American Association for Cancer Research
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615 Chestnut Street | 17th Floor
Philadelphia, PA 19106-4404
215-440-9300 | 215-440-9313 Fax
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July 13, 2026

The Office of Management and Budget (OMB), Executive Office of the President (EOP)

Submitted to: https://www.regulations.gov/commenton/OMB-2026-0034-0001

RE: Docket OMB-2026-0034; Federal Register Number 2026-10817; Proposed Rule: Regulation for Federal Financial Assistance

To Whom It May Concern,

The American Association for Cancer Research (AACR) is the world's first and largest professional organization dedicated to advancing cancer research and its mission to prevent and cure all cancers. Representing more than 66,000 members, AACR serves as a leading voice for cancer science and medicine, as well as evidence-based public policy. Its membership includes laboratory, translational, and clinical researchers, population scientists, health care professionals, and patient advocates working across the cancer continuum at research universities and affiliated academic medical centers and research institutes across the United States and the world. Through its advocacy efforts, AACR works to strengthen the nation's medical research enterprise, promote sustained investments in cancer research, and advance policies that accelerate scientific discovery and improve patient outcomes. AACR champions research policies that foster innovation, support the cancer research workforce, reduce barriers to scientific progress, and ensure that lifesaving advances reach all patients.

Over the past 25 years, federally funded research has catalyzed many of the most important breakthroughs in cancer treatment. These advances include immune checkpoint inhibitors, CAR-T cell therapies, targeted therapies, and precision medicine approaches. Together, these innovations have contributed to remarkable improvements in cancer survival, helping drive a decline of more than one-third in the U.S. cancer death rate since the early 1990s.[1] Because of these scientific advances, many millions of Americans are living longer and better lives, demonstrating the extraordinary return on the nation's investment in medical research.

On May 29, 2026, the Office of Management and Budget (OMB) released a proposed rule titled Regulation for Federal Financial Assistance that significantly alters how the government handles the management of grants and other forms of financial assistance. Among the many changes in this proposed rule, OMB proposes giving political appointees greater control over the grant selection process, expanding the discretionary authority of the government to terminate active grants, and placing new substantial restrictions on the use of federal funds. The proposed rule represents one of the most radical revisions to the framework governing federal financial assistance, the "Uniform Guidance," since its establishment.

According to OMB, the proposed revisions are intended to improve transparency, accountability, and oversight of federal awards while reducing administrative burden and ensuring responsible stewardship of taxpayer resources. AACR shares these goals and supports efforts to strengthen the

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effectiveness, integrity, and accountability of federal grant programs. However, many of the provisions included in this proposal would have the opposite effect, increasing administrative complexity, creating uncertainty for grant recipients, reducing transparency in funding decisions, and undermining the merit-based processes that have long guided federal research investments.

The proposed rule contains numerous substantive changes. We strongly urge OMB not to finalize the proposed rule in favor of additional analysis, careful review of submitted comments, and further engagement with recipients of federal financial assistance. AACR's comment focuses on the provisions that raise the most significant concerns for the cancer research community and the medical research enterprise. For each provision, AACR explains how the proposed change would harm stakeholders and fail to meet the goals of the proposed rule. We offer recommendations for revision, alternate approaches, or withdrawal.

1) §200.201

Fixed amount awards were incorporated into the Uniform Guidance because they can provide an efficient funding mechanism for projects with clearly defined objectives, milestones, deliverables, or scopes of work. Under such arrangements, recipients receive funding based on successful completion of agreed upon activities rather than detailed reimbursement of every individual cost incurred. As a result, both recipients and agencies can devote fewer resources to routine financial administration and more resources to project execution and oversight of outcomes.

Although medical research is primarily funded through cost-reimbursement grants, fixed amount awards remain an important tool for supporting discrete components of the cancer research enterprise. Examples include pilot research projects, shared resource activities, training and educational programs, technical assistance activities, and community outreach initiatives. As a specific illustrative example, the National Cancer Institute Early Career Cancer Clinical Investigator Award (ECIA) is a fixed amount award to support early-career investigators who aim to pursue a career in cancer clinical research. Fixed amount awards can provide an efficient mechanism for supporting discrete activities while minimizing administrative overhead.[2,3] Eliminating this funding mechanism would unnecessarily reduce agencies' flexibility to select the most appropriate award structure for these well-defined activities.

The elimination of fixed amount awards in §200.201(b) would likely have a disproportionate impact on smaller institutions, community-based organizations, and other partners with limited administrative capacity that often lack the financial and staffing resources needed to manage more complex reimbursement and reporting requirements.[4] These organizations play an increasingly important role in implementation science, patient and community engagement, cancer prevention initiatives, clinical trial recruitment, and efforts to improve access to care, particularly among medically underserved populations.[5] Additional administrative requirements may discourage participation by these partners, reduce the diversity of organizations able to participate in federally funded research, and ultimately diminish the effectiveness and reach of cancer research programs.

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The proposed change would also increase administrative costs for universities, cancer centers, and research institutions that would be required to track and document expenses that would otherwise be managed through milestone-based agreements. These additional costs ultimately increase recipient burden and reduce the resources available for research activities.

AACR recommends that OMB remove the proposed revision to §200.201(b) and retain existing authority for federal agencies to utilize fixed amount awards where appropriate and instead strengthen guidance regarding their implementation, oversight, and use of performance metrics. Such approaches would preserve the flexibility and administrative efficiencies associated with fixed amount awards while addressing any legitimate concerns regarding accountability and stewardship of federal funds.

2) §200.202

The proposed language in §200.202 directs agencies to consider broad policy objectives and requires additional scrutiny of international elements while providing limited guidance regarding how these determinations should be made, who should make them, and what standards should apply. As written, this provision creates substantial uncertainty for both agencies and grant recipients and may result in inconsistent implementation across the federal government.

AACR supports longstanding prohibitions on the use of federal funds for partisan political activities, electioneering, lobbying, or activities unrelated to authorized public purposes. Federal research funds should be used for research, training, scientific infrastructure, and other authorized purposes established by Congress. However, AACR is concerned that the proposed language in §200.202(c) extends beyond these well-established restrictions and may be interpreted broadly to allow politically based judgments regarding the content, objectives, or potential implications of scientific research. OMB has not provided sufficient guidance regarding how agencies should distinguish between prohibited political activities and legitimate scientific research that may have policy relevance.

Research findings frequently inform public policy discussions, clinical practice guidelines, regulatory decisions, and public health interventions. The fact that scientific evidence may ultimately be relevant to policy discussions does not mean that the underlying research constitutes political advocacy. For example, federally funded cancer research may examine the effects of tobacco control policies, cancer screening programs, environmental exposures, health care access, vaccination programs, or disparities in cancer outcomes. Such research provides evidence that policymakers may later consider, but the conduct of the research itself is not lobbying or political activity. AACR is concerned that the proposed language could create uncertainty regarding whether certain research topics or dissemination activities might be viewed as “political advocacy” or “attempt to influence legislation” and therefore become subject to additional scrutiny.

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AACR is particularly concerned by the requirement that agencies apply a "domestic-first" framework and obtain additional approvals for international components of research and development programs outlined in §200.202(e). Modern cancer research is inherently global, and scientific discoveries increasingly depend on international collaborations that allow researchers to access specialized expertise, unique datasets, patient populations, technologies, and research infrastructure.[6,7] Many cancer studies involve multinational clinical trials, international biobanks, genomic databases, surveillance systems, and collaborative research networks that no single country could replicate independently.

The United States has long benefited from leading and participating in international scientific collaborations. Numerous analyses have demonstrated that internationally collaborative research is associated with higher scientific impact, increased citation rates, broader expertise, better training for young scientists, and more rapid dissemination of discoveries.[8–10] AACR argues that the available evidence demonstrates that the vast majority of international scientific collaborations already satisfy the proposed standard that a "compelling interest exists for the agency's mission, the administration's priorities, and the United States" and the criteria outlined in §200.202(e)(3). The proposed rule assumes that broad prohibitions are the appropriate mechanism for managing foreign collaborations without demonstrating why existing safeguards are insufficient or considering the likelihood of the necessity of numerous exemptions. Many international cancer research collaborations involve low-risk scientific activities that advance U.S. scientific leadership, accelerate innovation, and ultimately benefit American patients. Restricting international collaborations may therefore reduce the scientific return on federal research investments and undermine U.S. leadership in medical innovation. OMB has not explained why a categorical prohibition is necessary in place of a more targeted, risk-based oversight framework.

AACR is also concerned that OMB has not adequately assessed the administrative burden associated with these requirements. The proposed rule does not specify:

- Who is the “agency senior appointee” responsible for evaluating international elements, whether this would be one or more individuals, and whether that information will be public;
- Whether scientific expertise would be required as part of the review process outlined in §200.202(e)(3) and how this would be incorporated into the decision-making process;
- Whether determinations would be subject to appeal or review; and
- What timelines would govern these reviews.

Without clear standards, agencies may adopt inconsistent approaches that increase delays, create uncertainty for applicants, and discourage beneficial scientific collaborations. Additional reviews, approvals, and documentation requirements would require substantial effort from both federal agencies and grant recipients while providing unclear benefits. As written, the proposal will increase administrative burden and reduce transparency in direct opposition to OMB’s stated goals.

