD/PI competing renewal applications: If previously supported through a single PD/PI award, the new application must state the changes in the project's management that led to the proposed Multi PD/PI model.

Public Policy Requirements

Requirements in Appendix D: Administrative and National Policy Requirements apply, unless otherwise noted here or in awarding agency policies.

- Disclosure of financial conflicts of interest does not apply to Phase I of the SBIR and STTR programs.
- Under an SBIR or STTR award, the SBC should purchase only American-made equipment or products when possible.

Allowable Costs and Fees

Program Levels (Total Costs)

The SBA SBIR and STTR Policy Directive provides program levels for SBIR and STTR programs based on statutory guidelines. The directives allow awarding agencies to exceed these levels up to 50% over the guideline when the proposed budget and requested period of support are justified and scientifically appropriate for the proposed research.

In some cases, Phase II SBIR or STTR recipients may apply for Phase IIB competing renewal awards. These are available for projects that require extraordinary time and effort for R&D. Only those SBCs awarded a Phase II may apply for the Phase IIB award.

Applicants must request an appropriate level in the competing application. The awarding agency will not adjust it after submission.

Profit or Fee

SBCs can earn a reasonable profit or fee under Phase I and II of the SBIR and STTR programs.

- This profit or fee must be in the application budget.
- The profit or fee isn't considered a cost for determining allowable use, program income accountability, or setting audit thresholds.
- The SBC can use the profit or fee for any purpose, including investment into the awarded project.
- The intent is to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work. Typically, the profit or fee will not surpass seven percent of the total project costs for each phase.
- The profit or fee should be drawn from PMS in proportion to the drawdown of funds for direct and indirect costs.
- The profit or fee is exclusively for the SBC that receives the award. However, in line with regular commercial practices, the SBC can pay a profit or fee to a contractor that provides routine goods or services under the award.

Indirect Costs

If the applicant SBC has a currently effective indirect cost rate with a federal agency, the rate should be used when calculating proposed indirect costs for an application. The rates must be adjusted for IR&D expenses, which are not allowable under HHS awards.

If that applicant does not have an approved indirect cost rate, one can be proposed in the application. See below for specific requirements for each phase. If awarded at a rate, indirect costs cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with a federal agency. The awarding agency will not negotiate indirect cost rates for Phase I awards.

If you do not have an effective negotiated indirect cost rate, you may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs. You can charge only actual indirect costs to projects.

Phase II

If you do not have an effective negotiated indirect cost rate, you may propose an estimated indirect rate in the application.

If the requested rate is 40 percent of total direct costs or less, you do not need to provide further justification. You can charge only actual indirect costs to projects.

If you choose to negotiate an indirect cost rate greater than 40%, DFAS is the appropriate agency. Upon request, provide DFAS with an indirect cost proposal and supporting financial data for your most recently completed fiscal year. If you do not have financial data for the most recently completed fiscal year, submit a proposal showing estimated rates with supporting documentation.

Administrative Requirements

Market Research

HHS will not support market research, including studies of the literature that lead to a new or expanded statement of work.

No SBIR or STTR funds, direct or indirect, can be used to support commercialization.

For SBIR and STTR programs, market research is the systematic gathering, editing, recording, computing, and analyzing of data relating to the sale and distribution of the research subject. It includes research on:

- The size of potential markets and potential sales volume
- Identifying consumers most apt to purchase the products
- The advertising media most likely to stimulate their purchases

Market research does not include activities that include a public survey to determine the research subject's impact on the behavior of individuals.

Intellectual Property

The recipient keeps rights to data and software created with award funding. However, the federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use the material and to authorize others to do so for Federal purposes.

For SBIR and STTR awards, unlike other commercial awards, such data cannot be released outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

Data Rights

Section 9 of the Small Business Act, as amended (15 USC 638), allows SBC's under an SBIR or STTR award to retain their data rights for at least four years. The SBIR/STTR Policy Directive applies the following data rights:

- The Act allows small business concerns (SBCs) to keep the rights to data they create while working on an SBIR/STTR award. This helps encourage SBCs to participate in Federally funded research and supports them in commercializing their technology. The Federal Government will have access to this data to assess the projects and use the results, but it cannot use the data in ways that would hurt the SBC's rights or economic opportunities. The SBIR/STTR data rights provisions and definitions ensure that the Federal Government effectively protects properly marked SBIR/STTR data during the SBIR/STTR protection period just as well as it protects data developed at private expense.
- Federal agencies that participate in SBIR/STTR awards must make sure that SBC recipients keep appropriate proprietary rights to data generated while working on an award. In general, this means the Federal Government will have rights to that data during the protection period, except for certain types of data that are not subject to such data rights restrictions.
- SBIR/STTR data rights apply to all SBIR/STTR awards, including subcontracts, for all phases of the program (I, II, or III) as defined by the SBA Policy Directive from May 2, 2019. The rights for Phase III awards are the same as those for Phases I and II.
- SBIR/STTR data rights restrict the Federal Government's use and release of properly marked SBIR/STTR data only during the SBIR/STTR protection period. After the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes. At this time, the Federal Government is relieved of disclosure prohibitions related to such government purposes and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.

