EBRC Engineering Biology Research Consortium

Public Comment for The Office of Management and Budget (OMB)'s "Regulation for Federal Financial Assistance"

The Engineering Biology Research Consortium (EBRC) appreciates the opportunity to provide comment on proposed changes to regulation for federal financial assistance. EBRC is a nonprofit, public-private partnership that brings together scientists, engineers, and industry leaders to advance the field of engineering biology to address national and global needs. EBRC's members include experts from over 100 universities and research institutes (including trainees), leaders from more than 30 companies, and government representatives across the United States and the world. Working closely with partners across the engineering biology ecosystem, EBRC focuses on four key areas: Research Roadmapping, Policy & International Engagement, Education, and Security.

Engineering biology is a rapidly evolving field with applications across medicine, agriculture, energy, manufacturing, and the environment, with the U.S. bioeconomy projected to surpass $30 trillion by 2040. The National Security Commission on Emerging Biotechnology (NSCEB) 2025 Report, *Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity*, and the National Defense Authorization Act For Fiscal Year 2027 (FY27 NDAA) identify engineering biology as a priority for sustained federal investment, with recommendations spanning research infrastructure, workforce, and international engagement to ensure U.S. national security and economic competitiveness. Several of the proposed changes by OMB may negatively impact these priorities. Below we provide comment on the proposed rule for the Regulation for Federal Financial Assistance and urge OMB to consider the long-term implications of these changes.

[2 CFR 200.205; 200.340] Grant Review and Expanded Authority for Termination of Federal Award
Summary of proposed change

- Federal agencies must designate senior appointees to review proposals to ensure they align with federal law and "advance the President's policy priorities."
- Agencies can suspend or terminate active grants "based on discretion of Federal agency" without having to provide a "copy of the terms and conditions to the recipient."

The proposed rule would introduce non-scientific considerations into the merit review process and expand termination authority without clearly defined criteria or notice requirements. The proposed rule's presidential priorities requirement is irreconcilable with Congressional mandates for merit review of scientific proposals. There is no clear definition of presidential priorities, no guidance on how reviewers should weigh presidential priorities with merit review, and no instruction for how to assess presidential priorities over time. Without clear guardrails, agencies may rely on broad keyword- or topic-based screening rather than expert scientific review, potentially creating uncertainty about how research proposals will be evaluated. These changes will significantly weaken the efficiency, rigor, stability, and predictability of the U.S. research enterprise that have made the U.S. the global leader in biotechnology innovation.

As a field of study, engineering biology requires sustained investment to translate discoveries into real-world applications. Innovations in biotechnology that advance healthcare, food security, and defense often take years, and sometimes even decades, of basic research, testing, and scale-up before deployment. Introducing additional review criteria tied to presidential priorities risks uncertainty for researchers, institutions, and industry partners who make long-term investments in engineering biology. For example, the foundational technologies underlying modern gene editing, including clustered regularly interspaced short palindromic repeats (CRISPR) systems, were developed from decades of federally-supported research. A political appointee without deep technical knowledge required to assess the research and potential for applications across medicine, agriculture, manufacturing, and more might have missed the significance of CRISPR, despite its enormous potential value.

Similarly, the prospect of termination without cause–as the Rule proposes–introduces uncertainty that would disrupt the bedrock stability of federally funded research projects. Expanded authority to terminate active awards without clearly defined criteria could contribute to wasting scientific funding already invested in a project. Following an award, startup costs are incurred to hire and train students and postdocs, purchase equipment and materials, validate reliable and reproducible research protocols, generate data, and establish collaborations across institutions and sectors. Early termination wastes these resources.

The next generation of engineering biology researchers would additionally be negatively impacted. Engineering biology requires highly specialized expertise and studies that take years to develop; students, postdoctoral scholars, and early-career investigators make long-term decisions about which fields to enter, where to train, and whether to pursue research careers based on, in part, the stability and reliability of federal investment. If researchers think funding decisions or active awards could be terminated because of shifting political priorities, they may pursue other opportunities. The proposed rule would risk the loss of fresh talent and creative minds to other disciplines and industries outside of engineering biology, or even other countries, resulting in an attrition of U.S. research and innovation talent. The NSCEB identified the importance of out-competing international competitors to maintain U.S. leadership in biotechnology, which depends on both breakthroughs in discoveries and attracting and retaining top-tier talent to drive those discoveries.

The impact goes beyond individual grants. Engineering biology is built upon a connected innovation ecosystem across universities, national laboratories, startups, established companies, investors, and government agencies. Research-industry partnerships are important for research and development, biomanufacturing scale-up, and robust talent pipelines to the workforce. Research institutions make investments in specialized facilities and programs and projects with the expectation that federal funds will be available for scientists to utilize them. Investors and industry partners evaluate investments based on risk and reward. Expanded termination without clear criteria or notice will increase perceived risk, making these stakeholders less willing to pursue long-term investments. Uncertainty around the stability and sustainability of federal awards would discourage these collaborative research efforts.