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AACR recommends that OMB revise the proposal to provide additional clarification in §200.202(c) to help researchers and administrators better understand the differences between the use of federal funds that would be considered as political activities, advocacy, and/or lobbying versus the use of federal funds for legitimate scientific research that may have policy relevance, and to also specify who would make that determination. AACR also recommends OMB clarify the review process in §200.202(e) for assessing international elements when designing research and development programs and evaluating applications.

In addition, AACR is concerned by OMB's encouragement of agencies to broadly expand the use of multi-year funding approaches in §200.202(f). While multi-year awards may be appropriate for certain types of projects, programs, or infrastructure investments, OMB has not adequately evaluated the potential consequences of substantially increasing their use across the federal research portfolio, especially when the period during the transition to multi-year funding is taking place over a time frame when the agency budgets are declining from previous years.

Federal research agencies currently employ a range of funding mechanisms designed to support different scientific objectives, workforce needs, and stages of investigator professional development. This flexibility allows agencies to balance support for long-term projects with the need to fund new ideas, respond to emerging scientific opportunities, and provide entry points for early-career investigators. Encouraging a widespread shift toward multi-year funding could reduce the number of new awards made in a given fiscal year by committing a larger share of available appropriations to existing projects.[11,12] As a result, fewer investigators may have opportunities to compete for funding, potentially slowing the introduction of innovative ideas into the research enterprise.

This concern is particularly relevant for early-career researchers and investigators seeking to establish independent research programs, whose funding rates are already in decline.[13] New grant opportunities are often critical for recruiting and retaining talented scientists, supporting career transitions, and ensuring the continued vitality of the medical research workforce. Policies that reduce the number of new funding opportunities may unintentionally create barriers for the next generation of cancer researchers. OMB should provide an analysis for how expanded use of multi-year funding might further affect award rates, the number of funded investigators, workforce development, or agencies' ability to respond to emerging scientific priorities. Without such analysis, it is difficult to assess whether the anticipated benefits of expanded multi-year funding outweigh the potential costs to scientific opportunity and portfolio diversity.

AACR recommends that OMB remove §200.202(f) and preserve agency flexibility to determine the most appropriate funding mechanism for individual programs and initiatives rather than encouraging a broad expansion of any single funding approach. Federal agencies are best positioned to evaluate whether multi-year awards, annual funding mechanisms, cooperative agreements, or other approaches are most appropriate based on the scientific objectives, programmatic needs, and available resources of a particular initiative.

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3) §200.204

AACR is concerned that the changes proposed in §200.204 would reduce transparency in the funding process, increase administrative burden on applicants and agencies, and introduce additional uncertainty into the award process. The scientific community relies on open and transparent funding opportunities to ensure fair competition, broad participation, and public confidence in the allocation of federal research funds. Similarly, the grant review process is designed to evaluate scientific proposals based on merit and expertise. The proposed changes add additional layers of review without demonstrating how these would improve transparency, funding outcomes, or stewardship of taxpayer resources.

AACR requests clarification regarding the proposed authority in §200.204(a)(1) allowing agency heads or their designees to exempt Notices of Funding Opportunity (NOFO) from public announcement requirements. OMB has not provided sufficient justification explaining why such broad exemption authority is necessary or how it would improve accountability or efficiency. The proposal also does not specify the criteria for evaluating whether an opportunity would "pose a risk to national security or is in the national interest of the United States" and how that would be used to determine when an exemption is appropriate, creating the potential for inconsistent implementation across agencies. The absence of public notice and any justification would reduce transparency and undermine public confidence in the integrity of the grantmaking process, which is in direct opposition to OMB's stated goals. The proposal would also make it more difficult for Congress, stakeholders, and the public to understand how federal funding opportunities are being distributed.

AACR recommends that, at a minimum, OMB revise provision §200.204(a)(1) to clarify what documentation regarding exemptions will be required and mandate public disclosure of:

- **The identity of the agency official approving the exemption;**
- **The rationale for the exemption or the statutory or policy basis supporting the exemption; and**
- **Whether the exempted NOFO will be open competition, limited competition, or selection on a non-competitive basis.**

AACR is also particularly concerned by provision §200.204(c) encouraging Statements of Interest (SOIs) as a preliminary screening mechanism before full proposal submission. OMB proposes this change while agencies such as NIH have been directed to reduce the number of NOFOs and rely on fewer, broader funding announcements.[14] AACR is concerned that these two policies, when combined, are likely to substantially increase the number of applications received under each NOFO and consequently increase agency reliance on SOIs as a mechanism to manage application volume. As a result, the SOI process may effectively become an additional grant review stage that determines which applicants are allowed to submit full proposals for scientific review. OMB has not provided sufficient information regarding how SOI reviews would be conducted.

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Philadelphia, PA 19106-4404
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OMB should specify:

- Who would review SOIs including:
    - Whether scientific subject matter experts or peer reviewers would participate in the SOI review process;
    - Whether and how much political appointees would have a role in evaluating SOIs;
- How the criteria outlined in §200.205 would be applied to SOIs (which contain less detail than full applications) and used to determine which applicants advance;
- Whether applicants would receive feedback;
- Whether there would be any mechanism for appeal or reconsideration;
- An anticipated timeline for the SOI submission and review process; and
- How agencies would ensure consistency across programs and funding opportunities.

Without this information, it is impossible to assess whether the proposed process would preserve the principles of merit review and scientific excellence that currently guide federal research funding. Agencies, such as NIH, already use selective pre-application mechanisms in limited circumstances (letters of intent, concept proposals, U54 planning stages, etc.), but they employ such mechanisms based on agency evaluation of program-specific needs and are scientifically managed. OMB fails to provide justification for why a SOI pre-application process applied generally to all NOFOs is necessary.

Furthermore, the proposed SOI process may increase rather than decrease administrative burden. Applicants would be required to prepare an additional submission before being permitted to submit a full proposal. While SOIs are often described as a burden-reduction mechanism, investigators would still need to devote significant time and resources to preparing these submissions, particularly if they become a prerequisite for most funding opportunities. At the same time, agencies would be responsible for reviewing potentially large volumes of SOIs. OMB's Regulatory Impact Analysis states that implementation of §200.204 will have "no perceived impacts" but has not evaluated the staffing, expertise, or resources that would be required to review these submissions or how the additional review stage could affect funding timelines. Rather than streamlining grant review, the proposal may create an additional layer of review that would delay award decisions and lengthen the time between program announcement and grant issuance. Also, OMB has not analyzed how the proposed approach might affect scientific diversity, portfolio balance, or opportunities for early-stage investigators.

AACR further recommends that OMB remove the language in §200.204(c) encouraging routine use of SOIs as a preliminary screening mechanism. If OMB retains the provision, it should address the above concerns and clearly require that SOI evaluations be conducted in a transparent process, incorporate appropriate scientific expertise, include safeguards to

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Philadelphia, PA 19106-4404
215-440-9300 | 215-440-9313 Fax
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ensure that meritorious proposals are not excluded from peer review, and avoid adding significant delay to the grantmaking process.

4) §200.205

Federal medical research funding is currently evaluated through rigorous merit review processes involving subject matter experts who assess scientific rigor, feasibility, innovation, investigator qualifications, and potential public benefit. These systems have been refined over decades and are widely recognized as the international gold standard for evaluating scientific research proposals.[15–18] The proposed rule in §200.205(b) states that in addition to the merit review process, "one or more senior appointees" must perform pre-issuance review of all discretionary funding awards. The proposal includes instruction in §200.205(c) and §200.205(d) for the appointees to exercise independent judgment and that they may not "ministerially ratify or routinely defer" to the recommendations of reviewers and career staff. As a result, projects that have successfully completed scientific merit review could be denied funding based on considerations that are not clearly defined in the proposed rule.

As written, the rule provides insufficient information regarding who will conduct pre-issuance reviews, decision-making criteria or how decisions will be made, what documentation will be maintained, or how applicants will be informed when proposals are rejected at this stage.

OMB should specify:

- Who qualifies as a "senior appointee" for the purposes of conducting pre-issuance reviews;
- How awards would be evaluated in §200.205(b) as to whether they:
    - "Demonstrably" advance the "President's policy priorities" in §200.205(b)(1) or how those priorities are incorporated into a funding opportunity;
    - "Fund, promote, encourage, subsidize, or facilitate" as stated in §200.205(b)(2) the inadequately defined concepts that have no standard or recognized definition such as "compromising public safety or promoting anti-American values" in §200.205(b)(2)(iv);
    - Are given to a "broad range of recipients" as stated in §200.205(b)(4), and how a "broad range" will be defined;
    - Comply, commit, or implement "Gold Standard Science" in §200.205(b)(5), §200.205(b)(6), and §200.205(b)(7);
- Whether applicants will know when a proposal has entered pre-issuance review;
- Whether agencies must document the rationale for funding decisions made during pre-issuance review and if it will be made publicly available;

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- Whether applicants will receive any explanation if a scientifically meritorious proposal is denied funding following this review; and
- Whether agencies will publish procedures governing implementation of the pre-issuance review process.

The current grant review process promotes transparency by making its standing study section descriptions, evaluation guidelines, and expert panel rosters publicly available.[19] This openness allows the scientific community and the public to see who is evaluating grant applications, fostering accountability and ensuring a rigorous, vetted review of medical research. The proposal makes no mention of making the identities of the senior appointees known or requiring that they provide rationale for each pre-issuance review decision. Without these safeguards, applicants, institutions, Congress, and the public may have limited visibility into how funding decisions are ultimately made. This lack of transparency is inconsistent with OMB's stated objectives and risks undermining confidence in the integrity and fairness of the federal grantmaking process.