SBIR/STTR Data Rights - Main Elements:

- An SBC retains title and ownership of all SBIR/STTR data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR data that are not granted to the Government in accordance with the SBA Policy Directive. These rights of the SBC do not expire.
- The Government receives SBIR/STTR data rights during the SBIR/STTR protection period on all appropriately marked SBIR/STTR data. These rights enable the Federal Government to use SBIR/STTR data in limited ways within the Government, such as for project evaluation purposes. These rights are intended to prohibit use and disclosure of SBIR/STTR data that may undermine the SBC's future commercialization of the associated technology. The Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.
- After the SBIR/STTR protection period has expired, the Federal Government may use, and authorize others to use on its behalf, for government purposes, SBIR/STTR data that was subject to SBIR/STTR data rights during the SBIR/STTR protection period.
- The SBIR/STTR protection period begins with award of an SBIR/STTR funding agreement. It ends twenty years, or longer at the discretion of the participating agency, from the date of award of an SBIR/STTR award (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless the agency and the SBC negotiate for some other protection period for the SBIR/STTR data subsequent to the award.
- Any SBIR/STTR data that is delivered must be marked with the appropriate SBIR/STTR data rights legend or notice to receive the protections given to SBIR/STTR data pursuant to SBIR/STTR data rights. The Government is not liable for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR data that is not appropriately marked in line with agency procedures. If SBIR/STTR data is delivered without the required legend or notice, the SBIR/STTR recipient may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR data legend or notice, as applicable, placed on qualifying data. If SBIR/STTR data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the recipient's expense.

Negotiated Rights:

- An agency must not, in any way, make issuance of an SBIR/STTR award conditional on the SBC negotiating or consenting to negotiate a special license or other agreement regarding SBIR/STTR data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
- After issuance of an SBIR/STTR award, the SBC may enter into a written agreement with the agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR protection period. However, the agreement must be

entered into voluntarily, by mutual agreement of the SBC and agency. The agreement cannot be a condition for additional work under the funding agreement or the exercise of options. The agreement must be entered into only after the SBIR/STTR award, which must include an appropriate SBIR/STTR data rights clause, has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR funding agreement is signed. A decision by the recipient to relinquish, transfer, or modify in any way its rights in SBIR/STTR data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR data rights shall have no effect on the provision of SBIR/STTR data rights in a resulting Phase I, Phase II, or Phase III award.

- To ensure that SBIR/STTR recipients receive the applicable data rights, all SBIR and STTR NOFOs and resulting funding agreements must fully implement all of the policies, procedures, and requirements set forth in the SBA Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR NOFOs and awards. The SBA Policy Directive provides a sample SBIR/STTR data rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.
- The STTR program requires that the SBC and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research.

SBIR and STTR recipients are covered by 35 USC 200-212 and 37 CFR § 401 with respect to inventions and patents.

Data Sharing

For SBIR Phase II funding over $500,000 in a year in direct costs, applicants must follow the GPS on data sharing, unless the Small Business Act conflicts. If the data is proprietary or sensitive, the SBC should explain it in the application. Whether or not the award meets the threshold for data sharing under Intellectual Property, HHS won't share data outside the federal government without recipient approval for a period of 20 years from completion of the project.

For more information, please see NIH's SBIR/STTR information page.

Research Awards

Human Subjects in Research

The regulation for all HHS awards involving human subjects research is 45 CFR part 46, Basic HHS Policy for Protection of Human Subjects. Subpart A is also known as the Common Rule. These regulations

implement Section 491(a) of the Public Health Service (PHS) Act. These regulations apply to both domestic and foreign organizations.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy.

All NOFOs will clearly state:

- The parameters of human subject use
- The information and assurances required from you prior award

There is a single version of the Federal-wide Assurance (FWA) form and Terms of Assurance for domestic and international institutions.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities (45 CFR § 46.101(a) and 45 CFR § 46.103(a)).

Recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

Exemptions

Some human subject research is exempt from the requirements of the HHS regulations.

The categories of research that qualify for exemption are found at 45 CFR § 46.104(d)(1)-(8). HHS has final authority to decide if a particular research study supported by HHS is exempt from the HHS regulations. OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in 45 CFR § 46.101(c) regarding whether a particular activity is regulated by 45 CFR part 46. Contact OHRP for questions.

Policies for Non-Exempt Human Subjects Research

The recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA (45 CFR § 46.103(a)).
- Certify to the awarding agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA (45 CFR § 46.103(d)).

The OHRP website contains a listing of those organizations with OHRP-approved assurances.

