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Re: Comments of the American Society of Tropical Medicine and Hygiene on "Regulation for Federal Financial Assistance" - Proposed Revisions to 2 CFR Governing Federal Financial Assistance (91 Fed. Reg. 32198, May 29, 2026)

The American Society of Tropical Medicine and Hygiene (ASTMH) respectfully submits these comments on the proposed revisions to 2 CFR and related agency regulations governing Federal financial assistance.

ASTMH is a professional scientific society dedicated to reducing the worldwide burden of tropical infectious diseases and improving global health through research, education, clinical care, capacity strengthening, scientific exchange, and evidence-based policy. ASTMH publishes a peer-reviewed scientific journal, the *American Journal of Tropical Medicine and Hygiene*, and convenes a major scientific conference that enables researchers, clinicians, public health officials, trainees, government scientists, and partners from the United States and around the world to share findings essential to preventing, detecting, and responding to tropical diseases and emerging infections.

ASTMH strongly supports transparency, accountability, responsible stewardship of Federal funds, research integrity, and compliance with applicable law. However, the proposed rule would create substantial uncertainty and burden for the biomedical research enterprise, restrict scientific collaboration and dissemination, and undermine the very accountability and scientific rigor it seeks to promote.

The proposed rule would ultimately make Americans less safe by weakening the global health research and surveillance networks that serve as an early warning system for infectious disease threats.

Many of the pathogens that pose the greatest risk to the United States—including pandemic influenza, Ebola, mpox, dengue, Zika, malaria, antimicrobial-resistant organisms, and emerging zoonotic diseases—originate or are first detected outside U.S. borders. Federal investments in international research partnerships, field studies, surveillance systems, laboratory networks, and scientific collaborations allow U.S. researchers and public health agencies to identify threats before they reach American communities. These investments support the development of diagnostics, vaccines, and treatments, and inform preparedness and response efforts. By discouraging international collaboration, increasing uncertainty surrounding research funding, expanding discretionary termination authority, and creating barriers to scientific exchange, the proposed rule risks eroding the very infrastructure that protects Americans from global health threats. Infectious diseases do not recognize national borders, and reducing U.S. scientists' ability to conduct and participate in global health research will diminish our nation's capacity to anticipate, prevent, and respond to outbreaks that threaten the health, security, and economic well-being of the American people.

ASTMH urges OMB and the participating agencies to withdraw or substantially revise the proposal before finalizing.

[200.202] International Research and Development

ASTMH is deeply concerned that the proposed “domestic-first” framework for research and development awards, together with restrictions on awards to foreign entities and “international elements,” would impair the conduct of global health research.

Global health diseases, vector-borne diseases, parasitic infections, emerging infectious diseases, antimicrobial resistance, and epidemic threats do not respect national borders. Much of the relevant science necessarily occurs where diseases are endemic, where vectors circulate, where outbreaks emerge, and where clinical and public health interventions are implemented. U.S. scientific leadership depends on durable, ethical, reciprocal partnerships with scientists, clinicians, public health agencies, universities, nongovernmental organizations, and communities abroad.

These collaborations are not abstract international activities; they directly advance U.S. health and economic security. Diseases that are uncommon or not endemic in the United States frequently threaten Americans through travel, migration, trade, military deployments, and changing environmental conditions. Malaria, for example, remains a major global cause of illness and death and continues to cause imported cases in the United States each year, requiring ongoing research on drug resistance, diagnostics, vaccines, and vector control in endemic countries. Dengue has expanded dramatically worldwide and has already caused outbreaks in U.S. territories and locally acquired cases in several states, making international surveillance and research essential to protecting Americans. Likewise, the recent spread of New World screwworm in the Western Hemisphere demonstrates how animal and zoonotic health threats originating outside U.S. borders can endanger livestock, food security, and economic interests within the United States. Research partnerships conducted where these threats occur provide the knowledge, early warning systems, and new treatments and cures necessary to prevent, detect, and respond to risks before they reach American communities.