Furthermore, OMB has not adequately assessed the operational burden associated with implementing pre-issuance review for all discretionary awards. Federal research agencies collectively manage thousands of awards annually and NIH alone issues tens of thousands of grants, cooperative agreements, and other research awards each year. Requiring an additional layer of review by a select few appointees for every discretionary award would require substantial agency resources and could significantly lengthen award timelines. Analysis already indicates that new federal policies have introduced notable delays into the grantmaking process.[20–22]

Delays in grant issuance can have significant consequences for research institutions, investigators, trainees, and patients. Cancer research projects often depend on coordinated staffing, recruitment, procurement, and collaboration activities that are planned around expected funding timelines. Additional review stages may delay project initiation, disrupt workforce planning, and slow scientific progress. OMB's Regulatory Impact Analysis states that implementation of §200.205 will have "no perceived impacts" but has not provided an analysis or estimates regarding the personnel, time, or resources that agencies would need to implement this new review process or an evaluation of the likely impact on award timelines.

Overall, OMB has not sufficiently demonstrated that existing peer review systems are failing to identify meritorious projects or that additional political review would improve funding outcomes. Further, OMB has not provided evidence of the benefits of pre-issuance review for the stated goals of improving transparency, accountability, and oversight. Additionally, OMB has not adequately explained how this additional level of review would not result in significant delays in the awarding of grants.

AACR strongly opposes the proposed revisions to §200.205 and urges OMB to withdraw the requirement that agencies designate senior political appointees to conduct pre-issuance review of discretionary awards. If OMB implements any form of additional review, it should

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Philadelphia, PA 19106-4404
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address the above serious concerns and ensure that the merit of a grant application is based on the rigorous review of those grant applications by scientific experts and their assessment of the grants ability to improve public health.

AACR is also concerned by §200.205(e), which permits agencies to remove posted funding opportunities and to reissue them without making any awards. Research institutions and investigators invest substantial time and resources preparing grant applications. The proposal would allow agencies to cancel competitions after applicants have already devoted significant effort to proposal development, budget preparation, institutional review, and administrative compliance activities. This authority creates uncertainty for researchers and institutions, increases administrative burden, and may discourage participation in future funding opportunities. OMB has not analyzed the economic impact of this specific provision on applicants or explained what safeguards would prevent its overuse.

Therefore, AACR recommends removing or substantially narrowing §200.205(e) to ensure that agencies cannot routinely withdraw and repost funding opportunities without providing a public explanation and justification. At a minimum, agencies should be required to publicly document the rationale for such decisions and assess the burden imposed on applicants and institutions.

5) **§200.206**

AACR supports appropriate pre-award evaluation of an applicant's ability to act as a responsible steward of taxpayer funding. However, the proposed revisions to §200.206 are not sufficiently defined, lack adequate transparency, and may increase administrative burden for both applicants and agencies without meaningfully advancing OMB's stated objectives. AACR is particularly concerned by the proposal in §200.206(b)(2) to expand the factors that agencies may consider when evaluating applicants to include consideration of memberships, affiliations, and other poorly defined criteria as indicators of potential risk. While agencies should be able to identify legitimate compliance, financial, or integrity concerns, the proposed rule does not adequately define how these factors will be evaluated or what standards will govern their use.

As written, the proposed language in §200.206(b)(2)(viii) regarding memberships and affiliations is especially broad and unclear. Researchers, universities, cancer centers, scientific societies, professional associations, advocacy organizations, patient groups, and nonprofit organizations routinely participate in collaborative networks and maintain memberships in numerous organizations or coalitions as part of their scientific and professional activities. Such affiliations are often essential to advancing scientific research, promoting professional development, disseminating scientific findings, and fostering collaboration. The proposed rule does not explain which affiliations may be relevant to risk determinations, how agencies would evaluate those affiliations, or what evidence would be required before an affiliation could be considered indicative of risk.

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Philadelphia, PA 19106-4404
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OMB should clarify:

- What types of memberships or affiliations may be considered relevant and:
    - What constitutes activities that "undermine public safety or national security";
- What constitutes "publicly available and verifiable" information including:
    - Whether agencies may rely on media reports, allegations, complaints, or unresolved investigations;
- How agencies would assess public information and whether it is "verifiable" including:
    - What evidentiary standards will apply and who will make these determinations;
    - How agencies will distinguish verified information from unsubstantiated claims; and
    - Whether applicants will have the opportunity to review and respond to information relied upon by the agency;
- Who within agencies will be responsible for conducting these reviews, and whether this is part of the pre-issuance review process outlined in §200.205; and
- How agencies will apply these standards consistently across programs and departments.

While the criteria for risk assessment must be provided in the funding announcement per §200.206(b), there is no indication as to whether the agency must make their policies and procedures for conducting a risk assessment publicly available. The absence of clear standards creates uncertainty for applicants and makes it difficult to understand how risk determinations will be made. Publicly available information may be incomplete, inaccurate, outdated, taken out of context, or manipulated by bad actors. Reliance on such information without appropriate safeguards could lead to inconsistent and potentially erroneous risk determinations.

As a result, agencies may be required to evaluate increasingly broad categories of information that may have limited relevance to actual grant management risk. OMB's Regulatory Impact Analysis states that implementation of §200.206 will have "no perceived impacts" but has not provided an assessment of the resources that agencies would need to implement these expanded reviews or the potential impact on award timelines given a suggested timeframe of "no earlier than 30 days before award decision." The resulting process may increase administrative complexity without providing corresponding improvements in accountability or oversight.

The proposed rule also does not clearly provide applicants with an opportunity to review and respond to adverse information before specific conditions are imposed or funding decisions are made. Basic principles of transparency and fairness suggest that applicants should be informed when adverse information materially influences a risk determination, and they should have an opportunity to provide corrective information, context, or evidence of remediation. This is

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particularly important where agencies may rely on publicly available information, historical findings that have already been resolved, or information regarding affiliations that may be subject to differing interpretations.

AACR recommends that OMB revise §200.206 to focus risk assessments only on objective, verifiable indicators of grant management capacity, financial integrity, compliance history, and prior award performance. If OMB retains language regarding memberships, affiliations, or publicly available information, it should establish clear definitions, evidentiary standards, transparency requirements, and applicant response procedures. These revisions would better advance OMB's stated goals through consistently applied standards that recipients can understand and agencies can administer fairly. Agencies should also be required to make all policies and procedures for conducting an applicant risk assessment publicly available, document the basis for adverse determinations, and provide applicants with an opportunity to address material concerns before funding decisions are finalized.

6) **§200.218**

§200.218, as drafted, is overly broad, lacks sufficient definitions and implementation guidance, and creates significant uncertainty regarding the permissibility of research focused on health disparities, population differences in health outcomes, and other areas of medical research that are critical to improving public health. AACR is particularly concerned that the proposed language could be interpreted to restrict or discourage research aimed at understanding disparities in cancer risk, incidence, mortality, screening, treatment access, clinical trial participation, survivorship, and outcomes among different populations.

A substantial body of scientific evidence demonstrates that cancer outcomes vary across populations and that these differences may result from a complex interaction of biological, environmental, socioeconomic, geographic, behavioral, and health system factors.[23] Understanding these differences is essential to improving prevention, early detection, treatment, and survival for all patients.[23] Researchers routinely study differences in cancer outcomes by race, ethnicity, age, sex, geography, disability status, income, insurance status, and other factors to identify barriers to care and develop interventions that improve health outcomes. Such research is not intended to assign legal liability or advocate for particular policy outcomes; rather, it seeks to generate scientific evidence that can improve patient care and reduce preventable illness and death.

The proposed rule does not clearly distinguish between scientific research and activities that may be interpreted as "promoting or supporting" the use of disparate-impact liability. Without clear definitions and implementation guidance, recipients and agencies may reach different conclusions regarding whether particular federally funded research projects, training programs, public health initiatives, or data collection efforts fall within the scope of the prohibition. This uncertainty would reduce transparency, complicate compliance efforts, and increase administrative burden for both recipients and agencies.

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OMB should provide clarification regarding:

- Criteria for assessing whether an award activity would "promote or support theories that impose disparate-impact liability";
- Examples of scientific research activities that would or would not be permissible such as:
    - Research examining differences in health outcomes among populations based on "federally protected characteristics";
    - Data collection, surveillance, epidemiologic studies, and clinical research and recruitment involving consideration of "federally protected characteristics";
- How agencies will evaluate proposals focused on health disparities or population health for whether they are covered by this provision; and
- What standards agencies will use to ensure consistent implementation.

AACR recommends that OMB withdraw §200.218. At a minimum, OMB should explicitly clarify how the provision would or would not apply to specific scientific research, public health research, epidemiological studies, health services research, data collection, surveillance activities, clinical trial recruitment or other efforts designed to understand differences in health outcomes, disease burden, access to care, or treatment effectiveness among populations based on "federally protected characteristics" as well as provide implementation guidance for how this standard will be applied across agencies.

7) §200.220

AACR supports efforts to protect national security, safeguard sensitive technologies, and ensure appropriate oversight of foreign collaborations involving federally funded research. However, AACR is concerned that the broad prohibition proposed in §200.220(b) on all "direct programmatic activities, research, technical assistance, travel, or indirect costs allocable to such collaborations" is substantially broader than necessary to achieve these objectives and would unintentionally disrupt a wide range of legitimate scientific collaborations involving numerous institutions and participants across multiple countries.

