ENDOCRINE SOCIETY
Hormone Science to Health

June 24, 2026

TO: Office of Management and Budget (OMB)

RE: Comment on Proposed Revisions to 2 CFR Part 200

Submitted to regulations.gov docket OMB-2026-0034

The Endocrine Society submits these comments to express strong objection to the Office of Management and Budget's proposed revisions to 2 CFR Part 200, the Regulation for Federal Financial Assistance, also called the Uniform Guidance. The Endocrine Society is the world's oldest, largest, and most active professional medical and specialty society representing more than 18,000 endocrinologists, endocrine scientists, and allied healthcare professionals who are dedicated to advancing hormone research and improving the lives of patients with endocrine disorders such as diabetes, obesity, thyroid disease, osteoporosis, and reproductive health conditions. Many of our members' research programs rely on grants administered through federal agencies, including the National Institutes of Health (NIH), to support their research. We are deeply concerned that the proposed changes would adversely affect research and undermine the future of scientific advances critical to improving population health and health outcomes. We assert that the rule should be withdrawn and OMB's approach should be entirely reconsidered.

The United States' NIH-supported scientists drive fundamental biological discoveries that advance our understanding of disease, leading to applied therapies that improve our ability to treat health issues. As a critical component of the medical research enterprise, in recent years endocrine research has:

- Led to new medications for the treatment of diabetes and obesity that not only achieve weight loss equivalent to or better than surgery, but that are showing positive effects on heart disease, cancer, and dementia.
- Transformed the treatment of advanced breast cancer, tripling the 10-year survival rate.
- Delivered new therapies for osteoporosis that not only prevent further bone loss but rebuild stronger bones.

If implemented as written, the proposed rule will fundamentally disrupt the extremely beneficial medical research enterprise in the United States, which is currently the envy of the world. It will create an existential crisis for science, dry up our pipeline of talent, as we watch our best and brightest get lured to competitor nations, and lead to failure of our

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ultimate mission--to meet the needs of future patients with endocrine diseases. This will occur not because of the policies of any particular administration, but because of the underlying structural changes to how research is prioritized, supported, and communicated broadly. Changes to the Uniform Guidance will have lasting effects on all aspects of research; OMB must ensure that any changes are grounded in the operational realities of research and preserve existing features that enable scientific discovery and health breakthroughs. As we reasonably interpret the current proposed rule, it does not meet these criteria, and we urge OMB to withdraw the proposed changes in their entirety.

In our comments, we highlight areas of significant concern for our members: pre-award prioritization and selection (§ 200.205), administration of awards, including terminations (§ 200.340, § 200.333, § 200.305), the dissemination of research results through conferences, professional memberships, and publications (§ 200.432, § 200.454, § 200.461), and international collaborations (§200.220 and §200.202(e)).

I. § 200.205 — Pre-Award Review and the Displacement of Scientific Merit

The proposed rule requires that federal awards "demonstrably advance the President's policy priorities," thereby placing political priorities above scientific merit review for the selection of grants to support research programs. This is a fundamental departure from the framework that has governed federal research investment for decades and one that carries significant long-term risk.

Peer review has long served as an established and well-understood process for federal research funding that ensures prioritization based on scientific merit—a reflection of the significance and scientific rigor of the proposed research—and consistent with public health needs. For NIH, this process is embedded in statute (42 U.S.C. § 289a, 282(b)(16) and 284(c)(3)), operating as a principled, consistent mechanism for evaluating the promise of a proposal. This structure exists precisely to ensure that research investment decisions are grounded in evidence and expertise, supporting long-term national interests independently of short-term political considerations.

As written, the proposed standard further introduces a subjective and shifting criterion that cannot be consistently applied, is not subject to meaningful appeal, and does not require any subject matter or technical expertise in the subject area under review. This is compounded by another concerning provision: the proposed § 200.205 does not require that the person making a prioritization determination has any position within the agency that has authority over the award. This provision removes an important layer of institutional accountability and public oversight for scientific research grants, in contrast to the stated aims of the proposed rule.

Congress authorizes and appropriates research funding for specific scientific purposes—to understand and treat disease, advance public health, and develop novel diagnostic modalities

and new therapies. The proposed framework compromises this intent with a non-accountable prioritization layer between peer review and award decisions, which risks undermining this statutory objective. It will also erode confidence among the scientific community and patient groups that have invested decades in partnership with the federal government.