International research collaborations also advance U.S. interests by extending the standards of scientific rigor, research integrity, biosafety, biosecurity, ethics, data quality, and accountability that have long distinguished American science. Through partnerships with institutions abroad, U.S. investigators help establish and strengthen research practices consistent with internationally recognized scientific and ethical standards, while fostering transparency, responsible stewardship of resources, and reliable disease surveillance. These collaborations build trusted networks that enable rapid information sharing, coordinated outbreak response, early detection of emerging biological threats, and breakthrough treatments. Far from diminishing U.S. security, carefully managed international research partnerships enhance it by ensuring that research affecting

global health is conducted according to high standards, generating reliable data and trusted relationships that protect both the American people and the broader international community.

ASTMH recommends that OMB revise proposed section 200.202(e) to:

1. expressly recognize that international collaboration is often integral—not exceptional—to infectious disease, global health, epidemiology, entomology, vaccine, diagnostics, implementation science, and public health research;
2. remove any presumption against international research elements when such elements are scientifically justified and consistent with the award's public health objectives;
3. allow Federal agencies to support foreign subrecipients and collaborators when necessary to achieve scientifically valid and ethically conducted research;
4. avoid requirements that would delay outbreak response, field studies, clinical trials, surveillance, and capacity-building activities; and
5. ensure that decisions are made by program and scientific experts using transparent, discipline-appropriate criteria.

[200.205] Merit Review, Peer Review, and Scientific Independence

ASTMH supports rigorous merit review. However, the proposal's requirement that senior appointees conduct pre-issuance review of discretionary awards and its statement that peer review remains merely advisory, risk politicizing scientific grantmaking.

Scientific merit review must be independent, transparent, expert-driven, and insulated from political or ideological considerations. Peer review is not an exercise; it is the core mechanism by which Federal science agencies identify the most promising, rigorous, and impactful research. Public confidence in federally funded science depends on the integrity and independence of that process.

The proposed requirement that senior political appointees independently review all discretionary awards fundamentally alters the longstanding model of scientific grantmaking in the United States. While agencies appropriately retain final award authority, the scientific merit of biomedical, public health, and global health research should be determined primarily through expert peer review. Requiring political review of individual scientific awards creates uncertainty, risks inconsistent decision-making, and may discourage innovative, high-risk, or international collaborative research. Federal scientific agencies have earned global credibility because funding decisions are grounded in scientific excellence rather than political considerations. ASTMH urges OMB to preserve peer review as the primary basis for scientific funding decisions and eliminate requirements for independent political review of individual research awards.

ASTMH supports rigorous, transparent, reproducible science. However, the proposed references to "Gold Standard Science" lack sufficient regulatory definition and could create uncertainty for applicants and reviewers. OMB should clearly define how these principles will be applied, ensure they are developed in consultation with the scientific community, and confirm that they supplement rather than replace discipline-specific standards of scientific excellence and peer review.

[200.206] Risk Review of Applicants

ASTMH is concerned that the proposed risk factors—particularly references to "discredited or non-replicable studies," "questionable practices," and affiliations—are vague and may be misapplied to penalize legitimate scientific debate. Science advances through replication, disagreement, correction, and refinement. A study that is later revised, challenged, or not replicated should not automatically create institutional risk.

ASTMH recommends that OMB revise section 200.206 to require that any risk determination be based on documented findings of misconduct, fraud, legal noncompliance, or material failure to perform—not disagreement with scientific conclusions, controversial research topics, or participation in lawful academic or professional associations.

[200.218 and 200.300] Public Health Disparities, Nondiscrimination, and Scientific Inquiry

ASTMH supports compliance with Federal civil rights laws. However, the proposed provisions on disparate-impact liability, DEI, gender ideology, and related concepts are broad and ambiguous. They could chill lawful and scientifically necessary research on health disparities, disease burden, access to care, maternal and child health, sex-based differences, race and ethnicity as epidemiologic variables, and social determinants of infectious disease.

Global health and public health research often require analysis of differential disease burden across populations. Such analysis is essential to malaria control, neglected tropical disease elimination, vaccine delivery, maternal health, outbreak response, and health system strengthening. It is not discriminatory to study disparities, identify populations at risk, or design interventions to reduce disease burden.

ASTMH recommends that OMB clarify proposed sections 200.218 and 200.300 so that the rule does not prohibit:

1. epidemiologic, clinical, demographic, or public health research involving race, ethnicity, sex, age, disability, geography, socioeconomic status, migration status, pregnancy, or other relevant variables;
2. lawful efforts to expand access to research participation, training, mentorship, and scientific conferences;
3. health equity research and implementation science aimed at reducing disease burden;
4. journal publications, conference sessions, and educational activities addressing disparities in infectious disease outcomes; or
5. collection and analysis of demographic data required for scientific validity, public health practice, or compliance with law.

