



13 July 2026

Office of Management and Budget
725 13th St, NW
Washington, D.C. 20503

Re: OMB-2026-0034, Regulation for Federal Financial Assistance

The International Society for Stem Cell Research (ISSCR) provides these comments for docket OMB-2026-0034 and the associated proposed rule, Regulation for Federal Financial Assistance. The ISSCR is the leading international organization for stem cell science, representing approximately 5,000 stem cell researchers around the world, including over 1,400 members in the United States. The scientists, clinicians, ethicists, and developers of cell therapies who comprise our membership have leveraged research grants from the U.S. federal government to advance basic stem cell science and to develop medical breakthroughs that have improved patient care and human health. These comments are informed by their scientific expertise, their experience as recipients of federal awards for biomedical research, and the outcomes of the international collaborations that have been supported by these grants.

The proposed rule would not achieve the administration's stated objective of increasing transparency and decreasing burdens on recipients of federal awards. Instead, it would make federal grantmaking more opaque and less predictable by introducing political review standards, expanding discretionary review and termination authority, and restricting standard, integral scientific activities and international collaboration. Enactment of this rule would have a destabilizing effect on federally supported biomedical research. The increased burdens on awardees and agencies and the elevation of political judgment and priorities over scientific merit are counterproductive to the Office of Management and Budget's stated aims and would undermine decades of progress in stem cell science and regenerative medicine. **Given these harmful impacts, the ISSCR respectfully urges OMB to withdraw the proposed rule.**

1. The proposed rule reduces transparency in grantmaking.

If finalized, the proposed rule would increase opacity in all phases of federal grantmaking, making it less clear what scientific questions, methods, materials, researchers, research institutions, and collaborations can be reliably funded. While transparency should be a central component of how federal research dollars are awarded and used, the below provisions are more likely to reduce transparency in grantmaking.

[§ 200.202] – Requiring research grant programs to be “aligned with administration policies and priorities” is a significant shift away from the longstanding U.S. policy of merit-based scientific grantmaking. Researchers rely on stable, transparent, and scientifically driven agency planning to identify important research priorities and build long-term, sustainable research programs. By tying grant program planning more closely to political objectives, the proposed rule makes it less clear what research questions and methods may be eligible for federal support over both the near and long term. Because political priorities can change far more quickly than the timelines required for rigorous research, this shift would create uncertainty and undermine the stability needed for successful scientific programs.



[§ 200.205] – The proposed requirement of pre-issuance review would weaken merit-based grantmaking by adding an opaque political review process following successful scientific evaluation. Under the proposed rule, an application deemed scientifically meritorious could be denied for not being sufficiently aligned with current administration priorities, even where the research is consistent with the agency’s statutory mission. Without clear and consistently applied standards, applicants may not understand why an award was denied or whether similar research will be ineligible for federal support.

This confusion is compounded by numerous references in the rule to an undefined “Gold Standard Science.” This term is also undefined in the referenced executive order, E.O. 14303, “Restoring Gold Standard Science.” While pursuing merit-based, rigorous science grounded in evidence should be the basis for awarding federal dollars for research, it is not clear what standards are set by this term in the proposed rule. Without a clear definition, and when combined with political review of grants, the proposed rule establishes a grantmaking framework in which funding becomes a subjective political tool for any administration.

[§§ 200.340-342] – The proposed inclusion of termination for convenience clauses in scientifically meritorious research grants would undermine the transparency, reliability, and predictability of federal funding during an ongoing research project. Unlike termination for noncompliance, misappropriation of funds, or inadequate performance, termination for convenience may permit an agency to end an award even when the recipient is meeting the grant’s scientific and administrative requirements. Without clearly defined standards, researchers and the public may be unable to determine why their grant is terminated and whether similar projects remain eligible for support. This opacity would make it more difficult for investigators and institutions to plan future research programs and make informed decisions about personnel and infrastructure.

