July 10, 2026

Russell Vought
Director
Office of Management and Budget
725 17th St. NW
Washington, D.C. 20503

Re: OMB-2026-0034 – Regulation Federal Financial Assistance Proposed Rule
91 Fed. Reg. 32198 (May 29, 2026)

Dear Director Vought:

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) appreciate the opportunity to comment on the Office of Management and Budget's (OMB) Federal Financial Assistance Proposed Rule. The ACS mission is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer. ACS, operating throughout the United States (U.S.), is the largest voluntary health organization in the country. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates nationwide to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As ACS's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN advocates to ensure that the best scientific research that will advance health outcomes is funded and translated into interventions that are accessible by all. That means a process that is transparent, grounded in science, and merit based. Several aspects of this draft rule stand in the way of those tenets, creating an opaque and non-merit-based review process, setting unclear standards that discourage research and interventions critical to improving health outcomes, and generating an environment of uncertainty. Taken together, this rule will impede the federal research enterprise, stifle innovation, limit access to proven health interventions, and would risk not only American's health but also accelerate the ongoing loss of American leadership in biomedical research as talent and capital move to countries with more predictable research environments. As discussed in more detail below, ACS CAN strongly opposes the proposed rule and urges the administration to withdraw the rule.

We object to the proposed rule on a number of grounds:

- **The opaque and non-scientific criteria for proposed review will create uncertainty and stifle innovation.** The introduction of non-merit-based review means that researchers will no longer seek to advance the most scientifically promising research ideas but rather will be faced with trying to craft "safe" proposals that attempt to appeal to changing and subjective topics of interest to the administration or even specific appointed individuals charged with making award determinations.
- **Barriers to specific research fields and topics will stand in the way of progress.** Cancer mortality rates have dropped by 34% since 1991, but this progress has not benefited all groups equally. Further progress requires identifying where outcomes have lagged and understanding the causes of stark disparities in cancer incidence and survival across demographic groups. The proposed rule would discourage this work by creating uncertainty about whether health disparities research falls within the prohibition on "disparate impact studies" and by barring funding for programs with participation criteria that include race.
- **Grant cancellation for any cause creates an environment of fear and uncertainty and drives down investments in innovation.** In the past year, thousands of research and training grants were terminated or frozen, at a loss of hundreds of millions of already invested taxpayer dollars. In many cases, no reasons were provided for the disruptions causing confusion. As a result, biomedical graduate student admissions have dropped, the researcher employment outlook has dimmed, and other countries have sought to capitalize by recruiting U.S. researchers.[1]
- **Proven health intervention programs could be curbed, reducing progress.** While biomedical discoveries are an important part of improved patient care and outcomes, realizing these benefits requires effective implementation in real-world settings. This proposed rule could affect vital cancer control programs at the Centers for Disease Control and Prevention (CDC) and worsen cancer outcomes through decreased implementation of effective scientific discoveries.

SECTION-BY-SECTION DISCUSSION OF THE PROPOSED REVISIONS TO SUBTITLE A OF 2 CFR

Subpart C – Pre-Federal Award Requirements and Contents of Federal Awards

Section 200.205 – Federal Agency Review of Merit of Proposals

[1] STAT, 2026. https://www.statnews.com/2026/03/19/nih-funding-national-researcher-survey-finds-cutbacks-disruptions/ Accessed 8 June 2026.

