American Society of Echocardiography

July 13, 2026

The Honorable Russell Vought, Director
Office of Management and Budget
Attn: Regulation for Federal Financial Assistance
Washington, DC 20503

Re: Comments on Proposed Revisions to 2 CFR Part 200 [OMB-2026-0034]

Dear Director Vought:

On behalf of the American Society of Echocardiography, this letter outlines concerns regarding the Office of Management and Budget's proposed revisions to 2 CFR part 200 governing Federal financial assistance. ASE is the largest global organization for cardiovascular ultrasound imaging serving more than 20,000 physicians, sonographers, nurses, veterinarians, and scientists and as such is the leader and advocate, setting practice standards and guidelines for the field. Since 1975, the Society has been committed to advancing cardiovascular ultrasound to improve lives.

The proposed changes outlined in the proposed rule would materially alter the research environment for federally funded cardiovascular imaging, including echocardiography, by changing how peer-reviewed awards are evaluated and by limiting investigators' ability to use grant funds to publish results arising from federally supported research. These policy choices would weaken core foundations of the research enterprise, rigorous scientific peer review, and broad dissemination of findings, rather than strengthening accountability or stewardship. The Society offers the following comments.

§200.205 - Federal Agency Review of Merit of Proposals

Echocardiography studies often require multicenter collaboration, specialized core laboratory infrastructure, longitudinal follow-up, and rapid dissemination of results to clinicians, investigators, and patients. Any framework that diminishes the central role of scientific peer review or introduces new barriers to publication will slow innovation, impede collaboration, and delay translation of advances into patient care. The proposed revision to §200.205 is especially concerning because it would add a pre-issuance review layer for discretionary awards by senior political appointees designated by the agency head, who are instructed to exercise independent judgment rather than defer to established merit review processes, and to ensure that awards align with the Administration's policy priorities.

The proposal does not clarify the criteria by which a senior appointee may overturn or modify a funding recommendation that has already been through scientific peer review, whether such decisions will be documented, or whether investigators will have access to the rationale behind them. Greater transparency on this process is needed before it is implemented.

In practice, this structure could allow non-scientific considerations to displace expert peer review and create substantial uncertainty for meritorious echocardiography grants, including NIH-funded studies, training awards, multicenter registries, outcomes research, and advanced imaging method development. NIH cardiovascular imaging grants, including R01, K, and T32 awards and multicenter U-award consortia, could receive a high priority score on scientific merit at study-section review yet still be held or denied at the appointee stage, introducing unpredictability that did not previously exist once peer review was complete. This could also undercut the purposeful efforts by DHHS to establish study sections focused specifically on medical imaging grants, which already tend to receive lower impact scores relative to higher-risk "new therapies" grants, meaning imaging research is disproportionately exposed to an additional layer of discretionary review.

This uncertainty is particularly problematic for large academic medical centers and imaging core laboratories that maintain sophisticated research infrastructure, which may be disadvantaged by the proposal's express deprioritization of institutional reputation and stated preference for institutions with lower indirect cost rates, a criterion applied at the merit-review stage rather than through any change to negotiated rates. This preference could have unintended consequences for research-intensive academic medical centers that maintain cardiac imaging core laboratories and multicenter imaging networks, including the clinician-scientist and engineering partnerships these centers rely on to sustain cardiovascular imaging research, all of which require sustained institutional investment that lower-indirect-cost institutions may not be positioned to provide.

§200.205 - 'Gold Standard Science' as an Award Criterion

The rule's reliance on "Gold Standard Science" as a gating criterion for awards compounds these concerns. The proposal never clearly defines "Gold Standard Science". It is framed in broad conceptual terms (reproducibility, transparency, clear communication of uncertainty, falsifiability, and peer review) that already reflect well-accepted norms of rigorous scientific practice and existing federal research policies, but these descriptors gesture at the concept without amounting to an operational definition. The proposal would nonetheless require agencies to embed "Gold Standard Science" benchmarks into all awards, prioritize institutions that have "demonstrated success" under this label, and explicitly deprioritize institutional reputation, all without providing clear, measurable criteria for how success will be assessed within specific programs. For echocardiography and other research communities, this creates uncertainty about how proposals and institutions will be evaluated and risks inconsistent application of a loosely defined standard across agencies and funding mechanisms. Rather than improving rigor, the framework would introduce an additional, subjective test that sits on top of established peer review.

Cardiovascular imaging research in particular depends on specialized peer review. Many echocardiography grants involve complex imaging methodology, quantitative analysis, artificial intelligence, engineering collaborations, and imaging core laboratories that require evaluation by experts in the field. Preserving the central role of expert scientific review is especially important for these proposals, and any process that allows non-expert reviewers to modify or override that assessment risks misjudging technically complex applications.

For echocardiography, added review requirements and ill-defined standards could delay or disrupt research on valvular heart disease, cardiomyopathy, myocarditis, cardiac amyloidosis, congenital heart disease, ischemic heart disease, and quantitative tissue characterization, even when applications have already been favorably evaluated through scientific peer review. They could also slow development of artificial intelligence tools, multicenter imaging registries, and standardized quantitative imaging

techniques, all of which depend on stable, predictable award decisions and continued confidence in the integrity of the review process. This added uncertainty could disproportionately affect multicenter imaging studies, career development awards, and training grants, all of which require long-term planning and sustained institutional support that unpredictable, post-review reversals would undermine.

§200.461 - Publication and Printing Costs

The proposed revision to §200.461 would further weaken the research ecosystem by fundamentally changing how publication costs are treated under federal awards.