2. The proposed rule increases administrative burdens for grant recipients and the government

Contrary to the administration's goal of reducing burdens on grant recipients, the numerous provisions in the rule are very likely to increase burdens not only on awardees, but also on government agencies.

[§ 200.202] – For National Institutes of Health (NIH) grants, recent increased use of multi-year grant funding has been one factor leading to lowered NIH institute and center paylines. A funding scheme where multi-year funding is prioritized, encouraged, or is the default will decrease the success rate of any “shot on goal” and means any given applicant must submit more applications, on average, to receive the same expected amount of grant funding as compared to NIH’s traditional approach to grantmaking. This means every applicant must spend more time preparing and submitting additional grant applications, and agencies must handle and manage more applications for any given Notice of Funding Opportunity.

[§ 200.205] – Requiring all applicants to spend sufficient time understanding what research proposals will be deemed politically acceptable and “demonstrably” in alignment with an administration’s priorities is an additional burden that will cost time and money. Under the long-standing merit-based review system, researchers need only be concerned about designing scientifically meritorious proposals; but under the proposed changes,



researchers will have to spend additional limited resources analyzing, assessing, and planning around an administration's political priorities. Changes in political priorities, whether within or between administrations, could also require recipients to revise research plans during an ongoing grant cycle.

Agencies, too, will need to devote considerable time and resources to communicating shifting scientific priorities to award audiences, managing pre-issuance review, and triaging grants that require amendments to align with political imperatives. There are also opportunity costs in the form of lost alternate uses of those limited resources that would otherwise be used to drive research programs forward (coordination, planning, communication, etc.).

[§§ 200.340-342] – The proposed rule would significantly expand agency authority to suspend and terminate awards based on subjective shifts in agency priorities and whether awarded grants further the national interest. To account for this authority, researchers would need to develop contingency plans in the event of a suspension or termination before the scheduled completion of a project, increasing administrative burden and making long-term research planning more difficult.

[§ 200.432], [§ 200.454], [§ 200.461] – The costs addressed in these provisions (including conference travel, scientific society memberships, subscriptions, and publication costs) are standard research expenses that enable scientific exchange and the successful completion of research projects, while maximizing the dissemination and impact of federally funded research. Requiring pre-approval for these costs would impose additional administrative burden on grant recipients by requiring additional documentation, submission, and approval steps. Further, government agencies would also experience this increased burden due to the need to review and sign off on an extensive number of pre-approval requests.

3. The proposed rule would undermine stem cell research and regenerative medicine

Beyond its general effects on transparency and administrative burden, the proposed rule would specifically harm stem cell research and regenerative medicine.

[§ 200.202] – By mandating a domestic-first framework, the proposed rule undermines international collaborations necessary to drive progress in stem cell research and its clinical application. NIH funding has supported international collaborations led by American scientists that conduct clinical trials, establish safety and efficacy for cell therapies, generate manufacturing protocols and standards, and avoid unnecessary duplication of research. Rather than strengthening federally supported research, a domestic-first framework would limit access to the international collaborations, expertise, and patient populations that are needed to support rigorous and reproducible stem cell science.

Expanded use of multi-year funding would narrow the breadth of stem cell research across basic discoveries, preclinical studies, and clinical translation. By committing a larger share of appropriations to a smaller number of awards, a multi-year funding approach is likely to reduce the number of distinct research projects and scientific questions that can receive support each year. This concentration would be particularly consequential in stem cell science where progress relies on parallel investigation across diverse cell types, disease



models, manufacturing approaches, and translational strategies. Fewer awarded grants would also reduce the number of labs able to train graduate students, postdocs, and early-career investigators. This pipeline is essential not only for cultivating the next generation of academic scientists, but also for developing specialized expertise required by pharmaceutical and biotech companies. Over time, narrowed opportunities for junior investigators will weaken the talent pipeline needed to sustain the continued growth of the regenerative medicine sector.

