



Comments of the National Breast Cancer Coalition on the Office of Management and Budget Proposed Regulation for Federal Financial Assistance (OMB 91 FR 32198)

Introduction

Founded in 1991, the National Breast Cancer Coalition (NBCC) is a collaboration of advocates, survivors, researchers, policymakers, grassroots organizations, and other stakeholders united by one mission—to end breast cancer.

For more than 35 years, NBCC has worked to transform biomedical research by advancing three complementary principles:

- scientific independence,
- meaningful patient participation, and
- public accountability.

These principles are not in conflict. They strengthen one another and together create a research enterprise that produces better science, better public policy, and ultimately better outcomes for patients.

The Office of Management and Budget's (OMB) proposed Rule for Regulation for Financial Assistance (OMB 91 FR 32198) states that the purpose of the proposed Rule is to improve transparency, accountability, and oversight of federal financial assistance. NBCC supports those goals. However, several provisions of the proposed Rule risk weakening scientific independence while at the same time offering less-effective mechanisms for achieving public accountability than those already demonstrated to work.

Issue One: Meaningful Patient Participation Strengthens Research Planning

[§ 200.202] Program Planning and Design

NBCC supports the proposed language in § 200.202(b) encouraging Federal agencies to develop programs "in consultation with communities benefiting from or impacted by the program."

However, once those priorities have been established through this collaborative planning process and reflected in a Notice of Funding Opportunity, applications should be evaluated according to the published criteria through independent scientific peer review. Stakeholder engagement and scientific independence are complementary principles. Public consultation strengthens program design, while independent peer review ensures that the strongest scientific proposals are selected to achieve those publicly established goals.

Accordingly, NBCC encourages OMB to preserve and strengthen the consultation provisions in § 200.202(b), while ensuring that subsequent funding decisions remain grounded in independent scientific review rather than political discretion.

Meaningful engagement with patients, advocates, researchers, and other stakeholders is essential to designing research programs that address important public health needs and reflect the experiences of the communities they are intended to serve.

For more than 35 years, NBCC has advocated for exactly this type of meaningful stakeholder engagement. Through Project LEAD® and other education and training programs, NBCC has demonstrated that well-trained patient advocates can make important contributions to identifying research priorities, informing study design, improving clinical trials, and ensuring that research addresses outcomes that matter to patients.

We also agree that agencies should consider available evidence and lessons learned from prior programs when designing new funding opportunities. Research priorities should be informed by scientific evidence, patient experience, and transparent public engagement.

Issue Two: Independent Scientific Peer Review Must Guide Funding Decisions.

Scientific independence is not intended to insulate researchers from accountability. Rather, it ensures that scientific questions are evaluated according to evidence, scientific merit, and established review processes rather than changing political priorities.

[§ 200.204–200.206] Selection of Recipients

Independent peer review remains the strongest mechanism available for evaluating scientific rigor, innovation, feasibility, and potential impact.

No review system is perfect. Nevertheless, decades of experience demonstrate that independent scientific review consistently identifies research most likely to advance knowledge and improve public health.

The proposed rule would diminish the role of independent scientific peer review in funding decisions by requiring an additional review by senior political appointees and expressly discouraging deference to scientific recommendations. While federal agencies have always been responsible for establishing research priorities and making final funding decisions, this proposal would substantially expand political discretion after scientific review has been completed.

As a result, funding decisions would be at greater risk of reflecting changing political priorities rather than scientific merit evaluated against published criteria. This weakens the predictability, objectivity, and independence that are essential to maintaining public confidence in federally funded biomedical research.

Federal agencies appropriately establish broad research priorities through transparent program planning. Once those priorities have been established and communicated through a Notice of Funding Opportunity, independent scientific peer review should determine which applications best satisfy those priorities using clearly defined scientific criteria. Maintaining this distinction protects both democratic accountability and scientific integrity.

[§ 200.340] Award Termination

Allowing active awards to be terminated because governmental priorities change introduces instability into the research enterprise, discourages innovative science and will ultimately, reduce confidence in federally funded research.

Scientific discovery often requires years of sustained work.

Government priorities should appropriately shape future funding opportunities but they should not, except under extraordinary conditions, retroactively alter scientific judgments previously made through independent review.

Issue Three: Public Accountability Is Strengthened by Patient Participation.

NBCC agrees that federally funded research should remain accountable to the public. However, accountability should come through transparency and meaningful public participation rather than political involvement in scientific review.

For more than three decades, NBCC has helped demonstrate that trained patient advocates strengthen scientific decision-making. NBCC-trained advocates have participated on peer review panels, advisory committees, clinical trial steering committees, and research planning efforts across the federal research enterprise. These advocates ensure that funded research addresses questions meaningful to patients while preserving scientific rigor.

This model demonstrates that scientific excellence and democratic accountability are complementary objectives and not competing ones.

Government has an important—but distinct—role.

NBCC fully recognizes the important role of elected officials and federal agencies in establishing research priorities. Those priorities should be established transparently during program planning.

[§ 200.202]

Federal agencies with broad public and patient input should determine:

- what problems deserve attention;
- what types of research (e.g., basic, applied, experimental, other) should be encouraged;
- what outcomes programs seek to achieve.

Once those priorities have been established and communicated through funding announcements, applications should be evaluated through independent review using clearly stated criteria.

Maintaining this distinction protects both democratic accountability and scientific integrity.

Issue Four: Scientific Progress Depends on Openness and Collaboration.

Patients depend on a scientific enterprise that is open, collaborative, and free to pursue discovery wherever the evidence leads. Policies that unnecessarily restrict scientific exchange and collaboration ultimately slow the development of the prevention strategies, diagnostics, and treatments that patients are waiting for.

[§ 200.432], [§ 200.454], [§ 200.461]

Scientific progress depends on the open exchange of ideas through conferences, professional societies, scientific publications, and responsible collaboration across institutions and nations. These activities are not ancillary to research; they are fundamental mechanisms through which scientific findings are scrutinized, replicated, refined, and ultimately translated into better outcomes for patients.

Policies that unnecessarily discourage these activities risk slowing scientific progress while reducing transparency.

[§ 200.220]

Biomedical research increasingly depends upon responsible collaboration across institutions and nations. Appropriate safeguards protecting national security are important.

However, restrictions should be carefully tailored, so they address genuine security risks without unnecessarily limiting scientific collaboration that benefits patients worldwide.

Conclusion

Patients deserve a research enterprise that is scientifically rigorous, transparent, accountable, and independent. These goals are mutually reinforcing. For more than three decades, NBCC has demonstrated that meaningful patient participation strengthens—not weakens—scientific decision-making.

OMB should revise the proposed Rule to preserve independent scientific review, strengthen transparency, expand essential patient participation, and maintain appropriate distinctions between the roles of policymakers, scientific experts, and the public.

Only by protecting scientific independence while increasing meaningful public engagement can federal research continue to earn the confidence of patients, taxpayers, and the American public.