ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Docket Number: OMB-2026-0034

Dear Office of Management and Budget (OMB), Executive Office of the President:

ISPOR—The Professional Society for Health Economics and Outcomes Research - is pleased to respond on behalf of its membership to your consultation titled "**Proposed Rule on Regulation for Federal Financial Assistance" (RIN 0348-AA31).**

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. ISPOR membership includes nearly 18,000 individual and chapter members from more than 100 countries worldwide. The number of individual members in the US exceeds 2,500. Our membership is uniquely diverse and represents a variety of stakeholder perspectives, including research organizations, academia, payers, patient groups, government, healthcare professionals, health technology assessment bodies, and the life sciences industry. ISPOR also publishes peer-reviewed scientific journals, develops internationally recognized Good Practices Reports, and convenes scientific conferences to communicate healthcare evidence to decision makers worldwide.

The response to this consultation was led by the ISPOR Scientific Initiatives Team. Comments were solicited from ISPOR's Board of Directors and Health Science Policy Council. The attached document summarizes our comments on specific provisions of the rule.

ISPOR would be happy to answer any questions about our response, serve as a partner, or participate in any follow-up consultations on the relevant program items mentioned in the report. We recognize that the proposed rule aims to increase the efficiency and value of federally funded research and respectfully urge OMB to carefully consider the suggestions and potential implications we raise when developing its final version.

Sincerely,

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Comments

ISPOR's comments are primarily directed toward proposed revisions to §§200.204 (Notices of Funding Opportunities), 200.205 (Federal Agency Merit Review of Proposals), 200.206 (Federal Agency Review of Risk Posed by Applicants), 200.218 (Prohibition on Using Federal Awards to Promote or Support Theories of Disparate-Impact Liability), 200.340 (Termination), 200.432 (Conferences), 200.454 (Memberships, Subscriptions, and Professional Activity Costs), and 200.461 (Publication and Printing Costs), because these provisions have the greatest potential implications for healthcare evidence generation, scientific dissemination, American competitiveness in biomedical innovation, and patient outcomes. ISPOR's comments emphasize the unique role of health economics and outcomes research in generating evidence that matters to patients, the importance of disseminating evidence to the American public, and the consequences of either terminating or curtailing federally funded research activities.

§200.204 - Notices of Funding Opportunities

Healthcare Evidence Is a Critical National Asset

Healthcare evidence should be viewed as a strategic national asset. Just as physical infrastructure supports economic activity, evidence infrastructure supports healthcare innovation, patient outcomes, efficient resource allocation, and informs public policy. Federal investments in health economics, outcomes research, comparative effectiveness research, and real-world evidence generate value far beyond individual grants. They create the evidence base that guides treatment decisions, informs healthcare spending, supports innovation, and helps ensure that public and private healthcare resources are used efficiently. Moreover, NIH funding and research are correlated with: 1) continuing declines in the prevalence of chronic disability and increases in active life expectancy and; 2) health changes that stimulate economic growth via improvements in labor force participation.[1-3]

A predictable and transparent evidence-generation environment is also important to US biopharmaceutical innovation and competitiveness. Innovator companies, emerging biotechnology firms, diagnostics developers, digital health companies, and the research entities that support them rely on federally funded methods, infrastructure, data resources, and scientific talent. There is evidence of positive returns to public investment in biomedical research in terms of patent developments, changes to medical practice, and health behaviors.[4] By one estimate, there is "1 private-sector patent generated for every 2 to 3 NIH-funded grants".[4]

American patients, including those with rare diseases, chronic conditions, disabilities, or complex treatment needs, also have a direct stake in how funding opportunities are structured. Patients benefit when federal research funding supports broad evidence generation that informs not only their treatment choices but also their access to treatments and shared decision making with their providers.

ISPOR encourages OMB to ensure that notices of funding opportunities preserve support for methodological

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innovation, investigator-initiated science, and research that improves the understanding of clinical outcomes, patient-centered outcomes, healthcare utilization, affordability, and value.

