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Re: Comments from the Global Health Technologies Coalition on "Regulation for Federal Financial Assistance" - Proposed Revisions to 2 CFR Governing Federal Financial Assistance (91 Fed. Reg. 32198, May 29, 2026)

Summary of Key Concerns & Recommendations to the Office of Management and Budget (OMB)

Shift from Peer Review to Political Review
OMB should preserve peer review as the primary basis for individual funding decisions and limit political appointee involvement to broader strategic priority-setting, ensuring awards remain grounded in scientific merit and expert evaluation.

New and Undefined Risk Factors Enhance Subjectivity
OMB should clarify and narrow disqualifying risk factors, particularly "memberships and affiliations," to ensure definitions are objective, consistently applied, and do not disadvantage qualified applicants engaged in legitimate scientific collaboration.

Mid-lifecycle Termination Authority Broadens
OMB should maintain the existing Uniform Guidance framework for suspension and termination and avoid expanding discretionary termination authority that could disrupt long-term research and reduce return on taxpayer investment, particularly in clinical and human subjects research.

Limitations on International Collaboration and Components
OMB should preserve scientifically justified international research and foreign subawards by establishing clear, stable criteria for covered foreign entities and ensuring that national security designations are transparent, consistently applied, and not disruptive to ongoing research partnerships.

Uncertainty Around Relevant Communications on Research Findings
OMB should maintain the current framework distinguishing lobbying from permissible scientific communication, ensuring researchers can continue sharing findings and technical expertise so that taxpayer-funded research can be translated into policy and public health impact.

Please refer to the full comment below for additional context and detailed explanations of these recommendations.

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 50 nonprofit organizations, academic institutions, and aligned businesses advancing the development of new drugs, vaccines, diagnostics, and other tools for global health—we submit these comments to the Office of Management and Budget (OMB) on the proposed rule amending 91 parts of Title 2 of the Code of Federal Regulations. Given the scope of this rulemaking, which adds 52 new subsections and fully restates 375 sections across 456 regulatory provisions, our comments focus on the sections most directly affecting the ability to carry out effective, safe, and efficient global health research and development across the federal enterprise.

We are concerned that several provisions in this proposed rule could undermine long-term research investments and weaken the conditions that enable scientific progress. We respectfully offer these comments to ensure OMB fully considers the cumulative impact these revisions could have on the United States' ability to maintain its leadership in biomedical innovation, maximize the return on taxpayer investment, and continue advancing research that improves health at home and around the world, while still strengthening transparency, accountability, and oversight in a way that does not fundamentally alter how federal research awards are administered.

Shift from Peer Review to Political Review
§ 200.205(b) — Pre-issuance review by senior political appointees

For decades, peer review has been the cornerstone of the federal research funding process, ensuring that funding decisions are guided by scientific merit, feasibility, and potential impact. This expert driven process has supported major advances in medicine, public health, and biomedical innovation while reinforcing confidence that taxpayer dollars are allocated effectively based on scientific evidence and expertise.

Section 200.205(b) would introduce a greater role for political appointees in the award approval process, undermining this confidence. Research funding decisions often require highly specialized knowledge of scientific methods, clinical design, and subject-matter context. Career scientists, physicians, and subject-matter experts are best positioned to assess these complex factors. Expanding political involvement in these determinations introduces the risk that considerations beyond scientific merit may influence outcomes, reducing consistency in this process and discouraging investment in areas of science perceived as more subject to shifting policy interpretation, despite their potential public health value.

Our community has seen recent examples where post-peer review intervention has delayed or disrupted otherwise strong public health projects. Even limited instances can create broader uncertainty, as research and institutions adjust to less predictable funding criteria. Over time this uncertainty may discourage investment in multi-year, long-term, complex or high-risk research areas and make it more difficult to attract and retain scientific talent, particularly among-early career researchers or those in specialized fields, in a global competitive marketplace.

GHTC urges OMB to revise Section 200.205(b) to preserve peer review as the primary basis for individual funding decisions, ensuring that award determinations remain grounded in scientific merit and the expertise of career scientists to preserve confidence in the fairness, stability, and effectiveness of the federal research funding system.

New and Undefined Risk Factors Enhance Subjectivity
§ 200.206(b)(2) — New disqualifying risk assessment factors

Assessing risk among potential recipients is an important part of responsible stewardship of federal funds; however, the criteria used should be clearly defined, objective, and applied consistently. Several of the proposed disqualifying factors in Section 200.206(b) raise concerns because they rely on broad concepts that may be interpreted differently across agencies, individual decision-makers, or administrations, creating uncertainty for applicants.

