

July 10, 2026

COMMENTS ON PROPOSED REVISIONS TO 2 C.F.R. PART 200

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The Harvard T.H. Chan School of Public Health (Harvard Chan School) appreciates the opportunity to comment on the proposed rule, which would revise 2 C.F.R. Part 200, and supports transparency, accountability, responsible stewardship of federal funds, and compliance with all applicable federal laws. At the same time, Harvard Chan faculty, researchers, students, and staff from across basic biological, quantitative, behavior health and policy science disciplines have raised concerns about several provisions that would substantially diminish the U.S.'s scientific innovation machine by changing how federally funded public health research is reviewed, conducted, sustained, and disseminated.

We strongly endorse the comment submitted by Harvard University under the signature of Senior Vice Provost for Research John Shaw and the comment submitted by Harvard Medical School under the signature of Dean George Daley. As a member of the Association of Schools and Programs of Public Health (ASPPH), the Association of American Universities, and the Council on Government Relations, we similarly endorse comments submitted by those organizations. The following statement summarizes concerns raised by the Harvard Chan community regarding several sections of the proposed rule that would most directly affect public health research.

[§ 200.205] Federal Agency Review of Merit of Proposals

Many across Harvard Chan School's research community are concerned that multiple provisions in this section of the proposed rule would deprioritize scientific merit in funding decisions. Of significant concern is the reduced role of peer review in grantmaking and the requirement for pre-issuance award reviews by political appointees to ensure alignment with the Administration's priorities.

Preservation of Peer Review is Paramount for Evaluating Technical Merits of Science and Advancing U.S. Innovation. Public health and biomedical research are highly specialized fields and peer review is the gold standard mechanism for evaluating scientific merit and identifying innovation. Peer reviewers' scientific credentials are heavily vetted to ensure that they are qualified to judge the impact and rigor of research proposals, and the peer review process requires multiple experts with relevant subject matter expertise to evaluate the merit of a proposal against well-established review criteria. Their expert knowledge qualifies them to make informed decisions about which projects are positioned to advance innovative ideas, develop novel approaches, and address scientific questions that are both feasible and valuable to answer. Independent peer review is a bedrock of the U.S.'s scientific investment machine, constructed to ensure strategic investment and responsible stewardship of taxpayer dollars. By subjecting proposals to rigorous evaluation by experts with relevant scientific and technical expertise, the peer review process helps ensure that federal investments are directed toward research most likely to produce reliable, reproducible, and

impactful results. A single political appointee, regardless of their affiliation with any particular administration, may not have the technical expertise needed to evaluate all aspects of proposals across the breadth of fields that are represented in peer review. The proposed requirement for pre-issuance political review has also led many Harvard Chan faculty to question whether to continue to devote substantial time and expertise to the voluntary peer review process if their scientific judgment will serve only an advisory role. By subordinating peer review to political review, the proposed rule is likely to diminish the impact and quality of research outcomes.

Pre-Issuance Political Review Risks Undermining Evaluation and Improvement of U.S. Government Programs and Policies. In addition, the institution of pre-issuance political review by any administration could discourage investigators from pursuing scientifically important but politically sensitive research questions. Public health research frequently evaluates the effectiveness of government policies and programs themselves. If investigators believe that research producing politically inconvenient findings is less likely to receive funding, they may increasingly avoid pursuing important policy questions, reducing the evidence available to inform future improvements in healthcare delivery, public health programs, and other federally supported initiatives. As one researcher who evaluates the health effects of housing and zoning policies observed, political review could discourage investigators from asking fundamental questions about whether government policies are effective, weakening the evidence needed to inform future policy decisions. For instance, the investigator noted that rigorous epidemiologic research is essential for determining which policies improve health outcomes and which do not, ensuring that public resources are directed toward interventions supported by evidence rather than assumption. As another example, a health policy researcher whose work examines the affordability, quality, and delivery of healthcare noted that their research has identified unintended consequences of Medicare payment reforms and demonstrated how hospital acquisitions of physician practices can increase healthcare costs. If political considerations influence funding decisions, research evaluating the effectiveness of government policies or identifying politically inconvenient findings could become more difficult to support. Over time, this dynamic risks narrowing the scope of scientific inquiry, reducing U.S. innovation, and diminishing the public value and credibility of federally funded research. This would undermine the strength of the U.S. biomedical research enterprise, which has long rested on the widely held confidence that federal funding decisions are grounded in rigorous peer review, scientific excellence, and transparent evaluation rather than changing political priorities.