Recommendation: Withdraw the proposed changes to § 200.205 and retain scientific merit as the primary criterion for federal research awards. Decision-making authority over awards should rest with formally appointed or confirmed agency officials guided by peer-review panels with relevant subject-matter expertise and clear lines of accountability.

II. § 200.340, § 200.333, § 200.305 — Administration of Awards, Including Termination, Fixed-Amount Subawards, and Drawdown Requirements

Expanded Termination Authority

Existing authority already allows NIH and other agencies to terminate awards for noncompliance, mutual agreement, recipient withdrawal, or where an award no longer effectuates program goals or agency priorities. The proposed § 200.340 expands this authority to permit termination where work no longer advances "current program goals, agency priorities, or the national interest," including through stop-work orders for up to 90 days.

The term "national interest" is undefined in the proposed rule, and the text does not specify who makes this determination or by what criteria. In the absence of clear guardrails, this provision appears to function as a termination-for-convenience clause, presumably under the authority of a political appointee charged with advancing presidential priorities per § 200.205. This uncertainty itself is harmful to the research enterprise, separate from any individual termination decision. Researchers operating under multi-year awards cannot plan, hire, or make long-term commitments to patients in clinical trials in an environment where grants are subject to termination on undefined grounds by unspecified officials. Graduate students, postdoctoral fellows, and other federally funded trainees also depend on a stable environment to complete their dissertation projects and achieve their degree. If implemented, the proposed changes to this section will create an extreme barrier to clinical trials and graduate education in the sciences in the United States.

Terminating research mid-course for reasons other than health and safety will also conflict with fundamental protections for patients enrolled in clinical trials and create direct harm for patients who enroll for access to a potentially beneficial therapy. Changing national and political priorities, which cannot be foreseen in advance, cannot be disclosed to patients during enrollment; this creates a conflict with the informed consent framework that patients rely on when agreeing to participate and is mandated by the Common Rule (45 C.F.R. § 46.116(b)(2)-(4)). Terminating a trial before statistical endpoints are reached produces

inconclusive data and wastes valuable resources including patient time and effort while slowing progress towards a healthier future.

Elimination of Fixed-Amount Subawards

Current § 200.333 permits fixed-amount subawards up to $500,000 with prior written federal approval; this mechanism often is used to support research consortia, pilot programs, and multi-institutional collaborations. The proposed rule would eliminate fixed-amount subawards entirely absent specific statutory authorization, fundamentally altering the structure of collaborative grant arrangements.

This change would require institutions to convert existing and future arrangements to cost-reimbursement subawards—a significantly more burdensome structure requiring detailed financial tracking, invoicing, and audit trails. For small institutions, early-career investigators, and international partners, this shift could limit participation in collaborative federal grants.

Drawdown Payment Justifications

Current § 200.305 allows recipients with adequate financial controls to draw down funds in advance. The proposed rule will require recipients to submit a brief drawdown payment justification before each drawdown. While presented as a modest administrative requirement, this rule is redundant, adds recurring burden across thousands of grants and is inconsistent with stated goals of the rule to streamline compliance and reduce administrative load.

Recommendation: Withdraw the revised provisions in § 200.340, 200,333, and 200.305. Maintain procedural requirements including written notice with rationale, and an opportunity for the recipient to respond prior to termination consistent with foundational due-process protections. Determination of funding priority should be applied prospectively to new competitions, not retroactively to active, compliant awards. Retain fixed-amount subaward authority at current or updated thresholds. Limit drawdown restrictions to high-risk recipients (e.g., with inadequate management or accounting systems), awards under active monitoring, or drawdowns above a specified threshold.

III. § 200.432, § 200.461, § 200.454 — Dissemination of Research Results: Conferences, Publications and Professional Memberships

The proposed rule requires prior authorization for activities that are currently allowable under the existing Uniform Guidance including conference costs (§ 200.432), publication costs (§ 200.461) and professional memberships and subscriptions (§ 200.454) This is a significant departure from established practice and contradicts other federal requirements mandating rapid dissemination of research results e.g., open access publishing, which carries significant costs. The proposed rule again provides little guidance on who would

grant authorization, what criteria would be applied, or within what timeframe decisions would be made.