The awarding agency must make sure an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award unless there is a specific condition in the NoA restricting expenditures for this purpose.
- You initiate human subjects research, and the awarding agency removes any related NoA specific condition.
- Approving a post-award change in scope that will result in human subjects research.

The specific award condition must indicate that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving human subjects at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.

The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Research Involving Animals and Their Welfare

Requirements for using live, vertebrate animals apply to all PHS agencies and other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, OASH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).
- Incorporate the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training.
- Require the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals.
- Require compliance, as applicable, with the Animal Welfare Act and other federal statutes and regulations relating to animals.

You must establish appropriate policies and procedures to ensure the humane care and use of animals, and you are ultimately responsible for compliance with the PHS Policy.

You can get information about animal welfare topics from the Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW. The list of organizations with approved assurances is on the OLAW website for both domestic institutions and foreign institutions.
- Verify, as part of the application or before award, current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. PHS Policy requires that IACUC approval must have happened within three years of the period of performance start date for new or renewal awards and at least every three years after that.
- Comply with the awarding agency's internal IACUC requirements if a cooperative agreement.

If you do not have a current Animal Welfare Assurance (or made alternative arrangements, like an inter-institutional assurance acceptable to OLAW) or has not provided the required verification by the

time an award is to be made, the awarding agency will notify the PO and the applicant. The awarding agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals.
- Include a specific condition in the NoA restricting expenditures.

The award condition must state that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving animals at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.
- The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Before approving changes involving animal research after award, the awarding agency needs to confirm that there's a proper Animal Welfare Assurance with OLAW. They also need verification from the IACUC.

Reporting

Reporting requirements under the PHS Policy include an annual report to OLAW describing:

- Any updates in your animal care program as mentioned in the Assurance.
- Changes in IACUC membership
- The dates when the IACUC reviewed your program and facilities.

Lastly, the IACUC must quickly report any serious issues or breaches in policies, guidelines, or any suspensions through the official who signed the Assurance.

Foreign Applicants

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which includes:

- Institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted
- A commitment to follow the International Guiding Principles for Biomedical Research Involving Animals.

Awards to Individuals

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy.

Appendix D: HHS Administrative and National Policy Requirements

Please go to the following page to see updated HHS requirements:
https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf

Additional Information on Uniform Administrative Requirements

As stated in the information linked above, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75) apply to all HHS awards, unless specifically exempted by 45 CFR § 75.101(d) or (e).

As of October 1, 2024, the following provisions from 2 CFR part 200 are effective for all new HHS awards or monetary actions (new, continuation, and supplements):

2 CFR § 200.1 Definitions: Modified Total Direct Cost (MTDC), which increases the exclusion threshold of subawards from $25,000 to $50,000 for modified total direct costs, definition of Equipment, which increases the threshold for determining equipment from $5,000 to $10,000, definition of Supplies, which increases the threshold for determining supplies from $5,000 to $10,000;

2 CFR § 200.313 (e) Equipment: Increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency" (*see 2 CFR section 200.313(e)(1)*). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.

2 CFR § 200.314(a) Unused Supplies: Increases from $5,000 to $10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items (*see 2 CFR section 200.314*).

2 CFR § 200.320 Micro-purchase Threshold: Increases the micro-purchase threshold to $50,000 (*see 2 CFR 200.320*).[1]

2 CFR § 200.333 Fixed Amount Awards Subawards: Increases from $250,000 to $500,000 the amount of fixed amount subawards that a recipient may provide with prior written approval from the Federal agency (*see 2 CFR section 200.333*).

2 CFR § 200.344 Closeout: Increases the time period for recipients to submit final reports in support of closeout of the award from 90 to 120 days (*see 2 CFR 200.344*).[2]

2 CFR § 200.414(f) De Minimis Indirect Rate: Increases from 10% to 15% the rate that recipients of Federal funds may use for indirect costs without negotiating an alternative rate with the relevant

[1] This provision has already been adopted by HHS by operation of law, Pub. L. No. 115-91, and OMB Memorandum 18-18. It is included to be clear that this regulation is in force for HHS.

[2] This provision has already been adopted by HHS. See 88 FR 63591 (Sept. 15, 2023). It is included to be clear that this regulation is in force for HHS.

Federal agency (*see 2 CFR section 200.414*). Note that this does not apply to HHS Training or Foreign awards, for which HHS proposes to maintain a modification that caps the de minimis at 8%.

2 CFR § 200.501 Single Audit: Increase from $750,000 to $1,000,000 the level at which a recipient of Federal funds is required to conduct a single audit or a program specific audit (*see 2 CFR section 200.501*).

Appendix E: Financial Assistance General Certifications and Representations

In almost all instances, applicants must have a SAM.gov registration. Agreement to a list of general certifications and representations is required for registration.

Please go to the following page to see updated Certifications and Representations:

https://www.hhs.gov/sites/default/files/financial-assistance-general-certification-representations.pdf