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Healthcare Alert

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NIH seeks reduction of research indirect cost rates to 15%

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On February 7, 2025, NIH issued guidance that seeks to immediately reduce indirect cost rates to 15% for all existing and new NIH research grants.



What's the impact?

- If implemented, the reduction in indirect cost rates would severely disrupt research conducted across medical and research institutions nationwide, resulting in a multi-billion dollar reduction of research funding and leaving institutions with critical and potentially insurmountable funding gaps.
- Three federal lawsuits filed in the District of Massachusetts resulted in the issuance of a February 10, 2025, Temporary Restraining Order (TRO) on the Guidance, with a court hearing scheduled on February 21, 2025.
- Funding levels beyond FY 2025 remain uncertain.

April 8, 2025, Update: On April 4, 2025, at the request of all parties, the District Court entered a permanent injunction prohibiting the government from enforcing the Guidance, pending a

future decision by an appellate court. On April 8, 2025, the government issued a Notice of Appeal to the First Circuit.

Separate from the above matter, on April 2, the ACLU, on behalf of individual researchers, sued the National Institutes of Health (NIH) in a Massachusetts federal court seeking to restore recently canceled funding for grants that failed to effectuate NIH's current "agency priorities." These grants purportedly relate to DEI research. Additionally, 16 states filed a lawsuit on April 4, seeking to restore \$2.4 billion in similar funding, claiming that NIH's reasoning—that NIH may cancel a grant solely because such research is not an "agency priority"—is not a statutorily valid basis for canceling or refusing to review grants until new HHS regulations become effective in October 2025. Accordingly, the two new complaints argue that without a different statutory basis underlying NIH's decision, the funding must be immediately restored, regardless of the research's focus.

March 5, 2025, Update: On March 5, 2025, the district court granted a nationwide preliminary injunction, enjoining the government from "taking any steps to implement, apply, or enforce the [Guidance] in any form with respect to institutions nationwide." The court stressed that because the Guidance was so sweeping in substance, only a nationwide injunction could serve as an appropriate remedy.

The court substantiated all of the plaintiffs' legal theories, finding that NIH may not issue a blanket rate for all awards, the Guidance was arbitrary and capricious, contradicted existing NIH policy, and is expressly prohibited by the existing congressional legislation. The government has 60 days to appeal the district court's order, and the litigation remains ongoing pending a future full hearing on the merits.

The National Institutes of Health (NIH) published <u>guidance</u> on Feb. 7, 2025, titled, "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates," and announced that "this Guidance implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance. Pursuant to this Supplement Guidance, there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant."

The Guidance sent shock waves through medical and research institutions across the United States, as existing negotiated indirect cost rates range from approximately 20–60%, and the newly announced rate cap collectively threatens billions of dollars of academic and medical research funding.



NIH grants permit awardees to negotiate indirect cost allocation as a percentage of a research grant award. The indirect cost rate is intended to support facilities and administrative expenses, which encompass substantial expenses necessary to supporting vital scientific research. Indirect cost rates include, for example, costs for infrastructure, equipment, and support staff.

DISTRICT OF MASSACHUSETTS LAWSUITS

On February 10, 2025, three lawsuits were filed to enjoin the Guidance. As of February 10, 2025, the plaintiffs include twenty-two state governments,¹ five trade groups,² and sixteen universities.³ The lawsuits assert multiple violations of the Administrative Procedure Act (APA), including the following.

- / Plaintiffs allege that the Guidance is arbitrary and capricious because it fails to justify its immediate and striking deviation from historic negotiated rates and because it fails to account for each individual institution's specific reliance on indirect costs.
- Plaintiffs allege that the Guidance exceeds the NIH's statutory authority because the manner in which the Guidance seeks to alter indirect cost rates directly violates an existing congressional directive. In 2017, the first Trump administration proposed a similar policy to set blanket rate caps at 10%. Congress rejected this push and provided in the 2018 budget, and all subsequent budgets including for 2025, that NIH may not alter indirect funding rates.
- / Plaintiffs allege that the statutory authority providing NIH with the power to negotiate individual rates with awardees implicitly prohibits the NIH from enacting a blanket rate.⁶

On February 10, 2025, the District Court for Massachusetts issued a nation-wide temporary restraining order barring enforcement of the Guidance, pending a February 21, 2025, hearing.⁷

The complaints contain extensive allegations outlining the drastic impact of the reduction in indirect cost rates. For instance, the University of Michigan alleges that it currently has a

⁷ Order Granting Plaintiffs' Emergency Motion for Temporary Restraining Order, Association of American Medical Colleges, et al. v. National Institutes of Health, et al., No. 1:25-cv-10340-AK (D. Mass., Feb. 10, 2025).



¹ Commonwealth of Massachusetts, et al. v. National Institutes of Health, et al., No. 1:25-cv-10338-AK (D. Mass., Feb. 10, 2025).

² Association of American Medical Colleges, et al. v. National Institutes of Health, et al., No. 1:25-cv-10340-AK (D. Mass., Feb. 10, 2025).

³ Association of American Universities, et al. v. National Institutes of Health, et al., No. 1:25-cv-10346-AK (D. Mass., Feb. 10, 2025).

⁴ See OMB, Major Savings and Reforms: Budget of the US Government Fiscal Year 2018, at 43 (2017).

⁵ See Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 224, 226; Consolidated Appropriations Act, 2025, Pub. L. No. 118-83, §§ 101, 106 and Further Consolidated Appropriations Act, 2025, Pub. L. No. 118-158, § 101.

^{6 45} CFR § 75414(c)(1)-(3).

negotiated indirect cost rate of 56%, which is similar to the rates alleged for other research institutions like Oregon Health and Science University (56%) and the University of Colorado Anschutz Medical Campus (56%).⁸ If the Guidance is upheld and implemented, the rate cut would "eliminate approximately \$181 million in funding" to the University of Michigan, \$80 million to the Oregon Health and Science University, and \$74 million to the University of Colorado Anschutz Medical Campus.⁹ Notably, these institutions allege that the rate cut would limit research into areas that include "life-saving" treatments, "ongoing clinical trials," and "new approaches for [treating] Alzheimer's disease." These examples reflect a small sampling of the scientific and clinical areas that would be affected by the rate decrease, as outlined in the complaints.

ADDITIONAL CONSIDERATIONS

The funding shortfalls that would arise if indirect cost rates were reduced to 15% portend additional funding questions that institutions will need to address beyond FY 2025, as indirect cost rates are generally (with some exceptions) negotiated on an annual basis. The funding uncertainty is likely to impact future planning and resource allocation unless and until more clarity is provided.

These funding uncertainties also may raise ancillary legal, business, and operational questions, such as adherence to contractual commitments with third-party sponsors or other research funders, personnel retention and HR implications, regulatory compliance commitments, and capital resource questions.

Nixon Peabody attorneys familiar with the Guidance and associated litigation are monitoring the fast-moving litigation and related developments.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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¹⁰ *Id.* at ¶¶ 98, 137, and 112.



⁸ Complaint at ¶¶ 98, 137, and 113, Commonwealth of Massachusetts, et al. v. National Institutes of Health, et al., No. 1:25-cv-10338-AK (D. Mass., Feb. 10, 2025).

⁹ Id.