To protect the innovation bioecosystem that has historically enabled the U.S. to translate federally funded research to economic growth and strengthen national security, EBRC recommends that OMB:

- Remove the requirement that senior appointees review proposals for alignment with Presidential priorities, preserving Congressionally mandated merit review as the sole basis for funding decisions;
- Clearly define the criteria under which termination authority may occur, and require agencies to document and disclose reasons for termination; and
- Establish a mandatory notice period before termination of any active award, providing recipients with an opportunity to respond.

[2 CFR 200.218 / 200.300] Prohibition on Using Federal Awards to Promote Theories of Disparate-Impact Liability

Summary of Proposed Change

- To "establish a government-wide policy in 2 CFR regarding use of Federal financial assistance to promote or support theories that impose disparate-impact liability based on federally protected characteristics such as race, sex, or age."
    - "to reinforce the principle that merit-based opportunity… will govern the administration of federal awards."

EBRC urges OMB to revise the proposed prohibition on using federal awards to promote or support theories of disparate-impact liability. As currently drafted, the rule combines two distinct ideas: advancing theory of disparate-impact liability, and conducting outreach and education to broaden participation (in biotechnology).

Without further clarification, the proposed rule risks creating uncertainty around federally-funded workforce initiatives that are essential to maintaining leadership in engineering biology and the global bioeconomy.

Engineering biology is a rapidly growing field that requires a highly skilled workforce spanning research, biomanufacturing, entrepreneurship, education, and community engagement. In the 2025 report, the NSCEB underscored workforce development as a national priority. Maintaining U.S. leadership in biotechnology requires a workforce that draws from the diverse spread of highly skilled American talent. For example, women represent approximately 50% of the U.S. population, but remain significantly underrepresented in STEM fields, including engineering biology. The same is true across other factors, including geography, socioeconomic background, and educational status. Building the workforce requires identifying and recruiting talent wherever it exists. Federal awards used to promote participation among underrepresented groups in a field, via targeted outreach and education to specific groups and individuals, helps ensure meritorious Americans have the opportunity to participate in science and engineering, without imposing harm on those already well-represented. By engaging with communities, institutions, and populations that have historically had less participation in the bioeconomy, these programs expand the pool of potential talent, innovators, and researchers. If the final rule does not make this distinction clear – that conducting education and outreach to grow the talent pool is separate from promoting theories that impose disparate-impact liability – institutions may end or narrow such efforts out of caution, limiting available talent just as the demand for a specialized, highly-skilled workforce increases.

Additionally, without further clarification of language, this rule change may have unintended impact on certain avenues of innovation and scientific advancement supported by the current administration. For example, many applications in biotechnology and engineering biology, including diagnostics, medicines, and biomanufactured drugs and therapeutics, depend on research on diseases and conditions that affect men and women differently. Developing effective sex-based health solutions requires understanding how biological sex influences disease risk and response to treatment. For example, cardiovascular disease disproportionately affects men, while major depressive disorder is more common among women. These biological differences are a foundational component of biomedical science and require research on disparately impacted groups and individuals. For decades, federal agencies have recognized this importance through policies requiring sex to be considered as a biological variable. Without clarification, institutions may become hesitant to support sex-informed studies, slowing scientific progress towards improved health outcomes for both men and women. The goal of this work is not to impose liability, but to maintain the opportunity for using federal funds to advance research that addresses areas where disparities in health impacts are well documented.

EBRC urges the OMB to include explicit definitions and language in the final rule, clarifying that the prohibition does not apply to:

- Recruitment and retention programs that engage communities, institutions, and populations with limited participation and representation in scientific fields;
- Mentorship, fellowship, and career development programs that expand access to education and workforce pathways;
- Community engagement and science communication initiatives (e.g., workshops, webinars, science fairs) to raise awareness of engineering biology; and
- Federally-funded science and engineering research to address disparate impacts of harm due to biological characteristics such as sex.

[2 CFR 200.432; 200.454; 200.461] Memberships, Subscriptions, and Professional Activities
Summary of proposed change

- Conference, membership, and subscription costs must be "expressly approved by the agency and included in the terms and conditions of the award."
    - "Costs, including the costs of subscriptions or memberships in country clubs or organizations whose primary purpose is lobbying or issue advocacy, are unallowable."

- Dissemination of findings, including publication costs, page/figure charges, processing fees, and open access fees, are not allowed to be paid with federal funds, "unless such costs are expressly required by statute or approved in advance by the Federal agency on a case-by-case basis."

EBRC encourages revision of the proposed rule prohibiting the use of federal funds for conferences, memberships, subscriptions, and publications because these activities are essential components of the research infrastructure that supports engineering biology and biotechnology workforce development and innovation.

