July 12, 2026

Office of Management and Budget
Office of Federal Financial Assistance
Executive Office of the President

RE: Proposed Rule, Regulation of Federal Financial Assistance [2 CFR Parts 200, 300, 376, and 382 RIN 0991-AC35]

The Coalition for Clinical and Translational Science (CCTS) writes today to register strong reservations and provide feedback on the Office of Management and Budget's recent proposal to update the Uniform Guidance. CCTS recognizes and supports OMB's stated objectives of improving transparency, accountability, and stewardship of taxpayer resources across federal grantmaking programs. These are important goals, particularly for federally supported biomedical research, where taxpayer resources should be awarded and administered efficiently, responsibly, meritoriously, and in furtherance of scientific progress. Presently, the system delivers significant return-on-investment and financial benefit while driving notable progress improving human health and addressing disease. Any changes should seek to improve this dynamic and occur incrementally as to not disrupt a successful model.

Notwithstanding stated objectives, the proposed rule, as drafted, is not reasonably tailored to the operational realities of federally supported biomedical research and it unlikely to achieve its stated goals. Moreover, proposed changes could further challenge the research pipeline as investigators prioritize submitting large numbers of grants over specific and focused proposals. Rather than advancing efficiency, several provisions would have the cumulative effect of disrupting clinical and translational research by: **(1)** weakening the valuable role of unbiased scientific peer review and elevating senior appointee pre-issuance review over expert scientific judgment; **(2)** allowing ever shifting administration or political priorities to influence whether meritorious research receives and/or retains federal support; **(3)** expanding termination and suspension authority in ways that could waste public investment in partially completed studies, disincentivize efforts to retain the biomedical research workforce, and discourage investigators and institutions from undertaking complex multi-year projects, including scenarios where awards could be suspended or terminated without just cause or a meaningful opportunity to researchers to respond; **(4)** restricting long-standing international collaborations that are often necessary for rare-disease, specialized, or multi-site research; and **(5)** limiting conferences, professional memberships, publication costs, open-access dissemination, and public communications that are essential to scientific exchange, validation, replication, and the translation of federally funded findings into patient benefit.
The Association for Clinical and Translational Science, the Clinical Research Forum, the PIs of the NCATS funded Clinical and Translational Science Awards, and related stakeholders work together through CCTS to provide a unified voice on behalf of the clinical and translational research community. CCTS is a nationwide, grassroots network of researchers, clinicians, educators, institutional leaders,

trainees, and other stakeholders committed to advancing medical research, research training, and career development.

CCTS supports a policy environment in which basic scientific discoveries can be responsibly and efficiently translated into improved diagnostics, therapies, optimized care models, and ultimately into improved public-health outcomes. Clinical and translational science depends on sustained federal investment, rigorous expert review, predictable multi-year research infrastructure, interdisciplinary collaboration, and robust training and career-development pathways. These conditions are essential not only to the development, validation, dissemination, and translation of medical advances for patients and communities, but also to ensuring we train and retain the workforce of the future. https://coalition4cts.org/

While the current federal grant administration system is not perfect, the overall framework has fostered an ecosystem that has allowed the United States to become the world leader in biotechnology and has led to sustained breakthroughs that improve health, advance patient care, and address disease. Given that the provisions summarized below would materially disrupt ongoing and emerging medical research, CCTS urges OMB to withdraw the proposed rule and work with Congress, federal research agencies, and the research community on transparent, common-sense, incremental reforms in lieu of wholesale changes.

- Primarily, the proposed rule would shift the longstanding framework from guidance to more rigid government-wide regulation. Scientific advancement can move quickly. An overly prescriptive framework may become outdated and be difficult to adapt at the pace of innovation, thereby hampering timely progress and effective stewardship.
- Moreover, certain provisions would undermine basic tenets of the scientific process. Biomedical research is designed to generate knowledge through rigorous inquiry, including in areas where the answers are uncertain and the most promising avenues of investigation may not be apparent at the outset. For that reason, federal research funding decisions should continue to be grounded in expert, unbiased scientific peer review by those best qualified to evaluate scientific merit, rigor, feasibility, impact, and public-health importance, rather than subordinated to shifting administrative or political priorities. Accordingly:
    - Peer-review recommendations should not be reduced to merely advisory input.
        - The proposed enhanced merit-review, senior appointee pre-issuance review, and risk-assessment provisions are especially problematic because they would permit senior appointees to direct, second-guess, or effectively override scientific-review outcomes. That approach would reduce the value and impact of review by qualified scientific experts.
    - Funding decisions should not turn on shifting administrative policy preferences.