Modern biomedical research is inherently global and increasingly conducted through large international consortia, cooperative research networks, multinational clinical trials, and global data-sharing initiatives that bring together scientific expertise, patient populations, and resources from around the world. Cancer research depends on international collaboration to generate the large datasets and patient populations necessary for scientific discovery.[24–26] Many rare cancers, pediatric cancers, and molecularly defined cancer subtypes affect too few patients within any single country to support adequately powered studies. International collaborations allow researchers to combine expertise, biospecimens, clinical data, and patient populations to answer scientific questions that would otherwise be impossible to address. As an illustrative example,

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researchers in the United States participate in large international consortia and cohort studies such as the Consortium of Investigators of Modifiers of BRCA1/2 (CIMBA), Evidence-based Network for the Interpretation of Germline Mutant Alleles (ENIGMA), and BRCA BCY Collaboration that incorporate study groups and clinical sites from around the world, including in designated "countries of concern".[27–29] These international collaborations are fundamental to providing sufficient sample sizes to allow for the large scale studies necessary to reliably evaluate the effects of genetic modifiers on cancer development and progression.

Similarly, multinational clinical trials have become a critical component of cancer drug development.[30,31] These trials routinely involve research institutions across numerous countries, allowing investigators to enroll patients more efficiently, evaluate promising therapies more rapidly, and generate evidence that is broadly applicable across diverse populations. If U.S. institutions are unable to participate in multilateral collaborations that may include covered countries or entities, researchers may be excluded from important initiatives or studies, patients may lose access to clinical trial opportunities, and the development of new cancer therapies could be delayed. The proposal may also impede participation in global data-sharing efforts that have become central to advances in cancer genomics, precision oncology, artificial intelligence, epidemiology, and population science. Restrictions that discourage participation in multinational data-sharing initiatives may therefore reduce the scientific value of federally funded research and limit opportunities for discovery.

The proposal creates substantial uncertainty for long-term scientific collaborations. Many federally funded cancer research projects operate through international consortia that span multiple years and involve dozens or even hundreds of participating institutions. Under the proposed rule, an otherwise permissible collaboration could become prohibited if a participating institution, collaborator, or country is subsequently designated as a covered entity because of a future statutory, regulatory, or agency determination. Such designations may result from evolving geopolitical circumstances rather than any change in the underlying scientific activities. OMB does not clearly explain whether recipients would be expected to continuously monitor all collaborators over the lifetime of an award or what steps would be required if a participant becomes designated as or affiliated with a covered country or entity after an award is made. The proposal provides no guidance regarding whether recipients would be required to terminate existing collaborations immediately, how ongoing studies or clinical trials should be managed, or how agencies should balance the scientific, financial, and patient impacts of terminating established collaborations. Abruptly ending longstanding international partnerships could waste taxpayer investments, interrupt research already underway, and delay scientific discoveries that benefit patients in the United States and worldwide.

The proposal also creates considerable compliance uncertainty for recipients. There is no government-wide, or agency-specific, resource identifying covered foreign countries or entities across all applicable statutes, federal laws, Executive Orders, and agency determinations. OMB does not explain how agencies should evaluate whether a particular activity poses a national

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security concern or is in the national interest. The rule does not establish the analytical framework that agencies should apply when evaluating complex multinational research collaborations for any participation from covered countries or entities, and it does not describe what evidence recipients would be expected to provide. As written, the proposal does not clearly address the burden on agencies or recipients in determining whether a large collaboration may include a participant, institution, subrecipient, or affiliated entity located in or associated with a covered country or entity. Without transparent criteria, standardized procedures, and clear implementation guidance, agencies may reach inconsistent conclusions regarding identical collaborations. OMB must provide implementation guidance for how recipients should address otherwise permissible collaborations if a covered country or entity becomes involved at various award stages and whether recipients may seek clarification before undertaking collaborative activities.

AACR recommends that OMB revise §200.220 to ensure that restrictions are narrowly targeted toward specific activities or relationships that present identifiable national security concerns. At a minimum, OMB should clarify how the scope will apply to international consortia, multinational clinical trials, collaborative research networks, and global data-sharing initiatives as well as provide guidance for how agencies and recipients and/or subrecipients should monitor collaborations for compliance.

8) §200.300

The proposed provision in §200.300 prohibits activities that "fund, promote, encourage, subsidize, or facilitate" anything related to “diversity, equity, and inclusion” (DEI) or “diversity, equity, inclusion, and accessibility” (DEIA). As drafted, the provision relies on broad and poorly defined terminology that would create significant uncertainty for recipients, agencies, and researchers. The proposal could restrict federally funded medical research, including research focused on cancer disparities, health outcomes, access to care, and other areas that are central to improving public health. OMB does not explain how agencies should distinguish prohibited activities from legitimate scientific research, public health initiatives, workforce development programs, data collection efforts, or patient outreach activities that could be considered as in scope. In addition, the proposed provision would create significant administrative burden as agencies, institutions, and investigators attempt to determine whether specific activities fall within the scope of the prohibition.

Cancer incidence, mortality, screening rates, treatment access, clinical trial participation, and survivorship outcomes vary substantially across populations.[23] Understanding the causes of these differences and identifying effective interventions are essential components of cancer research and public health practice. Such studies often examine factors including geography, socioeconomic status, insurance coverage, environmental exposures, age, sex, race, ethnicity, disability status, and access to health care. Over the past two years, federal agencies have unlawfully terminated or restricted numerous grants, programs, and initiatives related to health disparities, minority health, social determinants of health, workforce diversity, and health equity.[32–34] Federal agencies have

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also removed health equity requirements from certain programs and discontinued initiatives specifically focused on reducing disparities in health outcomes. For example, CMS removed explicit health equity planning requirements from the Enhancing Oncology Model, and FDA removed Project Equity materials designed to improve representation in cancer clinical trials. These actions demonstrate that terms such as "DEI" or "DEIA" have been interpreted broadly in practice and have frequently encompassed activities extending far beyond traditional diversity programs. In addition, analysis shows the administration's targeting of "DEI" or "DEIA" has disproportionately impacted certain populations and sparked significant, legitimate concerns in the scientific research community regarding the future of health disparities research.[35,36]

OMB should clarify:

- Specific criteria for identifying "diversity, equity, and inclusion" (DEI) or "diversity, equity, inclusion, and accessibility" (DEIA) policies, principles, or practices;
- The meaning and scope of "promote," "encourage," "subsidize," and "facilitate" in §200.300(b);
- Who within agencies will be responsible for evaluating compliance; and
- Guidance to ensure consistent implementation between and within agencies.

AACR recommends that OMB withdraw §200.300. At a minimum, OMB should explicitly clarify how the provision applies to various categories of scientific research, public health research, epidemiological studies, clinical trials, data collection, surveillance activities, workforce development programs, or other activities intended to understand disease burden, health outcomes, treatment effectiveness, and access to care based on population differences as well as provide detailed guidance for consistent agency implementation. OMB must ensure that scientifically justified, legitimate health disparities research is excluded from this provision.

9) §200.303

AACR supports efforts to ensure compliance with federal employment laws and recognizes the importance of maintaining appropriate oversight and accountability for federally funded activities. However, AACR opposes the proposed addition of §200.303(f) requiring recipients and subrecipients to use the Department of Homeland Security's E-Verify system for all employees and contractors supported by federal awards. Research institutions frequently manage thousands of employees, trainees, contractors, and subrecipients across numerous federally funded projects. Establishment of this provision would require significant institutional resources for documenting verification activities and monitoring ongoing compliance, creating additional oversight responsibilities and increasing administrative complexity throughout the research ecosystem. Institutions may need to modify human resources systems, develop new compliance procedures, train personnel, update subcontracting processes, and establish new administrative procedures.

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OMB assumes these costs as minimal but has not estimated these costs or evaluated how they would affect recipients of different sizes and organizational structures.

AACR is particularly concerned that the requirement may be especially burdensome for large institutions and multi-institutional research collaborations involving numerous subrecipients and contractors. International scientists play a critical role in the U.S. medical research enterprise. Universities, cancer centers, and research institutions rely heavily on international postdoctoral fellows, graduate students, physician-scientists, and research staff who contribute to scientific discovery, innovation, and patient care.[37] According to analyses of the medical workforce, international researchers constitute a substantial portion of the postdoctoral and graduate research workforce supporting federally funded research.[38] The proposed requirement may create additional compliance barriers for institutions employing these individuals and could complicate workforce recruitment, onboarding, and personnel management. While the provision does not prohibit the employment of foreign nationals who are legally authorized to work in the United States, institutions may face additional administrative burdens and compliance risks associated with managing these requirements. OMB has not assessed how this requirement would affect workforce recruitment, research productivity, or the ability of institutions to compete for scientific talent. Also, OMB does not provide implementation guidance to agencies, including for compliance verification.

OMB should clarify:

- The documentation and recordkeeping requirements for recipients and agencies;
- Compliance monitoring and enforcement mechanisms;
- The anticipated administrative costs associated with implementation;
- How the provision meets OMB's goal of reduced recipient burden; and
- How the requirement would interact with existing federal employment verification requirements.