[200.205] The longstanding National Institutes of Health (NIH) review process is one that leverages peer scientific review by over 20,000 scientists every year to establish scientific merit of proposals through study sections.[2] This review provides scorings that allow proposals to be ranked, and at institutes like the National Cancer Institute (NCI) the very best proposals are funded at what is known as a payline. Even in this process there is some flexibility to fund otherwise highly scoring but unselected projects that address unmet needs. This general model of peer review is common across the biomedical research ecosystem, and a very similar program is employed by ACS to grant over $130 million per year to advance cancer research outcomes. Relying on the expert opinions of scientific peer reviewers, ACS has funded 53 innovative researchers who later received recognition of their cutting-edge work by winning the Nobel Prize. Many other investments identified through the rigorous ACS review process resulted in breakthroughs that have changed standard of care for cancer patients, from discovery of the first ever chemotherapy treatment almost 80 years ago to more recent targeted therapies that have substantially increased patient survival. Despite the proposed rule's statement in the preamble that "OMB proposes a variety of changes designed to ensure and emphasize the need for merit-based selection of recipients for discretionary Awards,"[3] the proposed rule nonetheless seeks to make this peer-review assignment of merit a secondary consideration in making awards. The proposed rule makes clear that political appointees would be the primary decisionmakers and "peer review recommendations remain advisory and are not ministerially ratified, routinely deferred to, or otherwise treated as de facto binding by senior appointees or their designees." [200.205(d)] The proposed rule charges these appointees to select award recipients based on ill-defined, subjective, and potentially ever-changing criteria, such as the "President's policy priorities" [200.205(b)(1)], "national interest" [200.205(b)], and avoidance of "anti-American values" [200.205(b)(2)(iv)].

While scientific peer review of proposals is unlikely to change drastically from year to year absent major scientific advances, the interpretation of the proposed review criteria based on priorities is likely to swing wildly from administration to administration. Combined with the rule's provisions on termination and suspension [200.340] that allow broad discretion for grant cancellations that do not meet "national interest as they exist at the time of the termination" [200.340(a)(2)], applicants are faced with the challenge of how to pursue research deemed of interest by one administration while not being in jeopardy of cancellation by the next administration which may have different interests. Such a policy would stymie long-term federal research as researchers would have no way of predicting the political interests of future administrations. In 2025 just such a swing occurred,

[2] NIH, Center for Scientific Review, 2022-2027 Strategic Plan, https://public.csr.nih.gov/sites/default/files/2022-09/CSR-strategic-plan.pdf. Accessed 10 June, 2026.
[3] 91 Fed. Reg. at 32204.

resulting in thousands of cancelled grants and a loss of nearly a half a billion dollars in sunk costs, a preview of what such subjective, non-scientific grant approval processes combined with an expanded ability to cancel grants portend.[4] Faced with such uncertainty, the best researchers are likely to no longer pursue the most scientifically meaningful research, but rather select low-risk, low-yield ideas; move to other countries with a more predictable funding environment; or leave research altogether. All of these would result in loss of American leadership in biomedical innovation. Importantly, this policy change would also likely slow down the pipeline of new patient care solutions. It takes 17 years on average for a biomedical discovery to be implemented into clinical practice.[5] Adaptation of research interests to target political interests would disrupt a researcher's focus of advancing promising health solutions that take more than a decade to achieve.

A further challenge with requiring detailed appointee review of grants prior to awarding is the effect on NIH's ability to release grants in a timely manner. NIH typically does not have many political appointees, and while this responsibility may be delegated, requiring all grants to be funneled through a handful of individuals creates a major bottleneck. This administration has already implemented such review, and the results are a record slow pace of grant approvals. As of June 2026, the rate of new grants issued is only at 48% of the rate seen in 2024, potentially creating funding gaps that lead labs to reduce personnel, or compressing timelines to use granted funds, which may lead to inefficient use.[6]

Lastly, the dependence on individual appointee review of grants runs counter to the administration's own calls for the pursuit of "Gold Standard Science." The Office of Science and Technology Policy's guidance for implementing Gold Standard Science lays out nine tenets, including one on the use of unbiased peer review. This tenet lays out a process for selecting grant recipients via peer review which states that "[s]ubjecting science to unbiased peer review (sometimes referred to as merit review) refers to the impartial and independent evaluation, by qualified experts" and requires that "[a]gencies shall **prioritize** unbiased peer review to advance sound science in the review, selection, and awarding of Federal grants and contracts."[7] Moreover, the administration states the process "should ensure appropriate reviewer selection, prioritizing expertise, independence, and viewpoint diversity…with clear disclosure of potential conflicts of interest," concluding that "**[a]wards must be**