[200.220] Covered Foreign Collaborations

ASTMH agrees that national security concerns must be addressed. However, the proposed prohibition on certain foreign collaborations is broad and may be difficult to implement, especially for multi-country infectious disease research, surveillance networks, outbreak investigations, and global health partnerships.

ASTMH recommends that OMB narrow section 200.220 to clearly defined statutory prohibitions and provide a timely, transparent waiver process for research and public health activities that advance U.S. health security, outbreak preparedness, and scientific objectives.

[200.340 and 200.341] Termination and Suspension

ASTMH is deeply concerned that the proposed termination and suspension provisions would allow Federal awards to be terminated or suspended based on broad and changing concepts such as “agency priorities” or “national interest.” Biomedical research often requires long-term commitments, including hiring staff, enrolling participants, maintaining field sites, supporting laboratories, sustaining international partnerships, and protecting human subjects.

Abrupt termination or suspension can waste Federal funds, harm trainees, disrupt clinical studies, compromise data integrity, damage U.S. scientific credibility, and undermine public health preparedness. It may also create significant ethical concerns, particularly when human participants have already enrolled in research studies or

clinical trials. Research participants often assume burdens and risks with the understanding that studies will be conducted in accordance with approved scientific and ethical protocols and that the knowledge gained may benefit future patients and communities. Sudden termination can interrupt access to study-related care, monitoring, investigational products, or follow-up activities; jeopardize participant safety; and prevent the collection of data necessary to answer important scientific questions. Such disruptions may undermine informed consent expectations, compromise obligations to participants and affected communities, and erode public trust in the research enterprise.

ASTMH recommends that OMB revise proposed section 200.340 and 200.341 to:

1. remove or substantially narrow discretionary termination authority;
2. require specific, written, award-related reasons for termination;
3. provide advance notice and a reasonable opportunity to address problems before terminating an award;
4. protect human subjects, research participants, animal welfare, data integrity, and closeout obligations, including ensuring appropriate participant follow-up, continuity of monitoring and safety assessments, fulfillment of ethical and regulatory obligations to enrolled participants, humane care and disposition of research animals, preservation of research records and specimens, secure management of data, and orderly completion of study closeout activities;
5. require payment of reasonable termination and wind-down costs; and
6. prohibit retroactive application to existing awards.

[200.432] Conferences

ASTMH is especially concerned by the proposed changes to conference costs. Scientific conferences are a primary mechanism through which federally funded research is scrutinized, validated, disseminated, and translated into public health practice. Requiring advance agency approval of conference participation in award terms would create a significant administrative burden and could limit the dissemination of emerging findings, particularly during outbreaks and public health emergencies.

ASTMH's annual scientific conference enables presentation of federally funded research, supports early-career investigators, facilitates outbreak and surveillance updates, and connects scientists with public health officials, clinicians, and policymakers. Requiring express agency approval in award terms before conference attendance may create delays, inconsistencies, and unnecessary administrative burden.

ASTMH recommends that OMB revise section 200.432 to preserve allowability of reasonable conference registration, travel, abstract presentation, poster, speaker, and dissemination costs when they are allocable to the award and consistent with existing cost principles. OMB should not require separate prior approval unless an agency identifies specific risk.

[200.461] Publication and Printing Costs

ASTMH strongly opposes making publication costs unallowable unless expressly required by statute or approved in advance. Publication is not ancillary to scientific research; publication in peer-reviewed journals is a cornerstone of scientific accountability. It enables replication, transparency, peer critique, clinical guideline development, public health decision-making, and public access to federally funded findings.

The *American Journal of Tropical Medicine and Hygiene* publishes research that supports U.S. and global efforts to prevent and control infectious diseases. Federal agencies routinely require dissemination of results, and publication costs are a normal and necessary part of responsible research.

ASTMH recommends that OMB revise section 200.461 to retain publication costs as allowable when reasonable, allocable, and consistent with award objectives, including article processing charges, open access fees, data and supplemental material charges, figure preparation, and related costs necessary to disseminate research results.