[§ 200.205] – Pre-issuance review would be especially harmful for scientifically meritorious research areas that are subject to strong partisan disagreement. Studies in these areas are typically already governed by statutes, agency policies, institutional oversight, informed consent requirements, and field-specific standards. By adding a political review process after scientific evaluation, the proposed rule allows lawful and rigorously reviewed research to be delayed or denied. This would chill lawful areas of research, contribute to further investigator uncertainty, and could ultimately result in important scientific work moving to countries with more stable funding systems.

[§ 200.220] – Certain clinical trials for stem cell therapies require large, multinational collaborations to ensure sufficient patient populations can be recruited and to ensure the necessary, highly specialized expertise can be leveraged during the trial. By placing broad restrictions on international collaborations, the proposed rule undermines the development of cell therapies.

[§ 200.432], [§ 200.454], [§ 200.461] – Professional societies, including the ISSCR, establish research and clinical-translation standards and guidelines, disseminate emerging methods and results, provide continuing education, and facilitate collaborations needed to advance stem cell research. These activities, and their associated costs, enable the successful completion of federal awards and enhance the impact of federally supported research in stem cell research.

4. The proposed rule hinders federally funded scientists and scientific collaboration

The proposed rule would limit American scientists' ability to do the best science by limiting international engagement and creating roadblocks to participation in essential practices central to the successful completion of federally funded research projects.

[§ 200.202], [§200.220] – A domestic-first framework would prevent American investigators from fully using specialized expertise, infrastructure, patient populations, and discoveries located outside of the U.S. Section 200.220 affords substantial discretion over which countries may become subject to restrictions. This funding framework could dissuade scientists from initiating collaborations with international scientists due to concerns (real or perceived) that a collaborator's home country could later be restricted for reasons unrelated to scientific research.

[§ 200.205] – Pre-issuance review is likely to disincentivize the exploratory basic research that drives transformational advances in biomedical science. Groundbreaking discoveries often arise when investigators pursue unexpected observations, test unconventional hypotheses, or develop new methodologies that are unlikely to be captured by politically driven policy assumptions and demands. Many foundational discoveries in stem cell science



are the result of curiosity-driven research. The discovery of induced pluripotent stem cells (iPSCs), a platform for the development of advanced therapeutics, is the result of decades of research on basic developmental biology and transcription factors that did not begin with consideration of clinical applications. And further research on iPSCs led to the creation of next-generation human-relevant models of disease-like organoids and assembloids. It is difficult to see how a short-term, politically directed research program could foresee these eventual applications of the original research ideas. By making federal funding more dependent on alignment with political priorities, the proposed rule would discourage precisely the type of investigator-led frontier research that can suddenly transform fields, deliver new therapies, and create new industries.

[§§ 200.340-342] – The possibility of midstream grant cancellations would disincentivize researchers and institutions from pursuing long-term research objectives that require sustained and significant investments in both human capital and research infrastructure. By doing so, these clauses would limit innovation and slow the progress of scientific fields that require long-term, reliable funding streams.

[§ 200.432], [§ 200.454], [§ 200.461] – Restricting conference attendance, publication costs, professional society membership, and subscriptions to academic journals would limit American researchers' participation in the scientific community and their access to emerging methods, results, standards, and collaborative partnerships. These restrictions would impede rigorous and reproducible research, weaken professional development and retention of the U.S. scientific workforce, and reduce the impact of federally supported science.

Conclusion

The proposed rule would weaken the stable, merit-based funding apparatus that has enabled major advances in stem cell science and regenerative medicine. Narrowing the range of research that can receive support, adding a layer of vaguely defined, fluid political review to the grantmaking process, and imposing barriers to international scientific exchange would slow progress in biomedical research and ultimately delay the delivery of new therapies to patients. **Given these harmful impacts, the ISSCR respectfully urges OMB to withdraw the proposed rule.**

For information or clarifications on our comments, please contact ISSCR Director of Policy Tyler Lamb, JD (tlamb@isscr.org) or ISSCR Manager of Policy Andrew Bremer, PhD (abremer@isscr.org).

Respectfully,

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