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[4] Grant Witness https://grant-witness.us/nih-data.html. Accessed 8 June 2026.
[5] Rubin R. It Takes an Average of 17 Years for Evidence to Change Practice-the Burgeoning Field of Implementation Science Seeks to Speed Things Up. JAMA. 2023 Apr 25;329(16):1333-1336. doi: 10.1001/jama.2023.4387. PMID: 37018006.
[6] Association of American Universities, 2026. https://www.aau.edu/newsroom/leading-research-universities-report/new-reporting-shows-nih-grantmaking-slowdown. Accessed 8 June 2026.
[7] Office of Science and Technology Policy, Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities, https://www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf. Accessed 10 June, 2026.

granted based on merit, without bias in the selection of awardees." (emphasis added) The OMB rule runs counter to this guidance, indicating that appointees are not to defer to peer review, but rather "must instead use their independent judgment when evaluating Federal award proposals" [200.205.(c)]. The proposed rule sets no process for ensuring that appointees or their designees who are responsible for determining which proposals to fund have met the gold-standard criteria for being a reviewer of proposals. This conflict between the Gold Standard Science guidance and the proposed rule will lead to further confusion as researchers attempt to navigate contradictory frameworks and be forced to guess how much one person's perspective may impact the likelihood of their application's success.

Subpart D – Post Federal Award Requirements

a. Section 200.300 - Statutory and National Policy Requirements

[200.300] Cancer impacts everyone, but it doesn't impact everyone equally. While it may not be the stated intent, the proposed rule would have a chilling impact on research and programs that aim to address differing health outcomes by including broad and unclear language regarding DEI and "disparate impact studies." In particular, the proposed rule bans use of federal funds for "disparate impact studies", and it is unclear how this applies to health disparities research, including research that aims to understand and remedy the disparities that result in starkly higher incidence and death rates for certain demographic groups. The term "disparate impact studies" is undefined, and the lack of clarity as to whether it includes health disparities research would have a severe chilling effect on this area of study. Furthermore, it is unclear how to interpret this language in concert with other federal requirements, including the *NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research*, which requires explicit consideration of race in order to ensure inclusion of minorities in clinical trials.[8] Further, the proposed rule removes existing regulatory language protecting against discrimination based on sexual orientation or gender identity [200.300(b)(2)]. Taken together with the administration's cancellation of disparities related grants and merit review restrictions that do not allow federal support for programs where participation criteria include race [200.205(b)(2)(i)], this proposal has the potential to effectively eliminate federally funded work to understand and address racial, ethnic, and gender-based health disparities.

ACS research shows how differences in social determinants of health, such as race, ethnicity, geography, disability status, sexual orientation, and socioeconomic factors, are associated with profound inequities in cancer incidence, care delivery, and patient outcomes, including stark disparities in survival.[9] For example, individuals diagnosed with cancer residing in rural areas face

[8] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html.
[9] American Cancer Society. Cancer Facts and Figures 2025. Atlanta: American Cancer Society; 2025.

challenges in accessing cancer care and experience worse outcomes than their counterparts living in more metropolitan areas, and are more likely to have limited incomes and face serious financial hardship.[10,11] Research has also shown similar disparities by race, ethnicity, and gender, and recent studies show that more than 25% of cancer survivors report significant levels of disability after cancer diagnosis, including disabilities that impact mobility and self-care.[12] Understanding the root causes of these differences is key to identifying solutions to improve outcomes for all people with cancer. The proposed rule, however, has the potential to selectively block federal funding for the subset of grants seeking to address disparities defined by race or transgender characteristics, despite these groups frequently experiencing some of the largest differences in health outcomes and mortality. Moreover, factors contributing to health disparities, whether rural-urban differences or those associated with race or ethnicity, are complex and intertwined. Meaningful results and solutions require research that takes all social determinants into consideration, where appropriate.