[200.201 and 200.333] Fixed Amount Awards and Subawards

ASTMH recommends that OMB not categorically eliminate fixed amount awards and subawards. Properly structured fixed amount mechanisms can reduce burden, support small organizations, facilitate capacity strengthening, and enable efficient milestone-based work. OMB should instead add safeguards, documentation requirements, and monitoring standards.

[200.202(f); 200.205(b)(3)] Multi-year grants and indirect cost preference

With respect to sections 200.202(f) and 200.205(b)(3),

- ASTMH is concerned that the proposed encouragement of multi-year awards may have unintended consequences for the overall research portfolio and the availability of funding for new scientific opportunities. While multi-year awards can reduce administrative burden and provide greater stability for complex projects, they also require agencies to commit larger portions of available funding for extended periods, potentially reducing the number of new awards that can be competed and funded in future years. This concern is particularly important in infectious disease and global health research, where agencies must retain flexibility to respond rapidly to emerging outbreaks, newly identified public health threats, and evolving scientific priorities. A broad shift toward multi-year awards could limit opportunities for early-career investigators, innovative research projects, and rapid-response funding initiatives that are essential to maintaining a vibrant and responsive research enterprise.

  ASTMH therefore recommends that Federal agencies retain broad discretion to determine when multi-year awards are appropriate and evaluate the impact of such funding commitments on the overall number, diversity, and scientific breadth of awards that can be supported.

- ASTMH is also concerned by the proposed requirement that, during pre-issuance review, "all else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rates" (§ 200.205(b)(3)). Indirect cost rates are negotiated and approved by the Federal Government and reflect legitimate institutional investments in research infrastructure, compliance systems, laboratory facilities, biosafety programs, data security, human subject protections, financial management, and other capabilities necessary to conduct high-quality research. Using negotiated indirect cost rates as a selection criterion risks disadvantaging institutions based on accounting structures rather than scientific merit, technical capability, public health impact, or value to taxpayers. ASTMH recommends removing § 200.205(b)(3) and ensuring that award decisions continue to be based on scientific excellence, programmatic relevance, demonstrated capacity, and the likelihood of achieving meaningful results.

[200.303 and 200.305] Internal Controls, E-Verify, and Payment Justifications

ASTMH supports strong internal controls and payment integrity. However, proposed E-Verify, payment-justification, and pre-payment verification requirements may impose significant burden on universities, nonprofit organizations, and international research collaborations. OMB should clarify applicability, avoid duplicative systems, and exempt personnel or contractors outside the United States where U.S. employment verification systems are not legally or practically applicable.

[200.421, 200.450, 200.454, and 200.467] Communications, Outreach, Memberships, and Scientific Dissemination

OMB should clarify that the rule does not prohibit reasonable scientific communication, public health education, community engagement, recruitment for research studies, dissemination of findings, journal activities, professional society engagement, or participation in scientific associations. These activities are often necessary to achieve award objectives and should remain allowable when reasonable and allocable.

Effective Date and Transition

Given the breadth of the proposed changes, the 45-day comment period and October 1, 2026, implementation date are inadequate. ASTMH recommends a substantially longer implementation period and phased implementation to permit agencies, research institutions, scientific societies, and award recipients to assess operational impacts and develop compliant systems.

Conclusion

Global health and infectious disease research often requires rapid mobilization during outbreaks and public health emergencies. New requirements related to international collaborations, prior approvals, payment justifications, political review, and termination authority could significantly slow the ability of researchers and public health agencies to respond to emerging threats. Delays in surveillance, field investigations, clinical research, and scientific communication can have direct consequences for public health preparedness and response.

ASTMH supports accountability, transparency, research integrity, and responsible stewardship of Federal funds. But the proposed rule, as written, would create uncertainty, burden, and risk for the scientific enterprise, particularly in global health. It would restrict international collaboration, weaken peer review, chill scientific inquiry into health disparities, impair publication and conference dissemination, and destabilize long-term research.

ASTMH respectfully urges OMB and the participating agencies to withdraw or substantially revise the proposed rule. At minimum, OMB should preserve independent scientific peer review, protect lawful public health and disparities research, maintain reasonable allowability of publication and conference costs, narrow foreign collaboration restrictions, and prevent broad discretionary termination of scientifically meritorious awards.

Respectfully submitted,

The American Society of Tropical Medicine and Hygiene