OMB has also not evaluated whether less burdensome approaches could achieve the same objective. OMB has not demonstrated that existing employment verification requirements are inadequate, nor has it provided evidence that the proposed requirement would meaningfully improve grant oversight, financial stewardship, or program integrity. As a result, the costs and burdens imposed by the provision appear disproportionate to the anticipated benefits. If OMB's goal is to ensure compliance with existing employment eligibility requirements, alternative approaches could focus on targeted enforcement, risk-based compliance reviews, or reliance on existing federal employment verification frameworks rather than imposing a universal E-Verify requirement as a condition of receiving federal financial assistance. OMB has not explained why these alternatives would be insufficient or why the proposed approach is necessary.

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AACR recommends that OMB withdraw §200.303(f). OMB has not demonstrated that the proposed requirement would meaningfully improve grant oversight or stewardship of federal funds, and the administrative burden imposed on recipients would likely outweigh any anticipated benefits. If OMB determines that additional employment verification measures are necessary, AACR recommends a more targeted approach that minimizes burden on recipients, clearly defines compliance obligations, and focuses on identified areas of risk rather than imposing a universal requirement across the entire federal research enterprise.

10) §200.305

AACR supports appropriate financial oversight and accountability for federal funds. However, the proposed requirement in §200.305(c) for agencies to create a system for federal grant recipients and subrecipients to provide brief, written justifications for each payment request would create a burdensome new administrative step for all federal awards, regardless of award size, recipient type, or prior performance history. Research institutions routinely manage hundreds or thousands of active federal awards, each requiring periodic drawdowns to support personnel, equipment, supplies, clinical research activities, and other approved project costs. Requiring individualized justifications for every payment request would significantly increase administrative workload for both recipients and federal agencies, which directly contradicts OMB's goal of reducing recipient burden in the proposed rule.

Institutions would likely need to modify financial systems, develop new internal review procedures, train personnel, and dedicate additional administrative resources to address this requirement. Federal agencies would likewise need to establish processes for receiving, reviewing, evaluating, and maintaining these justifications. OMB assumes these costs to be modest but has not explained how agencies will manage this increased workload or estimated the additional personnel and resources that will be required.

Federal research grants are already subject to extensive financial oversight and accountability requirements. Recipients must maintain detailed financial management systems, comply with federal cost principles, submit regular financial reports, undergo audits, retain supporting documentation, and certify that expenditures are allowable, allocable, and reasonable under applicable federal requirements. Federal agencies also retain authority to monitor recipients, conduct audits, impose specific award conditions, and recover improperly spent funds. NIH and many other agencies already operate through the Treasury's Payment Management System (PMS), which was specifically designed around the principle of reimbursement and cash management controls.

OMB has not identified evidence suggesting that existing controls are insufficient or that routine payment requests represent a significant source of waste, fraud, or abuse requiring additional government-wide regulation. OMB has also not demonstrated how the proposed requirement

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would improve transparency, reduce burden, or substantially improve oversight outcomes to justify regulatory change from existing systems and procedures.

AACR is also concerned that requiring agency review of payment justifications could slow the disbursement of funds needed to conduct research activities. OMB's Regulatory Impact Analysis indicates OMB expects no changes in overall funding transfers but does anticipate impact on the "timing and size of individual transfers." OMB should further evaluate the potential impact of the proposed requirement on payment timelines and research productivity.

OMB should clarify:

- Procedures and expected or estimated timelines for agencies to review and approve each justification prior to disbursement;
- Implementation guidance for recipients and subrecipients to submit justifications that enable approval;
- What agency personnel will review these justifications; and
- How agencies will manage the increased review workload.

If OMB believes additional oversight of payment requests is necessary, AACR encourages the adoption of an alternative, more targeted and risk-based approach. For example, agencies could require additional payment documentation for recipients with identified compliance concerns, awards subject to specific conditions, high-risk recipients, or projects involving known financial management challenges. This would be more consistent with longstanding federal grant management principles and would better align with OMB's stated goal of reducing administrative burden.

AACR recommends that OMB withdraw the proposed changes to §200.305(c) requiring justification for every payment request. Existing federal financial management requirements already provide extensive safeguards to ensure accountability and proper stewardship of taxpayer funds. If OMB determines that additional oversight is warranted, AACR recommends adopting a targeted, risk-based approach that focuses enhanced scrutiny on recipients or awards with identified compliance concerns.

11) §200.320

The proposed revisions in §200.320 to strongly discourage cost-reimbursement contracts fail to account for the unique nature of scientific research and could impede research progress, increase costs, and reduce flexibility for recipients conducting federally funded cancer research. AACR recognizes that fixed-price arrangements may be appropriate in certain circumstances; however, cost-reimbursement contracts remain an essential procurement mechanism for many research activities where costs cannot be reasonably estimated in advance. Scientific research differs fundamentally from many commercial procurement activities because research outcomes,

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technical requirements, and project needs often evolve as new discoveries are made.[39] Cancer research institutions routinely utilize cost-reimbursement contracts for activities where scientific uncertainty makes it difficult to establish a fixed price in advance.

Examples include:

- Clinical trial management and patient recruitment activities, where enrollment rates, treatment duration, and participant retention cannot be predicted with certainty;
- Genomic sequencing and molecular characterization services, where the number of samples requiring additional testing often depends on initial findings;
- Biostatistical and data management support for clinical trials and large research studies, where analytical requirements may evolve as data are collected;
- Laboratory research involving specialized scientific services that depend on experimental outcomes;
- Biospecimen collection, processing, and storage activities, where sample volume and processing requirements may vary substantially during a project;
- Research involving rare cancers or pediatric cancers, where patient availability and study requirements may change significantly over time; and
- Multi-site clinical studies, where unforeseen scientific developments require protocol modifications or additional analyses.

By discouraging the use of cost-reimbursement contracts, the proposed rule may force recipients to rely on less appropriate procurement mechanisms that either increase project costs or reduce the flexibility necessary to conduct high-quality scientific research, ultimately increasing costs to the federal government. Cost-reimbursement contracts, when appropriately managed, often provide a more efficient and cost-effective mechanism for supporting research activities because they align reimbursement with actual work performed rather than requiring vendors to price uncertain future risks.

OMB has not presented evidence demonstrating that discouraging cost-reimbursement contracts would result in lower costs or better outcomes for federally funded research. OMB should consider the economic consequences of discouraging cost-reimbursement contracts across all federal financial assistance and provide a detailed analysis that demonstrates how the proposed rule would promote efficiency, accountability, and performance in federal contracting.

OMB should clarify:

- What justifications for cost-reimbursement contracts are expected to be appropriate;
- Who within agencies will be responsible for reviewing justifications and have decision-making authority;

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- Expected timelines for agencies to respond to cost-reimbursement contract justifications when prior approval is required; and
- What rationale for agency decisions will be provided.

AACR recommends that OMB remove the language in §200.320 that strongly discourages the use of cost-reimbursement contracts and instead preserve recipient flexibility to select the procurement mechanism most appropriate for the scientific, technical, and operational needs of a project.

12) §200.332

AACR is concerned that the proposed revisions in §200.332 would impose significant new administrative burdens on recipients and pass-through entities, and do not provide sufficient clarity regarding how these requirements would be implemented in practice.

Provision §200.332(h) would require recipients to apply subrecipient and contractor classification requirements even when funds are distributed among organizational units within the same institution or affiliated organizational structure. Large universities, academic medical centers, cancer centers, and research institutions frequently operate through complex organizational arrangements involving affiliated hospitals, research foundations, faculty practice plans, and specialized research institutes that are subject to common governance and oversight structures. OMB has not demonstrated that existing oversight mechanisms for affiliated entities are insufficient or explained how imposing additional subaward classification, monitoring, and reporting requirements on internal organizational relationships would improve accountability. OMB's Regulatory Impact Analysis expects implementation of §200.332 to have no perceived impacts. Instead, the provision is likely to increase administrative burden, duplicate existing oversight processes, and divert institutional resources away from research activities without corresponding benefits.

The proposed language in §200.332(i), which would require pass-through entities to ensure that subrecipients do not take actions that could "significantly damage the reputation" of the pass-through entity, the awarding agency, or the federal government, is vague, subjective, and lacks clarifying guidance. The proposed rule does not define what constitutes "significant" reputational harm, what actions would trigger concern, who would make such determinations, or what evidence would be required to support them. It is also unclear whether reputational harm would be assessed by the pass-through entity, the federal agency, OMB, or another government official. Because OMB does not limit the provision to award-related conduct, recipients may be unable to determine the scope of their obligations, creating both compliance uncertainty and potential liability extending far beyond traditional grant management responsibilities, is inherently subjective, and is subject to change over time.

AACR recommends that OMB revise §200.332 to recognize existing institutional oversight structures and avoid imposing duplicative compliance requirements on relationships among

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commonly governed or affiliated entities where appropriate accountability mechanisms are already in place. AACR further recommends that OMB withdraw §200.332(i) or replace this reputational harm standard with clear, objective criteria tied to established compliance, performance, financial management, and program integrity requirements. If OMB retains the provision, it should clearly define the conduct covered, identify who is responsible for making the determinations, establish procedural safeguards, and explain how the requirement will be implemented consistently across federal agencies.

13) §200.333

Cancer research frequently involves collaborations among universities, cancer centers, hospitals, laboratories, community organizations, and other research partners. Fixed amount subawards are particularly useful when a subrecipient is responsible for a clearly defined scope of work with measurable deliverables.