Indirect Costs are Not a Proxy for Scientific Efficiency or Return on Investment. Harvard Chan researchers have also raised concerns that the proposed change to § 200.205 could inappropriately prioritize institutions with lower negotiated indirect cost rates over the strongest scientific proposals. Negotiated indirect cost rates are not measures of efficiency or scientific value; rather, they reflect the actual costs of maintaining the research infrastructure required to conduct safe, rigorous, and federally compliant research. These cost reimbursements support laboratory facilities, biosafety programs, human subjects protections, animal care, data security, regulatory compliance, hazardous waste management, research administration, and other systems that enable institutions to responsibly steward federal investments. Using lower indirect cost rates as a favorable selection criterion could inadvertently encourage funding decisions based on the apparent cost of conducting research rather than the quality, rigor, innovation, or potential public health

impact of the proposed work. Such an approach risks creating incentives that disadvantage institutions that have made substantial investments in research infrastructure and compliance systems that the federal government itself requires and that benefit research and the public. Ultimately, prioritizing lower indirect cost rates over scientific merit could reduce the long-term return on taxpayer investments by prioritizing the cheapest projects for funding, rather than supporting the institutions best equipped to conduct complex, high-impact research and encouraging additional institutions to make those investments.

Perceived Politicalization of Research Investments Fuels Public Distrust of Health Measures and Federal Agencies that Fund Public Health Research. Many among the Harvard Chan community have expressed grave concern that introducing non-scientific considerations into federal funding decisions could undermine confidence in the fairness, objectivity, and integrity of the federal grantmaking process among researchers, institutions, patients, and the public. Even the perception that funding decisions are influenced by political considerations rather than scientific merit risks eroding public trust in both federally funded research and the agencies responsible for administering the funds. Diminished public confidence can also reduce participation in scientific research. Investigators leading a long-running federally funded cohort study reported that participants requested to withdraw from the study after expressing concern that changes in federal policy could compromise the confidentiality of the data they had entrusted to researchers. This erosion of public trust can have real consequences for public health; and there are many cautionary examples in countries around the globe illustrating how politicalization of public health research/delivery and the resulting public distrust in health institutions can yield calamitous results. The recent Ebola crisis in West Africa highlights how distrust in the government and public health systems can yield devastating results, fueling the rate of disease transmission, illness and death. Conversely, when the public trusts in the merits and objectivity of the science that federally funded researchers produce, the collective U.S. public health research community is able to advance interventions, encourage individual health behavior changes, and recalibrate health systems to deliver better health outcomes and reduce the social and economic costs of illness, injury, and disease. Delivery of the polio vaccine, tobacco reduction interventions, and cancer screening protocols all provide examples of the power of trusted science to better the health outcomes of Americans.

Recommendation:

Harvard Chan School respectfully recommends that OMB not proceed with the proposed modifications to the peer review process. If OMB proceeds with rulemaking on this subject, it should revise the proposed § 200.205 to preserve rigorous, merit-based scientific peer review as the primary basis for funding decisions while maintaining appropriate agency oversight and accountability. Specifically, we recommend that OMB:

- Retain independent peer review as the principal determinant of scientific merit for research awards, with any senior-level review focused on ensuring compliance with applicable law, programmatic requirements, and responsible stewardship of federal funds rather than reevaluating scientific merit.
- Require that any funding decision by a political appointee that deviates from the percentile ranking determined in the peer review process be supported by a written, publicly documented justification tied to clearly articulated statutory and/or programmatic

considerations. This would promote transparency, accountability, and consistency while maintaining public confidence in the federal grantmaking process.

- Remove provisions that encourage consideration of negotiated indirect cost rates as a selection criterion. Funding decisions should prioritize scientific quality, innovation, feasibility, and potential public benefit. Negotiated indirect cost rates reflect the infrastructure necessary to conduct safe, rigorous, and federally compliant research and should not be treated as a proxy for efficiency or value.
- Clarify that evaluation of research proposals should be based on objective scientific, technical, and programmatic criteria rather than undefined or subjective concepts that may be interpreted inconsistently across administrations. A stable, predictable, and merit-based review process is essential to maintaining public trust, encouraging scientific innovation in the U.S., and ensuring that taxpayer resources are invested in the research most likely to improve the health and well-being of the American people.