The Unique Role of Health Economics, Outcomes Research, and Real-World Evidence

Traditional biomedical research often focuses on whether a treatment works in an experimental (e.g., randomized controlled trial) setting. Health economics, outcomes research, and real-world evidence address equally important questions:

- How well do healthcare interventions (e.g., treatments, devices, programs) perform in real-world settings?
- How does the intervention compare with available alternatives?
- What outcomes matter most to American patients?
- What is the economic burden of illness to American patients?
- What is the economic impact of healthcare interventions?
- Do healthcare interventions provide value that is commensurate with their cost?
- How can limited healthcare resources be used most efficiently?

As healthcare innovations become increasingly complex and expensive, including precision medicines, cell and gene therapies, specialty pharmaceuticals, advanced diagnostics, and digital health technologies, the need for rigorous outcomes research and real-world evidence continues to grow. Health economics and outcomes research is one of the few scientific disciplines specifically designed to help healthcare systems achieve biomedical innovation while maintaining healthcare affordability. ISPOR encourages OMB to ensure that notices of funding opportunities preserve support for investigator-initiated science, and research that improves the understanding of patient-centered outcomes, healthcare utilization, and affordability.

§200.205 - Federal Agency Merit Review of Proposals

Scientific Merit and Evidence Expertise Should Remain Central

ISPOR recognizes the Administration's authority to establish policy priorities and oversee federal resources. ISPOR also recognizes the continuing scientific discourse regarding the benefits and challenges with peer review processes.[5,6] At the same time, peer review remains the strongest tool to evaluate the rigor, relevance, and innovation of grant proposals. Peer review can be structured in a way that recognizes diversity of viewpoints while maintaining essential scientific rigor. OMB must ensure that funding for biomedical research is informed by individuals who possess – or have direct access to – expertise in the research domains about which they are making decisions. Having this type of expertise is essential to maintaining trust in government while ensuring that public funds are invested in research that will address key gaps in healthcare while advancing innovation competitiveness. With respect to health economics and outcomes research, ISPOR has access to a deep bench of scientists working in the public and private sectors who can contribute their expertise to this process. We welcome a conversation with OMB about this.

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§200.206 - Federal Agency Review of Risk Posed by Applicants

Preserving Multi-Stakeholder Evidence-Generation Partnerships

Risk assessment criteria should be objective, transparent, and consistently applied within a decision context that recognizes that unintended disclosures, cybersecurity failures, and unethical conduct can occur in the conduct of research and dissemination activities. Many important healthcare research initiatives involve collaboration among academic institutions, healthcare systems, patient organizations, innovator companies, contract research organizations, data partners, payers, and professional societies.

OMB should ensure that risk assessment criteria do not discourage collaborative evidence-generation partnerships. These partnerships are increasingly necessary to generate real-world evidence, conduct longitudinal outcomes research, evaluate patient-centered outcomes, and understand the affordability and value of healthcare interventions. ISPOR's multilayered engagement model supports strategic, cross-sector leadership input while providing mission-centered and ongoing collaborative opportunities. We encourage OMB to consider ISPOR's approach and other similar models to ensure that federal requirements preserve the flexibility that is needed to ensure collaboration and partnerships that drive innovation.

§200.218 - Prohibition on Using Federal Awards to Promote or Support Theories of Disparate-Impact Liability

Scientifically Relevant Patient Populations and Generalizable Evidence

As a scientific society, ISPOR strongly supports the inclusion of broad and clinically relevant patient populations in healthcare evidence generation. Policies intended to address administrative requirements should preserve the ability of researchers to design and conduct studies that include patient populations that are appropriate to assess health outcomes, costs, access, utilization, patient preferences, quality of life, and value.

§200.340 - Termination

Protecting Longitudinal Research, Patient Follow-Up, and Taxpayer Investment

Longitudinal outcomes research, registries, observational studies, implementation studies, and real-world evidence programs often require years of patient follow-up. Premature termination will reduce the return on prior taxpayer investments and diminish opportunities for dissemination of findings through scientific conferences and peer-reviewed publications.

Termination of ongoing research will have direct consequences for American patients. These patients and caregivers have contributed their time and data to studies that are designed to answer questions relevant to treatment choices, safety, quality of life, access, and affordability. If such studies are terminated suddenly or before findings are generated or disseminated, patients will lose the opportunity to benefit from the knowledge their participation helped create, which will erode trust in research and the American system.

