American Society of Human Genetics
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Re: Proposed Rule – Regulation for Federal Financial Assistance
Docket No. OMB-2026-0034

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I. Introduction

The American Society of Human Genetics (ASHG) submits these comments in strong opposition to the proposed revision to 2 CFR Part 200, Regulations for Federal Financial Assistance, published in the Federal Register on May 29, 2026 (Docket No. OMB-2026-0034). We offer these comments in our capacity as the world's largest professional organization for human genetics research. Our membership includes researchers, academics, physicians, technicians, genetic counselors, and others with an interest in human genetics and genomics. Our members are supported by the National Institutes of Health (NIH), the National Science Foundation (NSF), and other federal agencies. These federal grants support thousands of principle investigators, postdoctoral research and clinical fellows, graduate students, research coordinators, and technical staff. If enacted, this rule would override federal agencies' decision-making authority while weakening their scientific independence, a key feature of the United States' research and development ecosystem that has enabled our global leadership for over seven decades. It would also undermine the scientific, merit-based peer-review system and cause a brain-drain of the best and brightest scientists to other countries.

We recommend withdrawing the proposed rule and undertaking a comprehensive reassessment of the approach to this issue. We highlight below the provisions of greatest concern to our members. For each, we identify the relevant regulatory text, explain why the proposed change raises scientific issues, and provide specific recommendations.

II. Mandatory Political Appointee Review of Discretionary Grants Threatens the Integrity of the Federal Research Funding System [§200.205]

Section 200.205 would require senior political appointees to conduct a "pre-issuance review" of every discretionary federal award before it is issued. Furthermore, Section 200.205(d) states that peer review recommendations "remain advisory and are not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding." This marks a fundamental departure from the framework that has governed federal science funding since the establishment of NIH's study section system in 1946 and the creation of NSF in 1950. In effect, it calls for abandoning more than 75 years of established practice

without piloting an alternative approach and without meaningful consultation with the scientific community. Moreover, the preamble provides no evidence that the current peer review process leads to inferior scientific outcomes or that review by political appointees would yield better results. In fact, since World War II, the current system has been a key driving force behind the United States' position as the leading R&D ecosystem in the world to date.

Congress has consistently directed federal science agencies to award funding based on scientific merit. For example, the Public Health Service Act (42 U.S.C. § 289a) requires NIH grant applications to undergo peer review by experts in the relevant scientific fields, while the National Science Foundation Act (42 U.S.C. § 1862s) affirms that NSF should support basic research through a merit-based evaluation process.

The provision is also scientifically unsound and operationally impractical. Established merit review systems such as NIH study sections, NSF panels, and similar agency processes exist precisely because evaluating scientific quality requires deep subject-matter expertise. NIH alone supports research across hundreds of disease areas and relies on thousands of expert reviewers organized into standing and special emphasis study sections with defined areas of expertise. A political appointee, regardless of intent, cannot replace the collective judgment of these experts in assessing a project's scientific premise, approach, innovation, and feasibility. No single individual possesses that breadth of expertise, and no pre-award checklist can serve as an adequate substitute. A regulation that explicitly bars agencies from relying on expert judgment is inconsistent with the statutes that established those agencies and defined their missions.

Multi-year research programs like clinical trials, training grants, and institutional commitments are built on the reasonable expectation that funding decisions prioritize scientific excellence, as determined by independent experts. Maintaining the integrity and independence of peer review is critical to justify infrastructure investments, plan long-term research initiatives, and recruit and retain top talent from around the world. Removing that expectation poses a structural risk to the research enterprise, regardless of any individual funding outcome.

Recommendation: Withdraw §200.205 as currently drafted. If any form of pre-issuance review is retained, it should be strictly limited to administrative and compliance checks, such as verifying eligibility, budget accuracy, and adherence to regulations. It should not include scientific evaluation, ideological screening, or consideration of political alignment. Determinations of scientific merit must remain solely within the domain of independent peer review.

III. Limits on Scientific Communication and Professional Engagement Would Undermine the Research Enterprise [§200.432, §200.454, §200.461]

These three provisions in the proposed rule would place significant limitations on the core professional activities through which science is conducted, validated, and shared. Taken together, they would isolate federally funded researchers from their scientific communities and restrict the transparent dissemination of research findings supported by public funds.