[§§ 200.340 and 200.341] Termination and Suspension; and Notification of Termination Requirement

Harvard Chan researchers expressed significant concern that the proposed §§ 200.340 and 200.341 would substantially expand federal agencies' authority to suspend or terminate awards for reasons unrelated to scientific performance, regulatory compliance, fraud, waste, abuse, or defined national security concerns. The School recognizes that federal agencies must retain the ability to address noncompliance, protect taxpayer resources, and ensure that federally funded projects remain consistent with statutory requirements, and our institution values the longstanding partnership and guidance provided by the federal government on sponsored research. However, the Harvard Chan community is concerned that the proposed discretionary termination authority is sufficiently broad that it could undermine the stability necessary for effective scientific research and responsible stewardship of federal investments.

Discretionary Suspensions and Terminations Undermine Scientific Integrity, Waste Taxpayer Dollars, and Pose Patient Safety and Population Health Risks. Public health and biomedical research frequently depend on sustained, multi-year commitments to recruit participants, build community partnerships, establish specialized laboratory capabilities, develop new methodologies, generate longitudinal datasets, and train highly skilled personnel. Research projects cannot simply be paused and resumed without substantial scientific, ethical, and financial consequences. A Harvard Chan researcher leading NIH-funded maternal and child health clinical trials in Tanzania explained that even brief interruptions in funding could disrupt follow-up care for mothers and children participating in those trials, raising ethical concerns for participants and compromising the scientific integrity of the research. An infectious disease researcher noted that abrupt termination could compromise time-sensitive outbreak investigations and surveillance efforts, result in the loss of perishable biological samples or animal models, and disrupt ongoing clinical care and follow-up obligations. These disruptions could have costly consequences and even put American lives at risk. A cervical cancer researcher explained that studies evaluating screening tools often require several years of recruitment because cervical precancers occur in only about 1 to 5 percent of a general screening population. After baseline screening, some participants require follow-up after 6 to 12 months to assess treatment effectiveness. Early termination could prevent valid analysis, affect

participant safety, and waste taxpayer investment because partially completed studies may never yield usable results. Rather than advancing scientific progress, terminating projects before they reach scientifically meaningful endpoints risks leaving important public health questions unanswered while diminishing the value of years of federally funded research.

Proposed Changes Undermine U.S. Competitiveness by Weakening the Country’s Scientific Workforce Pipeline. In addition, funding stability is fundamental to maintaining the nation's scientific workforce. Research programs depend upon recruiting and retaining highly trained investigators, postdoctoral fellows, research staff, trainees, and technical personnel whose expertise often requires years to develop. A laboratory researcher explained that their work depends on specialized expertise in mass spectrometry, microscopy, animal surgery, and complex biological models that require years of training before personnel become fully proficient. The prospect of abrupt grant termination would make it difficult to recruit and retain postdoctoral fellows and research technicians, discourage laboratories from developing new methodologies or experimental models that require long-time horizons, and ultimately shift research toward shorter-term, lower-risk projects at the expense of foundational scientific discovery. This uncertainty would make long-term workforce planning substantially more difficult, discourage recruitment into academic research careers and related jobs (with adverse consequences for the U.S. economy), and accelerate the migration of scientific talent to industry or to research institutions outside of the U.S., thus draining the next generation of scientists and weakening U.S. scientific competitiveness over time.

Harvard Chan School’s Termination Experiences Offer Evidence of Longstanding Financial, Scientific, and Human Costs Resulting from Suspensions and Early Terminations. The consequences of abrupt grant terminations are no longer theoretical. Following the widespread grant terminations and funding interruptions in 2025, investigators described significant disruptions to active research programs that continue to affect scientific productivity today. One of the NIH-funded clinical trials that was abruptly terminated was evaluating whether an inexpensive zinc supplement, added to standard antibiotic treatment, could improve survival for newborns with life-threatening sepsis. Sepsis remains one of the leading causes of infant death in the U.S., and if successful, the intervention had the potential to save the lives of *hundreds of U.S. infants each year* while offering an affordable treatment option worldwide. The study was terminated after only a fraction of the planned participants had been enrolled, leaving thousands of infants who would have participated without access to the intervention and preventing completion of research that could have changed the standard of care. Although the research team continued follow-up care for enrolled participants using institutional resources to meet their ethical obligations, the scientific question the federal government had elected to fund remains unanswered. This example illustrates that abrupt award termination does not simply halt research—it can leave lifesaving work unfinished, waste prior federal investment, and delay discoveries that patients and families are counting on.