GHTC is particularly concerned by the lack of clarity surrounding the proposed consideration of an applicant's "memberships and affiliations." The rule does not clearly define what constitutes an affiliation, how such relationships would be evaluated, or what standards agencies would use to determine whether an organization engages in activities that raise public safety or national security concerns. Many researchers—particularly those working in global infectious disease, pandemic preparedness, HIV/AIDS, and other areas of global public health—routinely collaborate across borders and maintain professional affiliations with international research institutions, as well as with community-based organizations serving historically underserved populations, as a necessary component of their work. These partnerships are essential to conducting rigorous, relevant research and delivering effective public health interventions. Without clearer definitions and transparent criteria, these provisions could be interpreted inconsistently across agencies or over time, leaving applicants uncertain about eligibility and raising concerns that subjective interpretations of an applicant's international collaborations, institutional partnerships, or community affiliations could inadvertently disadvantage qualified applications or influence funding decisions in ways not clearly tied to objective, merit-based criteria or legitimate security concerns.

GHTC urges OMB to revise Section 200.206(b) to provide clear, objective definitions and consistently applied standards for disqualifying risk factors—particularly regarding "memberships and affiliations"—to ensure that legitimate national security concerns are addressed without creating unnecessary uncertainty or disadvantaging qualified applicants engaged in scientifically justified collaborations.

Mid-lifecycle Termination Authority Broadens
§ 200.340(a)(2) — Expanded discretionary termination authority

Researchers build infrastructure, hire personnel, establish partnerships, and design multi-year scientific programs with the expectation that, barring scientific, safety, or compliance concerns, federally funded projects will be carried through to completion. While unexpected circumstances may occasionally warrant early termination, Section 200.340(a)(2) introduces a broader level of discretion that creates significant uncertainty for researchers and institutions undertaking long-term research and development.

These concerns are particularly significant for research involving human subjects and clinical trials. Unlike many other forms of research, clinical trials rely on the voluntary participation of individuals who assume personal risk and commit to carefully designed study protocols in pursuit of scientific advancement. They also require years of planning, substantial financial investment, extensive regulatory oversight, and coordination among research institutions, health systems, and community partners. Premature termination can compromise data integrity, reduce the scientific value of completed work, delay the development of new medical countermeasures, and require costly closeout activities that further diminish the return on prior taxpayer investment. It may also undermine the trust of research

participants and partner institutions whose continued engagement is essential to future public health research.

While there will always be circumstances in which awards must be terminated because of participant safety concerns, scientific misconduct, or recipient noncompliance, the proposed rule that grants broader termination authority across all awards does not distinguish between those involving human subjects research and other forms of federally funded research, nor does it establish additional considerations or safeguards for studies involving clinical trial participants.

GHTC calls for OMB to maintain the existing framework for award suspension and termination under the Uniform Guidance, which already provides agencies with robust tools to address performance, compliance, and stewardship concerns, rather than expanding discretionary termination authority in ways that introduce unnecessary uncertainty into long-term research and development and reduced return on prior taxpayer investment.

Limitations on International Collaboration and Components
§ 200.202(e) — Domestic-first framework for R&D awards
§ 200.220 — Prohibition on covered foreign collaborations

Many of the world's most pressing infectious diseases do not respect borders, and the United States cannot effectively prepare for or respond to emerging health threats without conducting research where those diseases occur. International components of R&D awards enable scientists to study diseases in the populations and environments where they are endemic, generating the evidence needed to develop effective vaccines, therapeutics, diagnostics, and other interventions that ultimately protect Americans alongside people around the world. These investments also maximize the value of taxpayer dollars by supporting research in the settings where it can generate the most meaningful scientific evidence, strengthening preparedness before health threats reach US borders and reducing the need for more costly emergency responses.

The framework proposed in Section 200.202(e) risks narrowing the scope of research in ways that may limit insight into global health threats. For many longstanding and emerging infectious diseases, insights into transmission patterns, intervention strategies, and the evaluation of medical countermeasures can only be generated through collaboration with international partners and research sites. These partnerships should operate with appropriate oversight, transparency, and compliance with US laws and national security requirements. However, restricting these collaborations may ultimately diminish the return on federal research investments by limiting opportunities to generate the evidence needed to inform prevention, preparedness, and response strategies that protect both US and global health.