For ACS CAN, advancing health equity means advocating for evidence-based policies that provide everyone with a fair and just opportunity to prevent, detect, treat, and survive cancer – regardless of income, race, sexual orientation, gender identity, disability status, or where they live. For instance, Black men in the U.S. have the highest documented prostate cancer incidence rates in the world and are more likely to be diagnosed at an advanced stage compared to non-Hispanic White men with prostate cancer, with mortality in Black men approximately two to three times that of men in other racial and ethnic groups.[13] Black women have a 40% higher breast cancer death rate despite having a 4% lower incidence rate than White women.[14] LGBTQ+ people also face a unique and increased cancer burden, disproportionately affected by disparities in risk factors and are more likely to be unhoused, and experience poverty and food insecurity,[15,16,17] which can lead to worse cancer outcomes.

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[10] Farhad Islami, Whitney E Zahnd, Daniel Wiese, Hyuna Sung, Elizabeth J Schafer, Rebecca L Siegel, Ahmedin Jemal, Long-term trends in cancer mortality by rural-urban status, United States, 1969-2023, *JNCI: Journal of the National Cancer Institute*, 2026;, djag047, https://doi.org/10.1093/jnci/djag047.

[11] American Cancer Society Cancer Action Network. The Costs of Cancer in Rural Communities; 2022.

[12] Chao Cao et al. Prevalence and Cancer-Specific Patterns of Functional Disability Among US Cancer Survivors, 2017-2022. J Clin Oncol 42, 2257- 2270(2024).DOI:10.1200/JCO.23.02536.

[13] Islami F, Arias G, Lee D, et al. American Cancer Society's Report on the Status of Cancer Disparities in the United States, 2025. *CA Cancer J Clin*. 2026;e70045. doi:10.3322/caac.70045.

[14] Giaquinto, A.N., Sung, H., Miller, K.D., Kramer, J.L., Newman, L.A., Minihan, A., Jemal, A. and Siegel, R.L. (2022), Breast Cancer Statistics, 2022. CA A Cancer J Clin, 72: 524-541. https://doi.org/10.3322/caac.21754.

[15] Romero, A.P., Goldberg, S.K., and Vasquez, L.A. (2020). LGBT People and Housing Affordability, Discrimination, and Homelessness. The Williams Institute.

[16] Brown, T.N.T., Romera, A.P., Gates, G.J. (2016). Food Insecurity and SNAP Participation in the LGBT Community. The Williams Institute.

[17] Hughes TL, Wilsnack SC, Kantor LW. The Influence of Gender and Sexual Orientation on Alcohol Use and Alcohol-Related Problems: Toward a Global Perspective. Alcohol Res. 2016;38(1):121-32.

Research that focuses on specific populations or demographics is vital to helping identify existing widespread disparities that help inform the best interventions and cancer treatments for everyone. For example, genetic factors can play an important role in the susceptibility of certain cancer types for particular populations. Per the increased incidence in prostate cancer for Black men mentioned above, a previous pooled study (that included ACS study data) showed the importance of large-scale genetic studies in men of African ancestry specifically to better understand prostate cancer susceptibility in this high-risk population and discovered nine novel risk variants for this population.[18] Population specific studies not only inform the contribution of genetic ancestry to cancer risk, but also help inform cancer prevention and early detection guidelines and whether certain guidelines are applicable across different populations.[19] By ensuring that everyone, including Black and LGBTQ+ communities for example, have access to care, serious diseases like cancer can be detected and treated earlier – often resulting in better health outcomes and lower costs for the entire healthcare system.

This proposed rule could also impact efforts to ensure clinical trials are representative of the U.S. population, a basic tenet underlying clinical trial validity, and is in direct conflict with the *NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research*.[20] Clinical trials are designed to test an intervention on a small group of people in a controlled setting to determine if the intervention is safe and effective for a broader population. But, for trial results to be relevant to the broader population, they have to mirror that population with respect to health, and socioeconomic and demographic variables. Failure to ensure representative populations can result in ineffective or dangerous drugs being used by the broader population, mask important differences that should inform clinical practice,[21,22] and also represents non-reproducible research, which the administration's Gold Standard Science initiative seeks to eliminate.