Scientific Innovation is Dependent on Stable Infrastructure and Funding. The mass terminations and subsequent reinstatement of funds in 2025 demonstrated that scientific research cannot simply resume where it left off after an interruption. As examples, one Harvard Chan project designed to preserve neurological function during life-saving pediatric cancer treatment and a second innovative project designed to develop mosquito-targeted malaria interventions that could have prevented

disease transmission and laid the foundation for future clinical trials were halted abruptly. In these instances, and in myriad other examples, when projects are paused or terminated, laboratories lose highly trained personnel who seek more stable employment, participant recruitment is interrupted, long-standing collaborations are weakened, carefully planned research timelines are permanently altered, and promising scientific discoveries may never come to fruition.

Destabilizing the U.S. Scientific Ecosystem Leads to More Expensive Research. The effects of funding instability extend well beyond individual research projects to the institutions that support them. One investigator leading a federally funded collaboration across sixteen institutions described how an abrupt funding termination left participating organizations with personnel already hired, purchasing agreements already executed, and financial obligations they could no longer support. Although funding was eventually restored, the disruption fundamentally changed how institutions approached future collaborations. Institutions became more reluctant to make long-term hiring commitments, delayed investments in equipment and infrastructure, and replaced cost-saving long-term purchasing agreements with smaller, more expensive purchases because they could no longer rely on the stability of federal commitments. These institutional responses increase costs, reduce efficiency, weaken multi-site research partnerships, and diminish the overall productivity of research institutions long after an individual award is restored.

Recommendation

Harvard Chan School respectfully recommends that OMB not proceed with the termination provisions of the proposed rule. If OMB proceeds with a termination provision, it should revise the proposed §§ 200.340 and 200.341 to preserve appropriate agency oversight while providing greater certainty for recipients of federal funding. Specifically, we recommend that OMB:

- Limit termination authority to clearly defined circumstances, such as material noncompliance.
- Exclude research involving human participants from discretionary termination unrelated to performance or compliance, recognizing the ethical obligations to research participants under the Common Rule and the substantial scientific and public health harms that can result from interrupting ongoing human subjects research.
- In cases where termination of an active research award is deemed necessary, require agencies to provide advance written notice and a clear explanation of the basis for termination. The agency's rationale should specifically address the scientific, ethical, financial, and public health consequences of terminating an active research award, including impacts on participant welfare, ongoing clinical obligations, preservation of irreplaceable research resources, and prior federal investment.
- Require agencies to have a formal and transparent appeal process that provides principal investigators (PIs) the opportunity to respond to an agency's rationale for discretionary termination before the project is suspended or terminated, except in circumstances involving immediate threats to public safety or national security. The appeals process should ensure that final termination decisions are based on a rigorous assessment of the project's scientific merits and impacts.
- When feasible, permit ongoing studies to reach scientifically meaningful endpoints or provide transition support that minimizes disruption to participants, collaborating

institutions, and research personnel while maximizing the value of taxpayer investments already made.

[§§ 200.202 and 200.220] Program Planning and Design; and Prohibition of Using Federal Funds for Covered Foreign Collaborations

Harvard Chan researchers recognize the importance of protecting national security, safeguarding against inappropriate foreign influence, and ensuring responsible stewardship of federal funds and intellectual property resulting from research – these issues are of paramount importance to the School and the University as a whole. At the same time, many investigators and collaborators within our community have expressed concern that the combined effect of the proposed "domestic-first" framework in § 200.202(e) and the broad restrictions on collaborations with covered foreign countries and entities in § 200.220 would unnecessarily limit scientifically essential international partnerships that directly advance the health, safety, and economic interests of the U.S.

International Research Collaborations Strengthen the Health of Americans. International collaboration has long been a defining strength of the U.S. scientific enterprise. Many of the most important advances in biomedical and public health research have been achieved through partnerships that combine complementary expertise, patient populations, research infrastructure, and data resources across countries. These collaborations enable U.S. investigators to answer scientific questions that cannot be addressed using domestic resources alone while ensuring that discoveries are translated into improved prevention, diagnostics, treatments, and public health practice for Americans. Rather than competing with domestic research, international collaborations frequently expand the capabilities of U.S. institutions, accelerate scientific discovery, and increase the return on federal research investments.