- **Reversal of current policy:** Current rules generally allow publication costs for electronic and print media, including page charges, article processing charges, and open-access fees, when they are reasonable and allocable to a grant. The current regulation is in fact explicit on this point, naming article processing charges and open-access fees as allowable costs of publishing federally funded, peer-reviewed work. The proposal would reverse this longstanding approach by making these costs unallowable unless specifically authorized on a case-by-case basis or where required by federal statute, creating a new barrier to dissemination of federally funded research.
- **Loss of the primary open-access funding mechanism:** The reversal is especially significant for open-access publishing, because article processing charges and open-access fees are the mechanism by which authors pay so that readers do not have to. Removing them as a routine allowable cost does not merely raise a budgeting hurdle; it strips out the primary funding mechanism that investigators have used to make federally funded results freely available, pushing more work back behind subscription paywalls at the moment public funding makes open dissemination most justified.
- **Direct contradiction within federal policy:** Existing open-access requirements, including the OSTP public-access policy and the public-access mandates at agencies such as NIH and NSF, remain fully in place and require grantees to make the results of federally funded research publicly accessible. The proposed rule would simultaneously forbid the routine use of grant funds to pay for that access. Researchers would be required to publish in publicly accessible forms while being denied the established means of covering the cost, an inconsistency the rule does not resolve and that warrants OMB's express attention.
- **Impact on cardiovascular imaging research:** This change would significantly impede publication of original investigations, technical standards, consensus statements, and multicenter trial results that translate federally supported science into clinical practice. Journals and professional societies rely on predictable publication pathways to share advances and evidence-based recommendations.
- **Disproportionate effect on under-resourced investigators:** If grant funds can no longer routinely support publication expenses, early-career investigators, smaller institutions, and under-resourced programs will be disproportionately affected, and important findings may become less accessible or substantially delayed.
- **Broader instability beyond individual grants:** Removing publication costs as a routine allowable expense would destabilize the predictable funding pathways that cardiovascular imaging research depends on, regardless of a given journal's business model. Authors would face new uncertainty about whether and how publication can be funded, agencies and recipients would have to negotiate publication costs into awards case by case, and the resulting friction would fall hardest on investigators and institutions with the least capacity to absorb it.

- **Erosion of access for clinicians and patients:** A decline in open-access publication would also make it harder for clinicians, trainees, patients, and researchers at institutions with limited library resources to access new data, technical guidance, and practice-relevant evidence generated with public funds. That access is precisely what open-access publishing and federal public-access mandates were designed to guarantee, and removing open-access fees as an allowable cost would erode it at the very point where public investment in the underlying research is most crucial.

In combination, the proposed changes to award review and publication costs would shift longstanding federal research policy away from scientific merit and broad dissemination and toward a more constrained, less transparent system.

Additional Considerations

Other provisions in the proposed rule carry similar consequences specifically for echocardiography. The expanded discretionary termination and suspension authority in §200.340 and §200.341 could halt multi-year longitudinal studies mid-stream based on only a brief written rationale, with no hearing right attached to that decision, and there is similarly little clarity about why a termination decision was reached. Landmark cardiovascular imaging studies, including pragmatic echocardiography-based implementation trials such as NOTIFY-LVF and multicenter CMR studies evaluating disease progression and therapeutic response such as VANISH, required years of stable federal support to sustain imaging core laboratories, standardized acquisition protocols, longitudinal follow-up, and coordinated data management. These completed studies demonstrate that high-impact imaging research depends on predictable, uninterrupted federal award administration throughout the life of a project. Had the proposed termination authority been in effect, studies of this kind could have been cut short at any point, forfeiting years of federal investment and the patient-level imaging data that investment produced.

The prohibition on covered foreign collaborations in §200.220 could also bar international multicenter consortia, shared imaging databases, and guideline-development collaborations with covered foreign institutions, a restriction that reaches even coordinator travel to such sites. As an example, many advances in echocardiography, including shear-wave elastography of the heart, super-resolution microangiography, sonothrombolysis, and carotid plaque content imaging, have originated at non-US research centers, and this restriction would limit access to these technologies and to the collaborations that produce them.

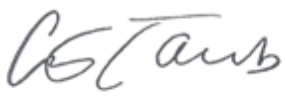
Conclusion

For these reasons, we respectfully urge OMB to withdraw the proposed rule. Should OMB decline to withdraw the rule, the following revisions should, at a minimum, be made. §200.205 should be modified to preserve scientific peer review as the primary basis for research funding decisions and to ensure that any additional administrative or pre-issuance review cannot displace expert assessment of scientific merit absent a clear, written, and narrowly defined justification grounded in law or program requirements. The "Gold Standard Science" construct should be anchored to existing, well-defined federal research integrity and rigor standards or replaced with discipline-neutral, operational criteria that can be applied consistently across programs without creating a new, subjective test layered on top of established peer review. §200.461 should be revised to retain publication costs, including page charges, article processing charges, and open-access fees, as allowable expenses for peer-reviewed articles and other scholarly products arising from federally funded research. Preserving open-access fees as an allowable cost is especially important, because the proposed rule would otherwise defund

the primary mechanism researchers use to satisfy the federal public-access mandates that remain in force at OSTP, NIH, and NSF. OMB should resolve that contradiction by keeping these costs allowable rather than requiring researchers to publish in publicly accessible form while denying them the established means of paying for it.

Echocardiography plays a vital role in the diagnosis, risk stratification, and management of patients with heart disease. Federal investment in this field should continue to be guided by scientific merit and supported by policies that promote, rather than hinder, timely dissemination of research findings. The proposed rule, as drafted, would move federal research policy in the wrong direction. We respectfully urge OMB to withdraw the proposed rule. If the rule is not withdrawn, OMB should, at a minimum, revise it to protect the integrity of peer review, maintain practical support for publication of federally funded cardiovascular imaging research, and avoid introducing new, loosely defined standards that are difficult to implement consistently over time.

Sincerely,



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