Conference participation, publications, and professional society memberships are not ancillary to scientific research—they are how innovative ideas are generated and how research findings reach clinicians, policymakers, regulators, and patients. A researcher who cannot attend or present at a scientific conference, or who cannot maintain the professional memberships necessary to access journals and other networking benefits and stay current in their field, is a researcher whose ability to conduct and communicate science is materially impaired. These restrictions would undermine the return on federal investment in research by limiting the public dissemination and utilization of scientific discovery while also making science more siloed and less transparent. Moreover, the proposed changes significantly disadvantage smaller or under-resourced institutions, limiting the pool of qualified applicants and the number of institutions able to participate in federally funded research programs—again in contrast to the stated aims of the proposal.

There is additional ambiguity about whether the criteria for authorization might include factors related to the content, positions, or priorities of the professional organization a researcher seeks to join or at which conference they seek to present. Any such criteria would raise serious First Amendment concerns and would exert a chilling effect on researchers' professional engagement and scientific communication.

Finally, we note that these provisions have direct implications for scientific societies and similar membership organizations. Professional society membership fees and conference registrations are a core component of many societies' operating models. A rule that introduces uncertainty or clearance requirements around these costs would affect not just researchers individually, but the organizational infrastructure of the scientific community including the peer-review, publication, and continuing education functions that professional societies provide in partnership with the federal research enterprise.

Recommendation: Withdraw the revisions in § 200.432, § 200.461, and § 200.454**.** Retain current allowability for conference costs, publication fees, and professional memberships under existing thresholds.

IV. § 200.220, § 200.202(e) Prohibition on International Scientific Collaboration

The proposal for section 200.220 would prohibit the use of any federal funds for bilateral or multilateral collaboration with "covered foreign countries" or entities affiliated with them, extending to travel, research activities, technical assistance, and allocable indirect costs. Section 200.202(e) would require that any international element of a federally funded R&D award be affirmatively justified on a case-by-case basis by agency officials, with foreign entities barred from receiving awards entirely absent political appointee approval. This presents a significant barrier to international collaboration.

Endocrine science is fundamentally global; diabetes, obesity, endocrine cancer, infertility, and other conditions our members study transcend national borders. International collaborations leverage various sources of expertise and approaches within different national contexts to identify promising treatments and therapeutic approaches. Advances in rare diseases would be made considerably more difficult under the proposal. Consider pheochromocytoma and paraganglioma (PPGL), rare endocrine tumors that occur in fewer than 1 in 100,000 people. Because of the low incidence of these tumors, no single country can generate the patient cohorts necessary to understand genetic drivers, evaluate novel therapeutics, or establish evidence-based treatment guidelines. The clinical knowledge we now have about PPGL exists because of international registries, multinational trials, and collaborative networks spanning the globe.

We recognize that legitimate national security concerns exist regarding certain foreign entities, particularly with respect to intellectual property theft and undisclosed foreign funding relationships. Those concerns are real and should be addressed through targeted, risk-based mechanisms—as they already are through existing disclosure requirements and export control regulations. The proposed rule does not target specific risks. It imposes a blanket presumption against all international collaboration, regardless of the country, the institution, or the nature of the research. For our field, where research on hormonal diseases depends on international patient registries and multinational partnerships, this approach would not protect national security; instead, it would eliminate the collaborative research environments that provide direct benefit to patients in the United States.

Recommendation: Withdraw § 200.220 and § 200.202(e) in their current form. International collaboration safeguards should be addressed through existing, targeted mechanisms rather than through a blanket presumption against all international research partnerships.

Conclusion

The Endocrine Society supports efforts to strengthen accountability, efficiency, and strategic alignment in federal grants administration; however, the proposed rule replaces many fundamental standards and best practices with unclear regulations that conflict with existing statutory authorities and even the administration's own stated rationale for pursuing this regulation. As written, the areas we have identified above introduce structural damage and uncertainty that will outlast any single administration and create real and foreseeable harm to the conduct of scientific research.

We strongly urge OMB to withdraw the proposed sections addressing pre-award prioritization (§ 200.205), administration of awards, including terminations (§ 200.340, § 200.333, and § 200.305), dissemination of research results through conferences, professional memberships, and publications (§ 200.432, and 200.454), and international

collaborations (§200.220 and §200.202(e)). We request that OMB engage in dialogue with the research community, scientific societies, and other stakeholders to explain the rationale for proposing a change of this magnitude.

The Endocrine Society remains committed to working constructively with the administration and federal research agencies to advance a grants administration framework that supports scientific excellence, public accountability, and the long-term health of the American people. We welcome the opportunity to discuss these comments further.