Several examples from the Harvard Chan research community illustrate why these partnerships directly serve the interests of the American public and advance U.S. innovation. A researcher studying viral encephalitis explained that severe West Nile virus cases in the U.S. increased by approximately 40 percent in 2025 and that encephalitis hospitalizations in the U.S. cost an estimated \$2 billion annually. Their research depends on an international consortium led by the University of Geneva that has assembled clinical and genetic data from more than 1,000 deeply characterized encephalitis patients—a resource with no domestic equivalent. U.S.-based laboratory studies use these international patient data to identify disease mechanisms and evaluate potential therapeutic strategies for American patients. Restricting access to these collaborations would not strengthen domestic research capacity; it would eliminate scientific opportunities that cannot presently be replicated within the U.S.

Proposed Restrictions would Weaken U.S.'s Competitive Position. The proposed rule would create substantial uncertainty regarding when international partnerships are permissible and would require agencies to justify international research through a "domestic-first" framework before such collaborations can be supported. While Harvard Chan School supports appropriate safeguards that are necessary to address genuine national security risks and works closely with federal agency partners to protect against such risks in sponsored research, Harvard Chan researchers have expressed concern that a categorical restriction on international collaboration could discourage long-standing scientific partnerships, and prevent investigators from accessing unique expertise and resources that are unavailable within the U.S. For example, advances in understanding common

neurologic and vascular diseases, including dementia and stroke, increasingly depend on access to large, long-running population-based cohort studies conducted outside the U.S. Longitudinal research programs in the Netherlands have followed tens of thousands of adults and children over decades, generating unique clinical, imaging, genetic, and environmental data that have fundamentally advanced our understanding of healthy aging, cardiovascular disease, dementia, stroke, and child development. Comparable resources do not exist in the U.S., making these collaborations essential for addressing scientific questions that cannot be answered using domestic data alone. These research partnerships are conducted with internationally recognized academic institutions that are appropriately screened and present little or no plausible national security concern. Harvard Chan School works closely with experts in federal funding agencies who advise on permissible collaborations advancing fundamental research in support of U.S. national security interests. Yet a broad domestic-first framework and increased barriers to international collaboration could nevertheless impede access to these irreplaceable scientific resources. Over time, these changes could weaken the ability of American researchers to lead multinational scientific efforts and reduce the U.S.'s competitiveness in fields that increasingly depend upon global collaboration.

Scientific discovery increasingly depends upon worldwide networks of expertise, and many of today's leading advances arise from multinational collaborations rather than isolated national efforts. Researchers are already accepting scientific positions outside the U.S. while scientific programs abroad continue to expand, raising concerns that policies discouraging international collaboration will accelerate the migration of scientific talent and research investment elsewhere – to the detriment of American scientific leadership and our economic competitiveness. Innovation frequently moves in both directions: discoveries made through international partnerships often produce benefits for Americans that could not have been anticipated when research was first initiated. Restricting these collaborations therefore risks diminishing—not strengthening—the nation's long-term scientific leadership.

Recommendation

Harvard Chan School respectfully recommends that OMB not adopt the proposed §§ 200.202 and 200.220. If OMB proceeds with rulemaking on these subjects, it should:

- Adopt a risk-based approach that preserves appropriate safeguards for national security, foreign influence, export controls, and accountability while permitting international collaborations, foreign subawards, shared research infrastructure, and multinational research partnerships when they are scientifically necessary, transparent, auditable, and demonstrably advance the health, security, and economic interests of the U.S.S. Specifically, OMB should:
 - Require case-by-case risk assessments rather than categorical restrictions based solely on country or institutional affiliation.
 - Limit restrictions to collaborations involving identifiable national security, export control, or foreign influence risks that cannot be adequately mitigated.
 - Allow agencies to impose tailored risk mitigation measures—including enhanced disclosure requirements, data security and cybersecurity protections, restrictions on access to sensitive technologies or controlled information, and additional oversight or reporting—in lieu of prohibiting collaborations outright.

- Require agencies to document why less restrictive mitigation measures are insufficient before denying or terminating an international collaboration on national security grounds.

[§ 200.300] Statutory and National Policy Requirements

Many researchers in the Harvard Chan community have expressed concern that § 200.300 could be interpreted to prohibit or discourage lawful, scientifically necessary research that examines how sex, gender, and related population characteristics affect health. The School complies with federal anti-discrimination law and supports clear prohibitions on unlawful discrimination. However, the proposed language is broad enough to create uncertainty about whether federally funded researchers may study sex- and gender-related health differences, recruit study populations affected by particular conditions, or examine barriers to care experienced by women, LGBTQ+ populations, and other groups.