- [2 CFR 200.432] Attendance at major **conferences** and professional convenings is foundational for the advancement of engineering biology. Conferences hosted by organizations such as EBRC, the American Institute of Chemical Engineers, the American Society for Microbiology, and the Society for Industrial Microbiology and Biotechnology, provide opportunities for emerging and established researchers to present findings, receive peer feedback, share best practices, and develop new collaborations that accelerate the field. Funding from federal awards is necessary for many professionals to participate in these events; however, the burden of express approval by the agency and inclusion in the award terms and conditions are likely to prevent participation, reducing opportunities for workforce development and knowledge exchange that are critical to sustaining innovation.

- [2 CFR 200.454] **Memberships and subscriptions** connect researchers to the engineering biology community, providing access to relevant information, professional development opportunities, and networks necessary to stay connected and collaborative. Access to relevant information, including peer-reviewed literature and current technical standards, is critical to conducting rigorous research. Researchers require access to literature to conduct reviews, identify knowledge gaps, and build on prior discoveries around biotechnology, artificial intelligence, and quantum science. Many of the institutions and organizations that provide these resources, such as professional science and engineering societies, use their expertise and experience to engage in nonpartisan issue advocacy. Restricting funds for memberships and subscriptions would significantly slow scientific progress and restrict access to centuries of knowledge.

- [2 CFR 200.461] Disseminating research findings is fundamental to advancing research. Currently, there is not an alternative method to journal-based peer reviewed publication for consistently identifying rigorous science at scale. Alternative approaches including distributed and open peer review, post-publication review, and publish-review-curate models should be pursued and promoted by federal funding agencies. In the absence of an alternative, federal funding for publication should persist and be phased out as alternatives to for-profit publishing emerge. Currently, publication costs – including open-access publishing, page charges, article processing fees, and others – ensure that scientific discoveries are broadly available to the research community. Many federal agencies, including the National Institutes of Health and National Science Foundation, encourage or require immediate public access to federally funded research findings. Similarly, requiring advanced agency approval for using federal funds for publishing on a case-by-case basis would be enormously burdensome, particularly for federal funding agencies and smaller institutions and organizations, and could significantly slow the pace of sharing research discoveries and innovation. Restricting the use of award funds for publication expenses could directly conflict with existing federal open-access requirements, creating inconsistency in federal policy.

To preserve the necessary academic and research infrastructure, EBRC recommends that OMB:

- Continues to allow conference attendance, professional memberships, subscriptions, and publication costs as legitimate use of federal funds when they are directly related to the objectives of the funded research and are reasonable in scope; and
- Provide clear guidelines to inform evaluation of the anticipated travel, conference participation, and related professional activities based on their relevance to advancing research objectives, disseminating findings, and supporting workforce development.

[2 CFR 200.220] Prohibition on using federal funds for covered foreign collaborations
Summary of Proposed Change

- Prevents using federal funds "to support bilateral or multilateral collaborations, agreements, programs, or activities with covered foreign countries or covered foreign entities, unless expressly authorized by Federal statute."
- To restrict the use of appropriated funds for bilateral or multilateral activities with foreign adversaries and entities affiliated with foreign military or intelligence services.
    - "The prohibition would apply regardless of whether Federal funds are used for direct programmatic activities, research, technical assistance, travel, or indirect costs allocable to such collaborations."

EBRC supports efforts to promote U.S. national security and safeguard sensitive technologies. However, EBRC recommends that OMB revise the proposed rule to ensure that restrictions intended to address security risks do not unintentionally limit international engagement that advances discovery and innovation is essential for maintaining U.S. leadership in the global bioeconomy.

The U.S. has maintained its leadership in biotechnology by collaborating with the scientific community and serving as a central hub for scientific innovation and talent. The NSCEB recognized this in its 2025 report, Pillar 6; "Mobilize the Collective Strengths of Our Allies." The Commission emphasized that maintaining U.S. leadership requires strategic engagement with allies and partners who share common interests in innovation, bioeconomic growth, and the responsible and secure research and development of emerging biotechnologies.

The proposed rule could restrict U.S. researchers from attending international conferences, hosting international colleagues, or participating in international research collaborations with allied nations. The isolation of U.S. researchers from the global scientific community risks driving top-tier talent away from the U.S., lowering the quality of our science and weakening U.S. leadership.

To prevent overly broad restrictions that could unintentionally reduce U.S. influence, limit access to global talent, and slow overall scientific progress, EBRC recommends that OMB:

- Narrow the definition of "covered foreign collaborations" to specifically focus on entities that present clearly identified national security risks, such as "countries of concern" as defined in 28 CFR 202.601;
- Establish a clear, transparent authorization process for international collaborations that fall within the scope of the rule but do not present security risks;
- Explicitly exclude participation in international scientific conferences, workshops, standards-development activities, and professional convenings that are primarily educational or scientific; and
- Reduce uncertainty by developing clear guidance for award recipients around *allowable* international engagement activities.