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ISPOR recommends that termination authorities consider impacts on ongoing patient follow-up, preservation of research datasets, planned dissemination activities, and the diminished taxpayer return on investment. At a minimum, agencies should provide written justification, reasonable notice, and opportunities to preserve core data and dissemination activities before termination decisions are finalized.

§200.432 - Conferences

Dissemination though Conferences Is Not Optional - It Is a Duty to American Citizens

Conferences are essential infrastructure for dissemination of federally funded research. Dissemination of federally funded research through scientific conferences is a professional responsibility. Research creates value not when data are collected, but when knowledge is shared and disseminated, evaluated, debated, validated, replicated and ultimately translated into healthcare decisions. Conferences also provide a unique platform to pressure-test research findings before the completion of studies, and, by so doing, are essential to the transparency of science. The real-time discussions, debates, and dialogue at conferences are designed to "root out bias, identify alternative explanations for evidence, and ultimately advance knowledge"[7] and cannot be easily achieved through other methods. Importantly, "Open discussion and debate allow researchers to address potential weaknesses, explore alternative explanations, and refine their interpretations."[7] Moreover, as an organization with diverse stakeholders, ISPOR recognizes that conference participation also benefits patients, healthcare industry professionals, and many others who are interested in research that aligns with their needs.

Scientific conferences are not merely venues for professional communication; they are an essential mechanism for generating public value on taxpayer-funded research. In the scheme of a multi-year federal biomedical grant, conference costs typically represent a very small fraction of overall project costs. Restricting dissemination will inadvertently diminish both the scientific and societal return on federal research investments by limiting awareness, evaluation, replication, and application of research findings. ISPOR recommends that conference-related costs deemed by the study investigators to be necessary for the dissemination of federally funded research remain an allowable expense.

§200.454 - Memberships, Subscriptions, and Professional Activity Costs

Role of Professional Societies in Evidence Translation

Restrictions on professional activities, such as membership in professional societies, and subscriptions will negatively impact researchers as well as the other participants in these activities which include patients, healthcare innovator and investment companies, community organizations, and other stakeholders. ISPOR's membership engages in conferences, journals, and programs focused on translating evidence into actual healthcare decisions. ISPOR recommends removing restrictions on professional activities such as memberships and subscriptions that facilitate access to results from federally funded research.

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§200.461 - Publication and Printing Costs

Publication, Scientific Discourse, and Public Value

ISPOR supports the publication of research findings across the full spectrum of healthcare evidence, including findings that support or challenge prevailing assumptions. Actual or perceived barriers to publication (particularly in journals that offer open access to articles) will negatively impact the dissemination of scientific findings and the public's right to evaluate, interrogate, and utilize scientific findings. Peer-reviewed publications and open scientific exchange are essential mechanisms[7] through which federally funded research achieves public value and supports innovation. Scientific publication is not simply about sharing positive results but provides a public and permanent platform that allows findings to be scrutinized, replicated, synthesized, and used by patients, clinicians, payers, policymakers, innovators, and investors. The ability to communicate differing findings and interpretations is not a weakness of science. It is one of its greatest strengths. ISPOR recommends removing restrictions on publishing results from federally funded research, particularly when publications are in journals that offer unrestricted and free access to articles.

Conclusion

Federal research funding is essential to the broader healthcare system. Research generates evidence; evidence informs decisions made by multiple stakeholders; and professional societies such as ISPOR are the backbone through which evidence is disseminated, scrutinized, debated, and translated into improved healthcare decision making and outcomes.

ISPOR's participation spans the constellation of stakeholders in the healthcare evidence ecosystem. Thus, the Society is uniquely positioned to understand the downstream consequences of policies that affect research funding, evidence generation, and scientific dissemination.

While ISPOR strongly supports efforts to enhance accountability, transparency, and stewardship of federal financial assistance programs, we urge OMB to ensure that implementation preserves the scientific integrity, dissemination, and efficiency of the healthcare evidence ecosystem.

We appreciate the opportunity to provide these comments and would welcome continued dialogue with OMB to ensure that implementation of these proposals supports healthcare evidence generation, fosters innovation, improves affordability and patient outcomes, and strengthens American competitiveness.

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