Understanding Health Disparities Across Specific Groups Strengthens Health Outcomes for All. Decades of public health research have demonstrated that understanding how social conditions, discrimination, and other structural factors influence health is fundamental to preventing disease and improving population health. Measuring differences in health outcomes across populations is a core scientific method used to identify preventable causes of illness, evaluate interventions, and improve health for all Americans. Restricting researchers' ability to examine these differences would weaken the evidence base needed to inform effective public health policy.

This concern is especially significant in public health because sex and gender are not peripheral to biomedical research; they are often central to understanding disease risk, symptoms, treatment response, prevention, and health outcomes. A Harvard Chan suicide epidemiology researcher explained that decades of epidemiologic research have shown substantial differences in suicide risk across sex, geography, economic conditions, Indigenous populations, rural communities, LGBTQ+ populations, and other groups. The researcher notes that effective suicide prevention depends on identifying which populations are at greatest risk so that interventions can be appropriately designed, evaluated, and targeted. Preventing researchers from measuring or analyzing these differences would undermine the evidence needed to reduce suicide deaths and improve mental health outcomes.

Ignoring these differences would not produce more neutral science. It would produce less accurate science and harm U.S. advancement and innovation, as well as public health outcomes. Harvard Chan researchers studying trauma have shown that the health consequences of traumatic experiences differ substantially across populations, informing prevention and treatment strategies for veterans, survivors of violence, first responders, and other affected groups. Measuring these differences allows federal agencies to target interventions where they are most effective and avoid investing in approaches that fail to improve health outcomes. Limiting the ability to study these differences would reduce the impact and clinical relevance of federally funded research programs.

Recommendation

Harvard Chan School respectfully recommends that OMB not adopt the proposed §§ 200.300. If OMB proceeds with rulemaking, we recommend that OMB:

- Revise the proposed § 200.300 to clarify that lawful, scientifically justified research on sex, gender, and population-specific health outcomes remains fully allowable when integral to the research design, consistent with statutory requirements, and necessary to improve health outcomes.
- Provide clear examples distinguishing prohibited discriminatory practices from permissible public health research, clinical trial recruitment, and intervention design that are grounded in scientific evidence.

[§ 200.218] Disparate Impact, Health Equity, and Rigorous Public Health Science

Harvard Chan researchers expressed related concerns that § 200.218 could be interpreted to prohibit or discourage research that measures whether policies, systems, programs, or interventions have different effects across populations.

Disparate-Impact Analysis is Fundamental to Gold Standard Science. Measuring differences in health outcomes across populations is a fundamental scientific method that underpins rigorous epidemiologic and biomedical research. These approaches—including stratified analyses, subgroup analyses, and evaluation of differential effects across populations—are essential for generating reproducible, generalizable evidence and are routinely used in public health research. For example, Harvard Chan researchers studying communicable diseases routinely stratify populations by characteristics such as age, prior immunity, vaccination status, underlying health conditions, and patterns of healthcare access to understand how infectious diseases spread and how interventions perform in different populations. These analyses are critical for understanding how protection in one population influences transmission, disease burden, and healthcare utilization across the broader community. Without evaluating these differential effects, researchers cannot accurately estimate vaccine effectiveness, identify gaps in protection, or design strategies that maximize population-wide health benefits. Failing to examine whether interventions, policies, or treatments produce different outcomes across populations would reduce scientific rigor by limiting the ability of researchers to identify important biological, clinical, environmental, and social factors that influence health outcomes.

This work is also central to OMB’s stated goals of accountability and stewardship. Without the ability to measure differential effects, federal agencies cannot know whether federally supported programs work as intended, whether they produce unintended harms, or whether resources are being used efficiently. One Harvard Chan researcher noted that many diseases differ substantially in their incidence, presentation, progression, and response to treatment between women and men. This is particularly true in autoimmune diseases, cardiovascular disease, and mental health, where understanding sex-specific differences has been essential to improving prevention, diagnosis, treatment, and clinical outcomes. Measuring these differences allows researchers to evaluate whether interventions are equally effective across patient populations, refine clinical recommendations based on evidence rather than assumption, and ensure that federally funded research produces findings that are broadly applicable. Disparate-impact analysis, in the scientific sense, is therefore not a threat to rigorous research; it is one of the tools that makes rigorous research possible.

Recommendation

Harvard Chan School respectfully recommends that OMB not proceed with the proposed modifications. If OMB proceeds with rulemaking on this subject, we suggest revising the proposed § 200.218 to:

- Clarify that empirical research measuring differences in health outcomes, access, exposure, treatment response, or policy effects across populations is fully allowable and encouraged when conducted for scientific, public health, program evaluation, or policy analysis purposes.
- Make clear that the rule does not prohibit standard epidemiologic, biostatistical, clinical, or health services research methods used to identify whether interventions are safe, effective, and beneficial across disparate populations.