The U.S. Food and Drug Administration (FDA) has rejected drug applications solely on the basis that the trials did not include participants representative of the U.S. population. Statutory requirements passed as part of the Food and Drug Omnibus Reform Act (FDORA) of 2022 require drug sponsors to

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[18] Chen F, Madduri RK, Rodriguez AA, Darst BF, Chou A, et al (2023). Evidence of Novel Susceptibility Variants for Prostate Cancer and a Multiancestry Polygenic Risk Score Associated with Aggressive Disease in Men of African Ancestry. Eur Urol. 2023 Jul;84(1):13-21. doi: 10.1016/j.eururo.2023.01.022. Epub 2023 Mar 3. PMID: 36872133; PMCID: PMC10424812.
[19] Melissa Boneta Davis, Rachel Martini, Precision oncology and genetic ancestry: The science behind population-based cancer disparities, Cancer Cell, Volume 43, Issue 4, 2025, Pages 619-622, ISSN 1535-6108, https://doi.org/10.1016/j.ccell.2025.03.022.
[20] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html.
[21] Anticancer Drug Pharmacokinetics May Differ by Sex (2025) https://ascopost.com/news/february-2025/anticancer-drug-pharmacokinetics-may-differ-by-sex. Accessed 25 June 2026.
[22] Roy AM, Patel A, Catalfamo K, et al. Racial and Ethnic Disparity in Preoperative Chemosensitivity and Survival in Patients With Early-Stage Breast Cancer. *JAMA Netw Open.* 2023;6(11):e2344517. doi:10.1001/jamanetworkopen.2023.44517.

submit diversity action plans to FDA for their pivotal drug trials that will ensure that trials reflect the U.S. population with a disease, as historically some racial and ethnic populations in the U.S. have otherwise been vastly underrepresented in cancer clinical trials that support new drug approvals. These action plans describe methods to ensure representative participation in clinical trials, which can help ensure that drugs developed are effective and safe across all demographics. While this administration has not begun enforcing this law, the proposed rule again stands in direct conflict to it. It is critical not only that this bipartisan provision be fully implemented, but that federally funded research efforts similarly ensure representative participation.

b. Section 200.340 – Termination and Suspension

[200.340] Since 2025, over 5,000 NIH research grants have been frozen or terminated.[3] Often, no reason was provided for the disruptions, which were apparently unrelated to research performance or misconduct. Although over 4,000 of those disrupted grants have been subsequently reinstated, the loss in research funding due to the disruption is approximately $459 million.[3] More significant, however, are the impacts the funding uncertainty has introduced in the research environment. Cancer research projects often take years of work by teams of researchers to yield the results that have given us breakthrough treatments and deeper understanding of the causes and early development of cancer. The value of early-stage research is lost when a project is unable to reach completion because funding was revoked. Moreover, fewer grants overall are being awarded, meaning many projects will never begin. As of late March 2026, for example, NCI had committed less than one-third of the funds for new and competing research awards than awarded during a typical year in the previous administration.[4]

The sudden and devastating disruptions to research when in-progress grants are cancelled would become an ongoing risk due to changes in the proposed rule that would codify a framework where grants can be terminated by the awarding agency for any reason. Historically, grants could only be prematurely terminated for misconduct or if the agency determined that the research would not accomplish the goals as stated in the original award. The proposed rule, in contrast, states that any grant may be terminated if the agency "determines that a termination is in the interest of the Federal agency or pass-through entity, including if a Federal award does not effectuate program goals, Federal agency priorities, or the national interest as they exist at the time of the termination." [200.340(a)(2)] The stated rationale for these changes is to align research award policies with the Federal Acquisition Regulation (FAR) which applies to procurement contracts. This represents a fundamental misunderstanding of the time scale and commitment needed for biomedical research and development, and these changes will have a severe chilling effect on investigators seeking to begin the kind of four- or-five-year research projects that can lead to breakthroughs and cures.