        - Introducing non-scientific considerations into decisions about which research receives federal support risks steering resources toward projects aligned with changing administrative priorities, rather than toward the most meritorious science or the research most needed to advance health.
    - The proposed approach to pre-issuance review would be especially harmful to early-career investigators.
        - Young investigators rely on a fair and scientifically grounded grant-review process to establish research programs, build teams, and remain in academic biomedical research. A process perceived as vulnerable to non-scientific override will discourage the next generation of investigators from pursuing federally supported research careers, even though those investigators are vital to sustaining the competitiveness of the American biomedical research enterprise. [Sec. 200.205]
- Expanded authority to terminate or suspend awards based on shifting program goals or agency priorities would create significant uncertainty for multi-year biomedical research. Clinical and translational studies often require years of planning and execution, including study design, regulatory approvals, staffing, participant recruitment, data collection, analysis, and dissemination. The ability to suspend, terminate, or redirect active awards based on shifting priorities could make complex projects more difficult to plan and responsibly execute. [Sec. 200.340, Sec. 200.341 and Sec. 200.342]
    - Late-stage termination could squander public investment. By the time findings are collected, analyzed, or published, substantial taxpayer resources may already have been spent to review, award, staff, and execute the study.
    - These provisions could also complicate workforce planning. Clinical and translational research depends on experienced personnel who support multi-year grant-funded projects. If awards may be suspended or terminated based on shifting priorities, institutions will face greater uncertainty in recruiting and retaining experienced personnel over the grant cycle.
    - Active awards should thus not be terminated or suspended without just cause and a meaningful opportunity to respond. Principal investigators and institutions should have an opportunity to address concerns before an award is discontinued or materially disrupted. Significant patient safety concerns and liability could arise in patient-oriented research with such suspensions without proper guardrails.
- Restrictions on international collaboration would undermine medical research in numerous areas. While the U.S. is currently the gold standard for research, there are many specialized international centers, particularly with expertise in rare conditions and

in locations that have higher prevalence of disease. Collaborative work leveraging these specialized resources ultimately benefits U.S. patients and the U.S. healthcare system. [Sec. 200.202 and 200.220]. Further, blocking international collaboration will not delay or disrupt parallel scientific efforts by competitors. By restricting international collaborations led by US scientists, the void will be replaced by international collaboration between other nations, including China and Russia, ultimately reducing US competitiveness.

CCTS would also like to raise concerns about proposals that would make it harder for researchers to participate in the ordinary channels through which science is conducted and communicated.

- We join with the broader community in raising concerns about new restrictions on publication costs and open-access fees.
    - Researchers must be able to publish the results of federally funded work, including where publication is necessary to make findings available to other scientists, clinicians, patients, and the public. Treating these costs as presumptively unallowable would place additional strain on already limited research resources and could slow the release of important findings. [Sec. 200.461]
- We are concerned that restrictions on public communications and outreach could limit appropriate dissemination of federally supported findings to patients, clinicians, policymakers, and the public.
    - Clinical and translational research depends not only on generating data, but also on communicating findings to the communities that can use them. [Sec. 200.421]
- Similarly, we are concerned with restrictions that would make it more difficult to join professional societies and access scientific journals.
    - Researchers rely on journals and professional societies to stay current, evaluate new developments, and collaborate with colleagues. [Sec. 200.454]
- Relatedly, we have concerns about limiting conference participation and attendance at professional meetings.
    - Not all conferences can be identified at the time a grant is submitted. As new data are generated, researchers need to be able to present findings, receive feedback, and learn from other work in the field. Requiring express pre-approval for these activities would create additional administrative burden and could interfere with timely scientific exchange. [Sec. 200.432]

Given the significant and sweeping proposed changes and the potential disruption to ongoing and emerging medical research, we urge OMB to delay further rulemaking and provide further opportunities for study and deliberation, including with congressional authorizers, or to withdraw the current proposed rule. Moreover, if incremental changes are proposed we recommend testing various concepts through pilot efforts to review evidence and impact before operationalizing any changes. This will ensure the scientific method is used to improve medical research and protect from negative outcomes that disrupt speed and efficiency.

Please consider CCTS a resource if you have any questions or would like any further information. Thank you for your time and for consideration of these comments.

Sincerely,
Coalition for Clinical and Translational Science
www.Coalition4CTS.org