[§ 200.461] Publication and Printing Costs

Harvard Chan researchers have expressed concern that the proposed § 200.461 would substantially restrict the allowability of publication costs, including article processing charges for open-access journals, except where required by statute or specifically approved by the awarding agency.

Peer Reviewed Publication is a Fundamental Check to Ensure Rigor, Reproducibility, and Scientific Impact. Publication is not an ancillary activity that occurs after a project is complete—it is an integral component of the scientific research process. Peer-reviewed publication allows findings to be scrutinized, validated, reproduced, and built upon by other investigators, ensuring that federally funded discoveries become part of the cumulative body of scientific evidence rather than merely isolated results. Restricting publication costs therefore undermines not only the dissemination of research, but also the rigor, reproducibility, and long-term scientific value of federally funded research.

Openly Accessible Scholarship Allows Taxpayers to Understand the Impacts of their Investments and Enables Decision-Makers, Practitioners, and Clinicians to Leverage Discovery in Real Time to Better the Health Outcomes of Americans. Dissemination is equally essential to ensuring that federal investments achieve their intended public benefit. Federal policy has increasingly emphasized broad public access to federally funded research because clinicians, policymakers, researchers, patients, and the public all benefit when new evidence is communicated rapidly and broadly. Publication in peer-reviewed journals—including open-access journals, where appropriate—is the primary mechanism through which scientific discoveries inform clinical practice, guide public health policy, and improve patient care. Limiting allowability of publication costs would therefore reduce the reach and impact of federally funded research, delaying the translation of new knowledge into improvements in health and public well-being. Timely dissemination of research findings is particularly critical during infectious disease outbreaks and other public health emergencies. It is specifically in these instances that clinicians, researchers, and public health agencies on the front lines rely on rapid access to protocols, interim analyses, and emerging evidence to inform response efforts. Dissemination of these real-time tools is critical to inform ongoing surveillance, diagnosis, and treatment. One infectious disease researcher noted that peer-reviewed publications, preprint servers, and related publication infrastructure are essential components of outbreak response, allowing new evidence to be shared and acted upon while an

emergency is still unfolding. Restricting publication costs could slow the flow of critical scientific information precisely when timely communication is most essential to protecting public health.

Burden of Publication Costs Too Great for Individual Researchers to Absorb. Publication costs cannot reasonably be absorbed by individual investigators. One recently federally funded R01 research project at Harvard Chan School generated 39 peer-reviewed publications. At an estimated average open-access publication cost of approximately \$5,000 per article, publication charges would total roughly \$195,000. This amount would be exponentially greater for large, multidisciplinary research programs. Program Project Grants, Centers, and other large collaborative awards frequently support dozens of faculty investigators, research scientists, postdoctoral fellows, trainees, statisticians, and technical staff working across multiple projects over many years. These programs often produce hundreds of peer-reviewed publications as an expected scientific output of the award. Requiring PIs or individual laboratories to independently absorb publication costs would be financially unsustainable and would create a disincentive to disseminate federally funded research, reducing the scientific return on substantial federal investments.

Recommendation

Harvard Chan School respectfully recommends that OMB not proceed with the proposed modifications. If OMB proceeds with rulemaking on this subject, we suggest revising the proposed § 200.461 to continue recognizing publication as an allowable and expected cost of federally funded research. Specifically, OMB should:

- Continue to permit reasonable publication costs, including article processing charges where appropriate, as allowable expenses directly supporting dissemination of federally funded research.
- Distinguish publication costs that directly advance the scientific objectives of a federal award from costs that primarily serve institutional or promotional purposes.
- Recognize publication, data sharing, and related dissemination activities as essential scientific outputs that maximize the public value, transparency, reproducibility, and long-term impact of federally funded research.
- Ensure that any prior approval requirements needed to use federal funds for publication are administratively practical and do not create unnecessary barriers to timely dissemination of research findings.

[§ 200.432] Conferences

Harvard Chan researchers have expressed concern that the proposed § 200.432 would make conference travel and registration costs allowable only when expressly approved by the federal agency and included in the terms and conditions of the award. This requirement would be difficult to implement for multi-year awards because conference schedules, abstract acceptances, invited presentations, and emerging scientific opportunities are often unknown when grant applications are prepared.