Examples include:

- Collection and transfer of a specified number of patient samples or biospecimens;
- Completion of genomic sequencing, molecular profiling, or other laboratory analyses on a defined number of specimens;
- Development of a research database, software tool, or data resource;
- Performance of specific statistical analyses or data management activities;
- Community outreach and patient recruitment activities tied to predefined enrollment targets; and
- Participation by community oncology practices in multi-site cancer studies where responsibilities and deliverables are clearly established.

As a specific illustrative example, Cancer Center Support Grant (P30) supplements use fixed amount subawards for a variety of milestone-driven collaborative projects, core services, and clinical trial support. For instance, the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) has utilized fixed per-patient subawards to participating institutions for studies such as the Hematopoietic Cell Transplant and Gene Therapy for Non-Malignant Blood Disorders Biobank Resource (HOPE Resource), in which participating sites receive $5,000 for each patient enrolled and treated under the protocol. In these situations, fixed amount subawards allow institutions to focus on achieving scientific outcomes rather than expending resources on burdensome financial reporting and cost tracking. The proposal in §200.333 to eliminate all fixed amount subawards would require recipients and subrecipients to transition many projects to cost-reimbursement arrangements that require substantially greater administrative burden including documentation, invoicing, monitoring, and audit activities. As described previously in the response to §200.201, this increased burden would be felt most acutely by smaller institutions, community-

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based organizations, rural health providers, and other entities that may have limited administrative infrastructure but play an important role in cancer research, clinical trials, patient outreach, and data collection efforts.

OMB has not provided evidence that the limited use of fixed amount subawards has resulted in widespread misuse of federal funds or demonstrated the anticipated benefits in accountability and oversight by eliminating this mechanism.

AACR recommends that OMB withdraw the proposed changes to §200.333 and retain the current flexibility allowing recipients to utilize fixed amount subawards when deemed appropriate by the awarding agency.

14) §200.339

Provision §200.339(b) does not provide sufficient clarity regarding the circumstances under which federal agencies may cooperate with third parties in pursuing enforcement, recovery, audit, or other award-related actions. The proposed rule does not define which entities may qualify as third parties, what authority they may exercise, what standards will govern their involvement, or whether recipients will be notified when such entities participate in agency actions. Greater transparency is needed to ensure consistent implementation and to allow recipients to understand their obligations and protections under the provision.

In addition, the proposed rule has potential implications for confidential research, proprietary information, and sensitive data maintained by research institutions. Cancer research organizations routinely manage unpublished scientific findings, intellectual property, clinical trial information, and other sensitive materials that may be shared with federal agencies in the course of award administration. OMB should clarify what safeguards will apply to protect confidential information when third parties are involved and how agencies will ensure that access to recipient information is appropriately limited.

AACR recommends that OMB provide additional guidance in §200.339(b) to clarify the scope of third-party involvement, establish criteria for how an agency determines that such cooperation is in the interest of the United States, establish clear confidentiality protections, and require transparency regarding the role and authority of any third parties participating in enforcement or recovery activities.

15) §200.340

The proposed revisions to §200.340 would radically expand agency authority to suspend or terminate awards based on changing priorities or determinations that a project is no longer in the agency's or government's interest. Researchers, institutions, and patients rely on the expectation that projects selected through competitive review will be allowed to proceed unless there are performance, compliance, or financial management concerns. The proposed provision weakens that expectation and introduces significant uncertainty into the federal funding process. Cancer

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research often requires years of sustained investment before meaningful scientific results can be achieved. Clinical trials, longitudinal studies, large-scale data collection efforts, and laboratory research programs frequently involve multi-year commitments of personnel, infrastructure, patient participation, and institutional resources. Under the proposed provision, projects could be terminated after substantial federal and institutional investments have already been made, resulting in wasted resources, disrupted research programs, and lost scientific opportunities. In clinical research, terminations may also affect patients who have enrolled in trials with the expectation that the research will continue through completion. Following widespread NIH grant terminations in 2025, studies found that ongoing clinical studies and participant follow-up activities were disrupted or suspended, creating substantial uncertainty for patients who had already enrolled in federally funded research.[40,41]

Provision §200.340(a)(2) effectively subjects active research awards to evolving agency priorities and interpretations of the "national interest" that may change multiple times during the course of a multi-year project. OMB should clarify who within agencies or the federal government will have decision-making authority when evaluating whether a federal award no longer "effectuates program goals, federal agency priorities, or the national interest" for discretionary terminations and suspensions. The complexities of scientific research necessarily require a long-term endeavor, and projects selected through rigorous merit review should not face termination because political priorities have shifted after an award has been made. Such uncertainty would diminish the value of the scientific review process, discourage ambitious research projects that have significant potential for public health, and have an adverse effect on U.S. competitiveness.

The proposed rule also does not assess the financial and scientific costs associated with terminating or suspending active awards. Federal research investments often support years of planning, hiring, training, equipment purchases, and collaborative research activities before significant results are achieved. OMB should clarify how these anticipated costs are considered when determining that this provision will improve the stewardship of taxpayer dollars.

OMB Director Vought stated in testimony to the House Appropriations Financial Services and General Government Subcommittee that the cancellation provisions in the proposal are needed "because when we find something that's problematic […] we need to be able to turn it off".[42] AACR agrees that federal agencies must have the ability to take prompt action when a grant recipient engages in fraud, waste, abuse, material noncompliance, or other serious misconduct that threatens the integrity of federal programs or the appropriate use of taxpayer funds. Existing federal regulations already provide agencies with substantial authority to suspend or terminate awards in these circumstances. Current Uniform Guidance provisions permit agencies to terminate awards for material failure to comply with award terms and conditions, mutual agreement, or other specified causes, and agencies retain broad oversight authorities through audits, monitoring, enforcement actions, and remedies for noncompliance. However, the proposed provision would grant agencies broad discretion to terminate awards for reasons unrelated to recipient performance.

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OMB has not identified evidence demonstrating that the existing authorities are insufficient or that agencies have been unable to address problematic awards under the current framework.

AACR strongly recommends OMB revise §200.340 to limit suspension and termination authority to circumstances involving noncompliance, financial mismanagement, fraud, waste, abuse, failure to meet award requirements, or other objective performance-related concerns. If OMB believes that additional termination authority is necessary beyond the existing framework, AACR recommends that such authority be narrowly tailored and supported by clear, objective, and publicly available criteria identifying the specific circumstances under which discretionary termination may be appropriate. At a minimum, the final rule should define the specific set of objective criteria by which grants will be evaluated for meeting "program goals," "Federal agency priorities," or the "national interest." OMB should also identify who within an agency is authorized to make these determinations, require written documentation explaining the basis for each termination decision, limit the exercise of this authority to clearly defined circumstances that cannot be addressed through existing compliance and enforcement mechanisms, and provide additional procedural safeguards (including opportunities for objections, hearings, and appeals as discussed in §200.342 below) to ensure transparency, consistency, and accountability.

16) §200.341

The proposed rule expands agency discretionary authority to terminate awards under §200.340, and in §200.341 proposes revisions that would require only limited agency explanation for those actions. Broad discretionary authority should be accompanied by robust documentation requirements to ensure accountability, consistency, and public confidence in the federal research funding process and to achieve OMB's stated goal of increased transparency.

Under provision §200.341(c)(1), agencies would be required to provide only a brief explanation of the basis for a suspension or termination and explicitly not required to "provide a detailed or exhaustive analysis." This standard is insufficient, particularly when awards may be terminated for broad, subjective reasons such as changing agency priorities, program goals, or determinations regarding the national interest. Explanations should provide meaningful insight into why a project was terminated, what criteria were applied, who made the determination, and how the decision aligns with agency policy. Without greater transparency, recipients will be unable to understand the basis for agency actions, and external stakeholders, including Congress, taxpayers, patients, and the research community, would be unable to assess whether termination decisions are being applied consistently and fairly.

AACR is particularly concerned by the language in §200.341(c)(1) permitting agencies to terminate entire classes of awards with a single brief explanation. Class-wide terminations could affect hundreds of competitively reviewed projects that span multiple institutions, scientific disciplines, and patient populations, yet the proposal does not require agencies to explain why all

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awards within a category would warrant termination or how such determinations would be made. Unlike many forms of government assistance, research awards represent individualized investments in specific scientific questions, investigators, institutions, or patient populations. Because each award undergoes its own merit review, funding recommendation, and agency approval process, termination decisions should likewise be based on project-specific circumstances rather than broad class-wide determinations.

Providing only a minimal explanation for these decisions will undermine confidence in the federal funding process and make it difficult for institutions to learn from or respond to agency concerns. This would also create uncertainty across the broader research community regarding what activities, scientific topics, or research approaches could place future awards at risk.

AACR recommends that OMB revise §200.341 to require agencies to provide a detailed written explanation for suspensions and terminations, including the specific basis for the action, the factors considered in reaching the determination, and the agency official or office responsible for the decision. OMB should also prohibit class-wide suspension or termination and require agencies to maintain publicly available documentation supporting discretionary suspension or termination decisions to ensure accountability and consistent policy application.

17) §200.342

In addition to the changes proposed in §200.340 and §200.341, the proposed revisions to §200.342 that would eliminate federal award recipients' ability to challenge or seek review of discretionary suspensions and terminations. While federal agencies must retain the ability to address noncompliance, fraud, waste, abuse, and other serious award management concerns, review and appeal mechanisms help ensure that agency decisions are applied consistently, supported by appropriate evidence, and are made in accordance with applicable policies and procedures. Removing these safeguards reduces accountability while providing recipients with no meaningful avenue to address factual errors, misunderstandings, or inconsistent application of agency policies.