A. §200.432 — Conference Attendance

The proposed rule would allow conference attendance only if it is "expressly approved by the Federal agency and included in the terms and conditions of the Federal award." Under current practice, travel to conferences that directly support a grant's scientific objectives is a routine, allowable expense that investigators plan for and manage within their approved budgets. The proposed change would remove that discretion entirely.

This limitation reflects a fundamental misunderstanding of how scientific progress occurs. Conferences are not ancillary activities; they are essential forums where researchers present preliminary findings for critical evaluation, share and assess new methods, form collaborations that lead to multi-site studies and multi-investigator grants, facilitate talent recruitment and workforce development, and introduce trainees to the broader scientific community. Rigor, reproducibility, and the avoidance of waste expressly depend on the open communication of research findings, including both successes and failures. Conferences also serve a critical accountability function by allowing researchers to communicate how federal dollars are being used and promote transparency of publicly supported studies.

If a new conference is announced after a grant has been awarded, investigators would be unable to attend because it was not explicitly included in the original award terms. This rigid requirement fails to account for the evolving nature of scientific research, where new and highly relevant opportunities for engagement frequently arise after funding decisions are made. The limitation becomes even more restrictive for multi-year awards, where the scientific landscape can shift significantly over time and new venues for collaboration and dissemination arise. As a result, researchers would be prevented from participating in timely and important scientific exchanges, limiting their ability to share findings, receive feedback, and remain engaged with the most cutting-edge developments in their field.

B. §200.454 — Professional Membership

The proposed rule would require prior written agency approval for all professional society memberships. Professional societies form a critical part of the scientific enterprise's infrastructure. They support peer review activities, establish research and clinical practice standards, offer mentorship, training, and career development opportunities, and serve as key representatives of the scientific community in engagement with government, including in rulemaking processes such as this one.

C. §200.461 — Publication Costs

The rule notes that publication costs "are not inherently necessary to carry out the core programmatic objectives of most Federal awards". The proposed rule would make all journal publication costs, including article processing charges, page charges, and open access fees, unallowable under federal awards. This provision is fundamentally inconsistent with existing federal policy. Researchers would be expected to comply with federal open access requirements while being denied the funding mechanisms that often make such compliance possible. In effect, the rule would place investigators in the untenable position of being required to publish their work in a manner that federal policy mandates, yet prohibited from using federal award funds to cover the associated costs.

These proposed revisions do not further the rule's stated goals of increasing transparency and accountability of federal funds.

Recommendation: Withdraw the proposed revisions to §200.432, §200.454, and §200.461 in full. Conference attendance, professional society memberships, and publication costs (including open access fees) that support the objectives of a federal award should continue to be treated as allowable costs.

IV. The Grant Termination Provision Introduces Significant Instability [§200.340]

Section 200.340 would permit agencies to terminate active grants mid-award on the grounds that they are "inconsistent with program goals or agency priorities," requiring only a brief written explanation and without any finding of noncompliance, fraud, or scientific failure. The proposed rule characterizes this authority as comparable to "termination for convenience" provisions used in federal contracting.

Federal research grants are fundamentally different from procurement contracts. Contracts are designed to deliver a defined product or service, whereas grants support scientific investigation, where outcomes are inherently uncertain and driven by discovery.

There are numerous examples of basic research discoveries that are key to unforeseen clinical applications. One such example is the discovery of CRISPR. While studying strains of bacteria used in yogurt fermentation, researchers noticed a potential link between the unusual repeating DNA sequences, the unique DNA fragments located between those repeats, and the bacteria's ability to resist specific viral infections. Through follow-up experiments, it was found that CRISPR is a system of adaptive immunity against the viruses that infect bacteria. This naturally occurring defense mechanism evolved in bacteria to protect against viral infections. In industrial fermentation, this mechanism helps yogurt cultures resist viruses that could otherwise destroy entire batches. This finding could not have been predicted *a priori* but nonetheless led to discoveries that have revolutionized the biomedical research enterprise. In a historic medical milestone in 2025, researchers at Children's Hospital of

Philadelphia (CHOP) and Penn Medicine successfully treated a child with a personalized CRISPR gene-editing therapy designed specifically for his condition. A rule that systematically disadvantages the type of fundamental research that underlies this therapeutic advancement will ultimately deprive the nation of future breakthroughs.