Section 200.220 raises related concerns by restricting collaborations involving "covered foreign countries" and "covered foreign entities." While the proposed rule references existing national security authorities, it does not provide sufficient clarity regarding which lists will govern these determinations, how frequently those lists will be updated, how changes will be communicated to recipients, or how agencies will apply those changes to ongoing awards. Given that these lists and associated national security designations can evolve over time, researchers and institutions may face significant uncertainty in determining whether existing or prospective collaborations remain permissible throughout the life of a multi-year project.

The proposed rule also provides limited guidance regarding how affiliations with foreign entities will be evaluated in practice or whether exceptions may be available when international collaboration is scientifically necessary to achieve the objectives of a federally funded project. Not all foreign entities present the same level of national security concern, yet the proposed framework does not clearly distinguish among varying levels of risk or explain how agencies will balance legitimate security considerations with the public health value of continued international research partnerships.

Over time, uncertainty surrounding the scope of permissible international engagement and the definition of restricted entities may disincentivize participation in global research partnerships. This could reduce the United States' ability to maintain on-the-ground research presence in regions where outbreaks originate, limiting early detection and response capacity. In the context of global infectious disease threats, reduced engagement in these settings may inadvertently increase, not decrease, vulnerability to emerging health risks that cross borders.

GHTC urges OMB to provide greater clarity regarding the standards governing international research collaborations, including the application of restrictions on covered foreign entities, while preserving the ability for scientifically justified international research and foreign subawards to remain integral components of federally funded research. The final rule should establish clear, predictable criteria and implementation guidance that protect national security while enabling US researchers to maintain the international partnerships necessary to maximize taxpayer investments, strengthen global disease surveillance, and advance the scientific discoveries that safeguard public health at home and abroad.

Uncertainty Around Relevant Communications on Research Findings
§ 200.450 — Issue advocacy prohibition / communications restrictions

Communicating research findings is an essential component of translating evidence into impact. Scientific discoveries achieve their greatest public benefit when researchers can share evidence, explain the significance of findings, and inform decision-makers responsible for translating research into policy and practice. The revisions proposed in Section 200.450, that includes terms such as "issue advocacy," "public messaging," and communications that "promote or oppose a particular social, political, or public policy position," are broad enough that recipients may struggle to distinguish between prohibited advocacy and allowable scientific communication.

Greater clarity regarding the scope of these restrictions would help ensure that federally funded entities can continue communicating scientific evidence and technical expertise while remaining fully compliant with longstanding prohibitions on lobbying. Preserving the ability to responsibly disseminate research findings and inform decision-making is critical to ensuring that taxpayer-funded research translates into improved public health policy, stronger preparedness, and better health outcomes.

GHTC recommends that OMB maintain the existing framework around messaging by preserving the longstanding distinction between prohibited lobbying activities and the responsible communication of federally funded research, while providing greater clarity where needed to ensure that taxpayer investments continue to translate into evidence-based policy maximizing public health benefit.

Conclusion

In considering these revisions, we encourage OMB to evaluate not only the intent and impact of each individual provision, but also the cumulative effect of implementing many significant changes simultaneously across the federal grantmaking framework. While each revision may be designed to strengthen oversight, accountability, or alignment with administration priorities, together they risk introducing a level of uncertainty that could fundamentally alter how research institutions, investigators, and partners engage with federally funded research and development.

The United States has long benefited from a research ecosystem that balances strong oversight with scientific independence, rigorous accountability with flexibility, and domestic leadership with strategic international collaboration. Preserving that balance is essential to ensuring that taxpayer investments continue to generate lifesaving discoveries, strengthen preparedness, and sustain America's leadership in science and innovation.

We appreciate OMB's consideration of these comments and respectfully urge the agency to consider and revise the provisions outlined above before finalizing the rule. If implemented as proposed, these revisions could discourage participation in federally funded research, disrupt critical collaborations, and slow the development of lifesaving technologies needed to address current and future health challenges. Oversight, accountability, and transparency can coexist with the stable and predictable funding environment that research and development requires, provided that efforts to strengthen stewardship of federal funds do not come at the expense of the conditions that have made the US research enterprise a global model for decades.

Please do not hesitate to contact GHTC's US Policy and Advocacy Associate Amanda Reiling at areiling@ghtcoalition.org or GHTC's Executive Director Dr. Kristie Mikus at kmikus@ghtcoalition.org if you have questions or need any additional information.

Sincerely,

Dr. Kristie Mikus, Executive Director of GHTC on behalf of the Global Health Technologies Coalition