

CLIENT ALERT

National Institutes of Health Newly Disseminated Guidance on Charging of Indirect Grant Costs

FEBRUARY 24, 2025

On February 7, 2025, the National Institutes of Health (NIH) announced that it will eliminate negotiated indirect cost rates for federal grants to organizations for research purposes. According to the <u>Supplemental Guidance NOT-OD-25-068</u> (the Guidance), the NIH will, instead, set a "standard indirect rate" of 15% for all NIH grant awards for indirect costs "in lieu of a separately negotiated rate for indirect costs in every grant." The new rate will be applied to all current grants for expenses from February 10, 2025, as well as all new grants issued by the NIH. The Guidance states that the rate is retroactive for all existing grants to institutions of higher education. If put into effect, this policy change will directly impact the availability of federal funds used to support biomedical research performed, often by public institutions, in the United States.

WHAT ARE INDIRECT COSTS?

"Indirect costs" for federal grants, defined by regulation as costs related to "facilities" and "administration," are largely related to overhead costs of a research institution or organization. Such overhead costs for health-related research can be expansive given the specialized requirements of biomedical research operations. These expenses were typically negotiated with federal agencies, which the NIH had generally accepted. However, through the Guidance, the NIH has elected to deviate from the negotiated indirect cost rate with a standard rate to "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." The NIH noted that the average indirect cost rate has been between 27% and 28% since 2009, with some organizations receiving over 60%. The Guidance presents as justification for the change the research organizations' arrangements with private foundations, which commonly do not fund indirect costs and sometimes set a similar cap on indirect costs. For example, the Guidance asserts that

[m]ost private foundations that fund research provide substantially lower indirect costs than the federal government, and universities readily accept grants from these foundations. For example, a recent study found that the most common rate of indirect rate reimbursement by foundations was 0%, meaning many foundations do not fund indirect costs whatsoever. In addition, many of the nation's largest funders of research—such as the Bill and Melinda Gates Foundation—have a maximum indirect rate of 15%. And in the case of the Gates Foundation, the maximum indirect costs rate is 10% for institutions of higher education. [i]

RESPONSE TO NEWLY PUBLISHED NIH GUIDANCE

On February, 10, 2025, a <u>coalition of 22 state attorneys general</u> filed suit in federal court in the District of Massachusetts against the Department of Health and Human Services (HHS), the Acting Secretary of HHS, in her official capacity, the NIH, and the Director of the NIH acting in his official capacity, for allegedly unlawfully cutting funds that support cutting-edge medical and public health research at universities and research institutions across the country. The plaintiffs allege that the executive branch has overstepped its authority under the constitutional separation of powers to enact changes to the grant-writing terms of the NIH without the explicit input of Congress. The same day, the court issued a temporary restraining order to hold the Guidance from going into effect in states that sued over the policy.

In the current environment, universities, particularly academic medical centers, pharmaceutical and medical technology companies, and other research-oriented organizations should carefully review and consult with knowledgeable advisors regarding the Guidance and their grant awards from the NIH, especially as the Guidance asserts that it applies to all existing grant awards. The organizations should also work to ensure that they use reliable cost accounting standards to correctly delineate direct costs from indirect costs to comply with the Guidance. As the federal government acknowledges, distinguishing indirect costs from direct costs is not always easy; Federal regulations advise organizations to consider the "association of a cost with a Federal award [as] the determining factor" in making the distinction. If implemented, federal grantees will be subject to potential federal False Claims Act liability for failing to properly measure and charge indirect costs associated with federal grant participation.

Nat'l Insts. Health, <u>Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates, NOT-OD-25-068</u>.

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

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