The implications for human subjects are particularly serious. Our members enroll patients in federally funded clinical trials across a range of disease areas. Participation in these trials carries clear ethical and regulatory obligations under the Common Rule (45 CFR Part 46) and in accordance with each study's IRB-approved protocol. Mid-award termination of a grant funding an active clinical trial would disrupt patient care, undermine informed consent commitments, and interrupt ongoing safety monitoring, treatment, or follow-up. A patient enrolled in a multi-year trial cannot ethically be told partway through treatment that funding has been withdrawn because a political appointee determined the research no longer aligns with agency priorities. Abrupt termination of an active study could place participants at increased risk of harm, including through loss of surveillance to identify and manage emerging safety concerns or adverse events, and in serious cases, allow disease progression. Patients with rare diseases, serious conditions, and limited treatment options have few alternatives outside of clinical trials; if funding ends unexpectedly without scientific justification, patients face increased risks to their health and well-being. Careful consideration must also be given to ensure a safe and appropriate transition for patients back to their pre-trial treatment regimen. The proposed rule provides no framework for addressing these obligations in the event of termination.

Furthermore, the United States' ability to attract and retain scientific talent is not guaranteed. Our leadership role relies on a research system that is stable, merit-driven, and shielded from political cycles. This provision would directly and predictably weaken that system and decrease our international competitiveness.

Recommendation: Restore the existing standard limiting grant terminations to cases of cause. If research priorities change, apply those decisions to future funding opportunities rather than existing, compliant awards. At a minimum, any retained termination authority should require clear safeguards for protection of human subjects and fulfillment of commitments to research participants and staff.

V. The Restriction on International Scientific Collaboration Would Erode Partnerships Critical to U.S. Scientific Leadership [§200.220, §200.202(e)]

Section 200.220 would prohibit the use of federal funds for bilateral or multilateral collaboration with "covered foreign countries" or affiliated entities, including support for travel, joint research, technical assistance, and related indirect costs. Section 200.202(e) would further require that any international component of a federally funded research and development award be justified on a case-by-case basis by agency officials, while barring foreign entities from receiving awards without approval from a political appointee. Together, these provisions would make international collaboration presumptively disfavored.

By discouraging international partnerships, the rule could reduce opportunities for U.S. researchers to participate in global projects and access the unique data and patient populations that drive innovation and discovery.

Human genetics and genomics are inherently international endeavors that depend on collaboration among researchers, institutions, and patient communities around the world to better understand human genetic variation and disease mechanisms that no single laboratory, institution, or country can assemble alone. Furthermore, sharing research results increases scientific rigor and reproducibility by enabling discoveries to be replicated across multiple populations, while international collaborations reduce unnecessary duplication of effort to maximize the public's return on investment.

We recognize that there are legitimate national security concerns related to certain foreign entities, particularly regarding intellectual property theft and undisclosed foreign funding relationships. These concerns should be addressed through targeted, risk-based approaches, as they are under existing disclosure requirements, export control regulations, and the NSPM-33 framework. The proposed rule does not focus on specific risks; instead, it imposes a broad presumption against international collaboration, regardless of the country or institution involved.

Recommendation: Withdraw §200.220 and §200.202(e) in their current form. Concerns related to international research security should be addressed through existing, targeted safeguards. Such an approach would better protect national interests while preserving the global partnerships that are essential to scientific discovery and innovation.

VI. Codifying Restrictions on Health Disparities Research Could Impede Public Health and Scientific Progress [§200.218, §200.300(b)]

Sections 200.218 and 200.300(b) incorporate a provision related to Executive Order 14281, *Restoring Equality of Opportunity and Meritocracy*, which would prohibit federally funded activities from advancing or supporting theories that assign disparate-impact liability on the basis of race, sex, or age.