OMB's proposed framework would allow agencies to terminate individual awards based on broad policy determinations while providing limited explanation and no meaningful mechanism for independent review. This approach would undermine confidence in the fairness and predictability of the federal research funding system. The availability of review would not prevent agencies from taking necessary actions; rather, it provides an important check to ensure that significant funding decisions with clear potential harm to recipients are supported by accurate information and applied consistently.

OMB has not provided evidence for why existing review procedures are insufficient or burdensome, or provided the rationale that would necessitate the proposed changes. OMB's Regulatory Impact Analysis anticipates no impact from implementation of §200.342, but OMB has not assessed the potential scientific and economic consequences of eliminating opportunities

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for objections, hearings, and appeals when combined with the expanded termination authorities proposed in §200.340 and §200.341.

AACR strongly recommends that OMB remove §200.342 and retain existing opportunities for recipients to seek review of all suspension and termination decisions. Federal funding recipients should have access to a transparent administrative review process that allows them to challenge factual errors, procedural deficiencies, or inconsistent application of agency policies.

18) §200.421

AACR is concerned that the proposed revisions in §200.421 will create substantial uncertainty regarding the allowability of communications, outreach, and public engagement activities that are frequently necessary to carry out federally funded cancer research and public health programs. While §200.421(b)(3) preserves an exception for advertising and public relations activities related to program advertising and outreach necessary for the performance of a federal award, the proposal does not provide sufficient guidance regarding how this exception will be interpreted or applied in practice.

Cancer research institutions routinely engage in communications activities that support the objectives of federally funded awards, including clinical trial recruitment, participant retention efforts, community outreach, public awareness campaigns related to screening and prevention studies, dissemination of information regarding research opportunities, and engagement with various patient populations. Although many of these activities could fall within the exception provided by §200.421(b)(3), the proposed rule does not establish clear standards for determining whether a particular activity qualifies. The proposal also does not explain who will make these determinations or enumerate processes to ensure that agencies apply consistent standards across programs, nor does the proposal provide examples, review procedures, or mechanisms for recipients to obtain advance guidance regarding potentially allowable activities. As a result, recipients may face significant uncertainty when designing and implementing the outreach activities necessary to achieve program goals. Institutions may adopt overly cautious interpretations to avoid audit findings or disallowed costs, potentially limiting communications activities that support research participation, patient engagement, and public awareness of federally funded programs. Without clearer guidance, recipients may be left to make subjective determinations regarding allowability, increasing compliance burdens and creating the potential for inconsistent interpretations across agencies and programs.

AACR recommends that OMB further clarify the unallowable costs covered by §200.421(a) as well as provide additional guidance related to the exceptions in §200.421(b)(3) to clearly define the scope of allowable outreach, recruitment, educational, and public engagement activities. OMB should require agencies to identify who is responsible for making exception determinations, provide review procedures, and establish a mechanism for recipients to seek advance clarification when needed.

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19) §200.432

The proposed revision in §200.432 would significantly restrict researchers' ability to participate in scientific conferences by requiring that conference attendance be expressly approved by the federal agency and included in the terms and conditions of the federal award. Scientific conferences play a critical role in the medical research ecosystem. Researchers participate in these conferences to present findings, receive scientific feedback, establish productive collaborations, learn about emerging discoveries, identify new methodologies, train early-career investigators, and accelerate the translation of research findings into clinical practice.[43,44] For example, the AACR Annual Meeting convenes more than 23,000 researchers, physician-scientists, clinicians, patient advocates, and industry representatives from around the world and features the presentation of more than 7,000 scientific abstracts reporting the latest advances in basic, translational, clinical, and population sciences. Similarly, AACR's Special Conferences and other topically focused meetings, including conferences on Drug Discovery and Development (D3), Tumor Immunology and Immunotherapy (IO), specific organ site cancers (e.g., breast, lung, prostate, ovarian, etc.), and the AACR Oncology Industry Partnering Event, bring together academic investigators, biotechnology and pharmaceutical companies, government scientists, and patient advocates. Comparable robust scientific exchange occurs at other major medical meetings, such as the annual meetings of the American Society of Clinical Oncology (ASCO), the Society for Immunotherapy of Cancer (SITC), and the American Society of Hematology (ASH). Attendance at these meetings is not ancillary to federally funded research; it is an integral component of disseminating research results, validating scientific findings, developing collaborations, stimulating innovation, training of early-career investigators, and accelerating the translation of discoveries into improved patient care.

The proposed provision appears to assume that conference participation can be anticipated and incorporated into award terms and conditions at the time an award is issued. In practice, many research awards span multiple years, and most relevant scientific meetings may not yet be scheduled, established, or known when the award is issued. Furthermore, researchers often cannot know at the time of award which conferences will be most relevant, whether new conferences will be established, whether existing conferences will change focus, or whether unexpected scientific findings will create opportunities to present important results. Similarly, conference invitations, speaking opportunities, and opportunities to present late-breaking research frequently arise during the course of a project and cannot reasonably be anticipated when award terms are negotiated. The proposed rule does not provide details regarding how approvals for conference participation would be administered.

OMB should specify:

- Who within a federal agency would review and approve conference requests;
- What criteria agencies would use when evaluating requests;

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- Processes or mechanisms for approvals after an award is issued;
- What timelines would apply to agency review; and
- Whether recipients could appeal denials or seek reconsideration.

OMB has also not considered how the proposal may disproportionately affect early-career investigators, trainees, and researchers at smaller institutions who rely on scientific meetings to build collaborations, share research findings, and establish meaningful professional networks. It may also delay the dissemination of federally funded research results and reduce opportunities for interdisciplinary collaboration that often lead to scientific breakthroughs.

AACR is also concerned that agencies could face substantial administrative burdens if they are required to review and approve large numbers of conference participation requests throughout the lifecycle of thousands of active awards. Scientific conference participation is already subject to longstanding federal cost principles requiring costs to be reasonable, necessary, and allocable to the award. OMB has not demonstrated that current requirements have resulted in widespread misuse of funds or that the proposed restrictions would generate meaningful improvements in the stewardship of taxpayer dollars.

AACR recommends that OMB withdraw the proposed revision in §200.432. OMB should permit conference participation when it is reasonably related to the objectives of the funded project and continue to rely on existing federal cost principles to ensure the appropriate stewardship of federal funds. If OMB seeks to retain the provision, it should require that agencies provide clear guidance regarding approval procedures, decision-making criteria, timelines, and ample opportunities for recipients to obtain approval for conference participation that arise after an award has been issued.

20) §200.450

Cancer research institutions, professional societies, academic medical centers, and research organizations routinely communicate scientific findings, public health information, and research opportunities to patients, health care professionals, policymakers, and the public. These activities may include dissemination of research results, educational materials regarding cancer prevention and screening, public awareness campaigns related to clinical trial participation, and communication of scientific evidence relevant to public health decision-making. Dissemination of findings related to such topics as health disparities, evidence-based cancer prevention, cancer screening, tobacco control, vaccination, environmental exposures, or access to care could be interpreted as "promoting or opposing a particular social, political, or public policy position," "messaging designed to influence public attitudes," or as attempts "to affect State agency policymaking, rulemaking, or administrative actions" as currently defined in §200.450(c)(1)(iv) and §200.450(c)(1)(v).

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The proposal does not explain what activities constitute "issue advocacy" or "public messaging" for purposes of the prohibition, how these concepts differ from existing lobbying restrictions, or how agencies will distinguish prohibited activities from legitimate scientific and public health communications. Without greater clarity, recipients may be unable to determine with confidence whether routine communications activities remain allowable.

OMB should clarify:

- Who within a federal agency will determine whether an activity constitutes prohibited "issue advocacy" or "public messaging";
- Specific and objective criteria that will be used to make such determinations;
- Procedures to ensure consistent standards are applied across agencies and programs;
- Whether recipients may seek advance guidance regarding proposed activities; and
- What recourse recipients will have after a determination has been made.

AACR recommends that OMB revise §200.450(c)(1)(iv) and §200.450(c)(1)(v) to provide clear definitions and objective standards regarding the activities covered by the prohibition as well as to require agencies to establish transparent procedures for making allowability determinations, identifying the officials responsible for those decisions, and providing recipients with a mechanism to seek guidance regarding potentially affected activities.

21) §200.454

Academic medical centers, universities, cancer centers, and research institutions rely on subscriptions to scientific journals, databases, bibliographic resources, and other information services to conduct research, design clinical trials, analyze data, and remain current with rapidly evolving scientific discoveries.[39]

OMB's Regulatory Impact Analysis anticipates no impacts; however, OMB has not adequately assessed the potential implications of §200.454(b) for institutional subscriptions, library resources, and other research support activities commonly supported through institutional infrastructure and library systems that are funded in part through federally negotiated indirect cost rates and institutional grants. Limiting the allowability of such costs could reduce access to the scientific literature that researchers need to conduct high-quality cancer research and translate discoveries into improved patient care.

Provision §200.454(d) makes costs associated with memberships in organizations whose primary purpose is "lobbying or issue advocacy" unallowable. The proposal does not define these terms or establish clear standards for determining when an organization's activities would be considered as covered by this prohibition.