Scientific Conferences Represent a Critical Ecosystem for Innovation. Scientific conferences are an essential component of the research process and one of the primary ways that scientific knowledge is tested, refined, and advanced. Conferences provide opportunities to present

preliminary findings, receive critical peer feedback, learn emerging methods and technologies, establish new collaborations, and disseminate research well before formal publication. This iterative exchange of ideas accelerates scientific discovery, improves the quality and rigor of ongoing research, reduces unnecessary duplication of effort, and fosters the innovation that federal research investments are intended to support. Many of the most important scientific collaborations and research directions originate through discussions at scientific meetings, making conferences an important catalyst for innovation across disciplines.

Conferences also play a vital role in translating federally funded discoveries into practice. In rapidly evolving fields such as infectious disease, timely scientific exchange enables researchers, clinicians, and public health practitioners to share emerging evidence months before peer-reviewed publication, informing outbreak response and accelerating the adoption of new scientific knowledge. Conferences are, likewise, essential for sustaining national and international research collaborations and for fostering interdisciplinary approaches to complex public health challenges. In addition, conference participation is particularly important for trainees and early-career investigators, who rely on scientific meetings to present their work, receive mentorship, establish professional networks, and develop collaborations that shape future careers. Limiting support for conference participation would reduce opportunities for scientific exchange, professional development, and dissemination of federally funded research, ultimately diminishing the long-term impact of federal research investments.

Recommendation

Harvard Chan School respectfully recommends that OMB not proceed with the proposed modifications. If OMB proceeds with rulemaking on this subject, we suggest revising § 200.432 to:

- Continue recognizing reasonable conference travel and registration costs as allowable expenses when directly related to the scientific objectives of a federal award.
- Maintain support for conference participation to promote scientific rigor, accelerate innovation, strengthen research collaborations, facilitate dissemination of federally funded discoveries, and maximize the public value of federal research investments.
- Restrict prior approval requirements to exceptional cases when conferences present specific policy or national security concerns, rather than routine scientific meetings.

Conclusion

Harvard Chan School appreciates OMB's efforts to strengthen accountability, transparency, and stewardship of federal financial assistance. These are important objectives that the School strongly supports. However, the Harvard Chan community is concerned that several provisions of the proposed rule, as currently drafted, may unintentionally undermine those very goals and negatively impact U.S. innovation, advancement, and leadership to the country's detriment.

For decades, the partnership between the federal government and American research institutions has been built on a framework that emphasizes scientific merit, rigorous peer review, stable long-term investment, academic independence, responsible stewardship of public resources, and broad dissemination of knowledge. That framework has helped establish the U.S. as the global leader in biomedical and public health research while producing discoveries that have improved Americans'

health, strengthened the U.S. economy, informed public policy, and enhanced national preparedness and security. The proposed revisions would alter multiple components of that system simultaneously—from how research is selected for funding and conducted to how it is sustained, communicated, and translated into practice. Considered individually, each change presents considerable risk. Taken together, they have the potential to introduce destabilizing uncertainty throughout the U.S. research enterprise in ways that may reduce scientific productivity, discourage innovation, weaken long-standing research partnerships, limit scientifically necessary and appropriately safeguarded international collaboration, and ultimately diminish the return on federal research investments.

The Harvard Chan community has continuously emphasized that responsible stewardship extends beyond ensuring that funds are awarded appropriately. It also requires preserving the conditions that allow federally funded research to achieve its intended public benefit. That begins with funding the strongest science possible through independent merit review, supporting rigorous scientific methods, and preserving scientifically necessary collaborations with domestic and international partners that strengthen U.S. research and public health preparedness. It also requires sufficient stability for complex research to reach meaningful endpoints, thus enabling discoveries to be openly evaluated and disseminated and ultimately ensuring that the knowledge generated can improve health, inform policy, and strengthen the nation's scientific capacity.

Absent substantial revisions, Harvard Chan School respectfully urges OMB to withdraw the proposed rule. If any changes are considered in the future, we strongly advocate that any revisions to the proposed rule be made in a manner that preserves the foundational principles of our current scientific enterprise while advancing the shared goals of accountability, transparency, and responsible stewardship of taxpayer resources. Doing so will help ensure that the federal grantmaking system continues to support the rigorous, innovative, and impactful research that has long served the health, security, and prosperity of the American people.

Sincerely,



Andrea Baccarelli, MD, PhD
Dean of the Faculty
Harvard T.H. Chan School of Public Health