Congress has long authorized and appropriated research funding to advance specific scientific priorities, including efforts to understand human genetic variation, broaden participation in the scientific workforce, and ensure that the benefits of research reach all people across the nation. Federal programs, including those supported by the National Institute on Minority Health and Health Disparities (NIMHD), play a critical role in studying the biological, environmental, social, and structural factors that contribute to differences in health outcomes and in developing evidence-based interventions to improve health for all populations.

The proposed provisions place at risk longstanding, lawful efforts to harness all domestic and international talent to strengthen the biomedical workforce by supporting students, trainees, and

researchers from a wide range of backgrounds. The provisions could also undermine research aimed at understanding how environmental exposures and access to care influence health outcomes. Faced with uncertainty about which activities remain permissible, institutions and investigators may become more reluctant to pursue studies focused on population health or the factors that contribute to uneven health outcomes. This could discourage important research involving rural communities, veterans, racial and ethnic minorities, people with disabilities, older adults, children, Tribal communities, and individuals living with rare or chronic diseases.

Recommendation: Withdraw §200.218 and §200.300(b) in their current forms. These provisions introduce significant ambiguity regarding the types of research activities, workforce development programs, and community engagement efforts that may be supported with federal funds. As drafted, they could discourage institutions from pursuing lawful, congressionally authorized activities designed to advance scientific knowledge, improve public health, and strengthen the nation's research workforce.

VII. Assertion of Binding Authority Over All Agencies Could Compromise Ability to Fulfill Statutory Missions [2 CFR 200 generally]

One of the most structurally significant changes in the proposed rule is the reclassification of 2 CFR Part 200 from guidance to a binding OMB regulation. A uniform, government-wide framework may not adequately account for the distinct missions, stakeholder communities, and operational needs of science agencies. By limiting agency discretion, the proposal could undermine longstanding practices that support scientific integrity, expert peer review, and mission-driven research funding.

Recommendation: OMB should reconsider this approach and preserve the ability of agencies to implement federal grant policies in ways that are consistent with their statutory authorities and the needs of the research communities they serve.

VIII. Undefined "Gold Standard Science" Standard Creates Conflicting Objectives

The proposed rule repeatedly references "Gold Standard Science," a concept tied to Executive Order 14303, *Restoring Gold Standard Science*, yet it fails to define the term in clear, measurable, or scientifically grounded terms. It nonetheless requires that all grants include benchmarks demonstrating compliance with this undefined standard and directs agencies to prioritize institutions that have "demonstrated success" in implementing it.

Furthermore, the proposed rule is inconsistent with Executive Order 14303, which calls for science that is reproducible, transparent, collaborative, interdisciplinary, subject to unbiased peer review, and without conflicts of interest. The proposed rule conflicts with these principles by substituting independent, unbiased review with political appointees, restricting international collaboration, which is

fundamental to how science progresses, and tying funding decisions to administrative priorities that may shift at any time.

Recommendation: Any standard of scientific quality used as a condition of federal funding eligibility must be developed and defined through a rigorous, expert-driven process with meaningful public input, grounded in established scientific principles, and applied consistently across applicants. The proposed approach satisfies none of these requirements and should be withdrawn.

IX. Conclusion

The United States' global leadership in biomedical research has been built over decades through a system that allocates federal investment based on scientific merit, as determined by independent experts through transparent, consistent processes insulated from political interference. This approach has helped sustain a robust talent pipeline and ensure that the nation fully harnesses the breadth of expertise across its scientific workforce. The proposed rule does not identify specific deficiencies in the current system that would warrant such changes, nor does it assess the costs and consequences of the proposed approach. These impacts include the loss of scientific talent, disruption of ongoing research, risks to human research participants, and damage to the United States' global scientific leadership.

ASHG appreciates the opportunity to provide these comments and remains committed to working constructively with the administration and federal agencies to advance a grants administration framework that supports scientific excellence, innovation, and public trust. We continue to support a research enterprise grounded in rigor, integrity, and transparency, and one that continues to enable human genetics and genomics research to improve health and benefit people everywhere.

We strongly urge OMB to withdraw the whole rule. We are especially concerned about the implications of the proposed changes to the following sections: §200.205, §200.432, §200.454, §200.461, §200.340, §200.220 and §200.202(e), §200.218, and §200.300(b). We welcome the opportunity to discuss these comments further.

Respectfully submitted,

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