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OMB should clarify:

- Who will be responsible for determining whether an organization's "primary purpose is lobbying or issue advocacy";
- What specific criteria will be used to make that determination;
- Whether agencies will maintain lists of affected organizations; and
- Whether organizations may seek clarification or appeal their inclusion.

AACR recommends that OMB remove §200.454(b) and remove or substantially revise §200.454(d). At a minimum, OMB should clearly define criteria for determining whether an organization's "primary purpose is lobbying or issue advocacy," establish transparent procedures for making allowability determinations, identify the officials responsible for those decisions, and provide organizations with a mechanism to appeal those decisions.

22) §200.461

Publication is fundamental to scientific progress.[45] Peer-reviewed publications allow researchers to communicate findings, validate results, build upon prior discoveries, avoid unnecessary duplication of effort, and accelerate the development of new prevention strategies, diagnostics, and treatments. Cancer research, in particular, depends on the rapid dissemination of scientific findings. Researchers routinely publish results from laboratory studies, translational research, clinical trials, epidemiologic investigations, implementation science studies, and public health research. These publications inform future research directions, clinical practice guidelines, regulatory decision-making, and patient care. The benefits of federally funded research are realized only when findings are disseminated to other researchers, clinicians, patients, and the public.

Importantly, the economics of scientific publishing have changed substantially in recent years. As scientific publishers have increasingly shifted toward open-access publication models, researchers are now frequently required to pay article processing charges (APCs) in order to publish their work and make it publicly accessible. Multiple studies have documented that APCs have increased significantly over time and now represent a substantial cost for many research projects.[46,47] Recent analyses have found that APCs commonly range from several thousand dollars per article, with many medical and high-impact journals charging publication fees exceeding $3,000-$5,000 per manuscript.[48,49] These costs are routinely incorporated into research budgets and have become an established component of disseminating federally funded scientific findings.

Eliminating publication costs as an allowable expense in §200.461(a) would create significant barriers to dissemination, particularly for early-career investigators, smaller institutions, community-based research programs, and investigators with limited discretionary resources. The result would likely be fewer publications, delayed dissemination of findings, and reduced public access to the results of federally funded cancer research. In addition, federal agencies such as NIH, as well as researchers and their institutions, evaluate research productivity and professional

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advancement through publications.[50–52] Publications are often the primary evidence used to demonstrate research outputs, progress, and impact in progress reports, competing renewals, and future grant applications. In effect, the proposed rule would prohibit spending on one of the very outputs that federal agencies rely upon to assess whether research funding has been successful.

Furthermore, the proposed provision directly conflicts with long-standing federal efforts to increase public access to taxpayer-funded research. In August 2022, the Office of Science and Technology Policy (OSTP) issued updated guidance directing federal agencies to ensure immediate public access to federally funded scholarly publications and supporting scientific data.[53] Federal agencies, including NIH, have since implemented policies designed to expand public access to research outputs and eliminate embargo periods that previously restricted access to published findings.[54] The proposed elimination of publication costs as allowable is fundamentally at odds with these important objectives. Open-access publication frequently requires payment of article processing charges, and federal agencies have recognized that publication costs are often necessary expenses for complying with public access requirements. OMB has not explained how recipients can reasonably be expected to provide immediate public access to federally funded research findings while simultaneously being prohibited from using federal funds to support this directive.

Provision §200.461(b) provides exception to publication costs that are "approved in advance by the Federal agency on a case-by-case basis." However, OMB has not provided guidance for procedures or standards for how agencies would administer this exception. The proposal does not identify who would review publication cost requests, what criteria would be used to determine approval, or how agencies would manage the likely numerous requests. Without clear implementation guidance, this provision risks creating a significant administrative bottleneck that would delay publication of federally funded research, increase burden on recipients and agency staff, and undermine the timely dissemination of important scientific findings.

Additionally, OMB has not provided the rationale for why such regulation reform is needed or how this would achieve the stated objectives of the proposed rule. This proposal appears to directly contradict OMB's stated objectives of improving transparency and reducing recipient burden. Scientific publication is one of the primary mechanisms through which research findings are shared with other researchers, health care providers, policymakers, patients, and the public to enable transparency regarding stewardship of taxpayer funding. Agencies, such as NIH, were already exploring alternative mechanisms to limit allowable APCs, but not fully eliminate them.[55] A general prohibition of publication costs would reduce transparency by creating barriers to dissemination of federally funded research while simultaneously increasing administrative and financial burdens on recipients seeking to comply with federal public access requirements.

AACR recommends that OMB withdraw the proposed revisions to §200.461 and retain publication costs as an allowable expense under federal awards. If OMB seeks to retain the provision, it should defer to agencies' ongoing efforts to address publication costs.

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Conclusion

AACR appreciates the opportunity to comment on OMB's proposed revisions to the Uniform Guidance. We recognize and support OMB's stated goals of improving transparency, accountability, stewardship of federal funds, and reducing unnecessary administrative burden on recipients. Federal research funding programs should be administered efficiently, responsibly, and in a manner that maintains public trust. However, as outlined throughout this comment, AACR is concerned that many of the proposed revisions would have the opposite effect.

The proposed rule would introduce significant uncertainty into the federal research funding system, increase administrative burden on recipients and federal agencies, reduce transparency regarding funding and termination decisions, create barriers to scientific collaboration and dissemination, and undermine the stability necessary to conduct long-term medical research. Many provisions rely on broad or undefined terms, including subjective concepts, such as "national interest," "public messaging," "issue advocacy," “anti-American values,” "DEI," and other standards that lack sufficient regulatory definitions or implementation guidance. As a result, recipients may face substantial uncertainty regarding compliance obligations, while agencies may develop inconsistent interpretations and enforcement approaches.

OMB has also not consistently identified the specific problems that these provisions are intended to address, provided evidence demonstrating that existing policies are inadequate, or shown how many of the proposed changes would meet stated objectives. In numerous instances, the proposal would replace established processes with new requirements that appear likely to increase costs, delay research activities, create duplicative reviews, and impose additional administrative obligations on both recipients and federal agencies. Furthermore, many provisions establish new approval, review, or oversight requirements without providing guidance for corresponding policies, procedures, standards, timelines, documentation requirements, or decision-making criteria necessary for effective implementation.

Therefore, AACR recommends that OMB withdraw or substantially revise numerous provisions of the proposed rule. In particular, AACR urges OMB to preserve merit-based scientific review as the primary basis for research funding decisions; maintain appropriate safeguards and review mechanisms for award suspensions and terminations; preserve researchers' ability to publish and disseminate federally funded research findings; avoid unnecessary restrictions on scientific collaboration, conference participation, and professional engagement; and provide clear, objective, and transparent standards for any new compliance obligations imposed on recipients.

Furthermore, AACR is particularly concerned that the timeline contemplated by the proposed rule does not adequately reflect the scale of the changes under consideration. The proposal would fundamentally alter numerous aspects of the federal grantmaking process that affect thousands of institutions, hundreds of thousands of researchers, and billions of dollars in federally funded research activities. Significant planning, guidance development, training, systems modifications, and stakeholder education would be necessary to implement many of these provisions.

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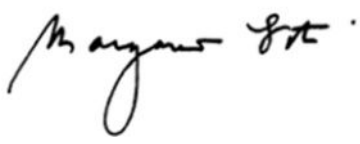
Moreover, the proposal appears impractical given the current operational realities across the federal government. Several of the proposed provisions rely on timely review and decision-making by senior political appointees, yet many agencies with substantial research portfolios currently lack permanent political leadership in key positions.[56–59] OMB has not explained how these responsibilities would be carried out in such circumstances, nor has it evaluated the resulting effects on award timelines, administrative burden, or agency operations. Absent substantial revisions, additional clarifications, and a carefully planned implementation strategy, the proposed rule risks creating confusion, disruption, and unintended consequences that could seriously impede scientific progress and weaken the Nation's research enterprise and global competitiveness.

OMB should also perform a more in-depth assessment of the rule's economic impact. Moody's Ratings concluded that the proposal is a "credit negative" for research universities because it increases uncertainty surrounding federal research funding and institutional financial planning.[60] Recent federal actions have already raised significant concerns regarding the United States' ability to maintain its global leadership in medical research and innovation. Multiple independent analyses have warned that these actions are eroding America's competitive advantage by disrupting research programs, discouraging scientific talent, and creating opportunities for competing nations to expand their medical research capacity.[61–63] These findings further underscore that the proposed rule would likely exacerbate these trends and have significant economic consequences that have not been adequately considered in the Regulatory Impact Analysis.

Given the breadth and complexity of the proposed revisions, additional stakeholder engagement and analysis are warranted before finalizing changes of this magnitude. Therefore, AACR recommends that OMB delay finalizing the proposed rule to address the major concerns and undertake a more comprehensive assessment of the potential impact of these proposed changes on the medical research enterprise, including the adverse effects on research productivity, grants administration and oversight, scientific collaboration and innovation, workforce development, public access to lifesaving research findings, and U.S. global competitiveness.

If AACR can provide any additional information or assistance to OMB, please do not hesitate to contact Jon Retzlaff, AACR Chief Policy Officer and Vice President of Science Policy and Legislative Affairs, at jon.retzlaff@aacr.org. Thank you again for the opportunity to provide comments on the proposed rule.

Sincerely,



Margaret Foti, PhD, MD (h.c.)
Chief Executive Officer
American Association for Cancer Research

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615 Chestnut Street | 17th Floor
Philadelphia, PA 19106-4404
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