In a climate of funding uncertainty, investigators cannot commit to hiring the staff needed to do the work. In a recent survey, 61% of researchers said that federal policy changes in the past year led to layoffs of postdoctoral researchers or staff, and 58% reported delayed hiring processes.[23] Early career scientists and emerging investigators hesitate to commit to research careers, potentially impacting the progress of science years and decades into the future.[24] In February of this year, NIH acknowledged that the changes to grant funding mechanisms have made it more difficult for early stage investigators to receive awards: the funding rate for these researchers dropped from 26% in 2024 to 19% in 2025.[25]

Until recently, the U.S. has been a global leader in biomedical innovation, including cancer research and treatment discovery. The chilling effect of recent changes to U.S. research funding has put this status in jeopardy. In a recent survey of NIH-funded researchers, 13% reported having lost laboratory researchers to institutions in other countries, and 8% have advised trainees to seek work outside the U.S.[29] We are already seeing the effects of these changes; in 2025, China passed the U.S. in the number of cancer research publications, and is rapidly gaining in other areas such as clinical trial openings.[26] In order to maintain U.S. leadership in discovery and innovation, retain exceptional scientists, and spur investment in cures, research must be reliably funded through a predictable, transparent process that is based on solid, unbiased scientific rationale.

IMPACT ACROSS THE CANCER CARE CONTINUUM

In addition to driving cancer research and innovation, federal grants and other financial assistance significantly impact cancer prevention, early detection, diagnosis, treatment, and survivorship. The CDC provides federal financial assistance to state, local, and territorial health departments, tribal governments and organizations, universities and academic institutions, nonprofit organizations, and healthcare systems to provide millions of cancer screening exams, collect and analyze cancer data, support community-focused cancer coalitions, improve cancer care delivery, and educate the public directly on cancer risk and survivorship. A reduction or loss in these programs due to the stipulations in the proposed rule would mean limiting people's access to proven cancer programs and risk worsening cancer outcomes. Lastly, we are concerned about limitations placed on the use of funds

[23] STAT, 2026. https://www.statnews.com/2026/03/19/nih-funding-national-researcher-survey-finds-cutbacks-disruptions/ Accessed 8 June 2026.
[24] STAT, 2026. https://www.statnews.com/2026/01/30/first-year-phd-students-squeezed-tighter-research-funding/ Accessed 8 June 2026.
[25] NIH https://grants.nih.gov/news-events/nih-extramural-nexus-news/2026/02/nih-support-for-early-stage-investigators-in-fys-2024-and-2025. Accessed 8 June, 2026.
[26] Nature, 2025. China overtakes the United States in cancer research output. https://www.nature.com/articles/d41586-025-01154-4 Accessed 8 June 2026.

for publication costs [200.461]. Patients, providers and other researchers utilize research findings to inform care and drive research progress forward. New discoveries can only benefit patients if they are published and accessible, yet the proposal would effectively curb that access.

CONCLUSION

Thank you for the opportunity to comment on the Office of Management and Budget's Proposed Rule. We appreciate the administration's commitment to accountability in federal spending and stand ready to partner on approaches that protect scientific excellence while delivering faster breakthroughs for patients. However, we reiterate our concern that this rule as drafted would actually waste invested dollars and further threaten our global leadership in scientific innovation. ACS CAN strongly opposes the proposed rule and urges the administration to withdraw the rule. Additionally, we urge the administration to extend the consultative process by 90 days so that smaller organizations can weigh in on its impact. If you have any questions, please feel free to contact us or have your staff contact Mark Fleury, Principal, Policy Development - Emerging Science at Mark.Fleury@cancer.org or Gladys Arias, Principal, Health Equity Policy Analysis & Legislative Support at Gladys.Arias@cancer.org.

Sincerely,

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William Dahut, MD
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