AHDA | ALLIANCE FOR HEADACHE DISORDERS ADVOCACY

July 13, 2026

The Honorable Russell Vought
Office of Management and Budget
Office of Federal Financial Management
Executive Office of the President
Washington, DC 20503

Re: Comments on Proposed Rule, *Regulation for Federal Financial Assistance* (Docket No. OMB-2026-0034; RIN 0348-AB86)

Submitted electronically via Regulations.gov

Dear Director Vought:

The Alliance for Headache Disorders Advocacy (AHDA) appreciates the opportunity to comment on the Office of Management and Budget's proposed revisions to the Uniform Guidance governing Federal financial assistance.

AHDA represents a coalition of patient advocacy organizations, patients, professional societies, healthcare providers, scientific researchers and likeminded stakeholders dedicated to improving the lives of the more than 40 million Americans living with migraine and the millions more affected by other headache disorders (Cohen et al., *Headache*, 2024). Federal investment in biomedical research has played a critical role in advancing our understanding of migraine as a complex neurological disease and has contributed to the development of innovative treatments that have improved the lives of many patients. Continued progress depends upon a federal research enterprise that is transparent, predictable, and grounded in scientific excellence. That investment also produces strong economic returns. According to United for Medical Research, every dollar of NIH funding generated about $2.56 in new economic activity in fiscal year 2024, while supporting 407,782 jobs across the country.

AHDA supports efforts to improve accountability and consistency in the administration of federal financial assistance. However, several proposed revisions could create negative consequences for biomedical research, clinical trials, and the patients who depend on continued scientific progress.

Furthermore, the complex nature of headache disorders demands a comprehensive biopsychosocial approach to research, which intrinsically requires sustained, multi-year funding. Migraine and other severe headache disorders frequently co-occur with psychiatric comorbidities, including depression, anxiety, and post-traumatic stress disorder (Minen et al., 2016), and are strongly associated with trauma, including adverse childhood experiences (Tietjen et al., 2010; Tietjen, 2016). Developing, testing, and validating trauma-centered, behavioral, and interdisciplinary interventions takes years of rigorous, multi-phase clinical trials. Subjecting these complex, person-centered research programs to fluctuating administration

priorities threatens to dismantle the precise long-term studies needed to treat the whole patient. Defunding or abruptly terminating these behavioral studies would disproportionately harm vulnerable patient populations whose trauma and mental health needs are deeply intertwined with their physical pain.

Comments on Proposed § 200.202 – Program Planning and Design

AHDA is concerned that the proposed revisions to § 200.202, which would require federal agencies to design programs that align with administration policies and priorities, could subordinate scientific merit to shifting political goals. In biomedical research, projects should be judged on their scientific quality and their potential to help patients. Priorities that change from one administration to the next create an unstable environment for the multi-year work that migraine and headache research requires, and they risk steering funding away from the scientific questions that matter most to patients.

AHDA is also concerned that the section's emphasis on multi-year awards, if it is not paired with a commitment to sustaining the number of new awards each year, could reduce how many new research projects agencies fund annually. Fewer new awards would fall hardest on early-career investigators, who depend on new grants to build independent research careers. For a small and still-growing field like headache medicine, where recent scientific advances have only begun to draw new physicians and researchers in, policies that shrink the research pipeline would slow that progress and deepen the workforce shortage described below.

Comments on Proposed § 200.205 – Federal Agency Review of Merit and Funding Decisions

AHDA is concerned that the proposed revisions to § 200.205 will diminish the central role of independent scientific peer review by requiring that all grants be approved by a senior political appointee. While agencies appropriately establish research priorities, competitively reviewed research awards should continue to be evaluated primarily on scientific merit, innovation, feasibility, and potential public benefit.

Scientific peer review has been the cornerstone of federally funded biomedical research for decades because it provides an objective, evidence-based process for evaluating competing proposals. Patients, researchers, and taxpayers benefit when funding decisions are made through transparent scientific evaluation rather than changing policy preferences.

Migraine remains one of the leading causes of disability worldwide and continues to impose substantial personal and economic burdens despite recent advances in treatment (Rhudy et al., *Headache*, 2024). Important scientific questions remain regarding disease mechanisms, prevention, health disparities, pediatric migraine, chronic migraine, and treatment-resistant disease. Preserving a rigorous merit review process is essential to ensuring that research addressing these unmet needs continues to move forward based on scientific opportunity and patient need.

Migraine disease remains one of the most underdiagnosed and undertreated neurological diseases in America, due in significant part to a severe shortage of trained providers. There are only approximately 900 UCNS certified headache specialists in the United States available to care for an estimated 40 million Americans living with migraine and headache disorders. That gap is a direct consequence of decades of underinvestment in migraine and headache medicine

research. Recent scientific advances and new treatment options have begun to change that trajectory, encouraging more physicians to enter the field because they can finally offer patients meaningful, evidence-based care. Removing scientific peer review from the allocation of research funding would threaten this progress, chill future investment in headache medicine, and deepen the access barriers already facing millions of Americans with migraine disease.

Additionally, migraine is a profoundly stigmatized, invisible illness, often diminished societally as 'just a headache' (Young et al., 2013). This deeply entrenched stigma has historically marginalized headache medicine, contributing directly to the severe underfunding and lack of widespread understanding of the disease's disabling psychosocial impact. Replacing independent, objective scientific peer review with approval by political appointees opens the door for subjective societal biases and historical stigmas to influence funding decisions. A rigorous, merit-based review by subject matter experts is the only safeguard to ensure that research addressing the devastating mental health, social, and functional impacts of headache disorders is evaluated on scientific necessity and person-centered outcomes, rather than fluctuating political optics or public misconceptions.

AHDA is also concerned by the proposed preference for awarding funds to institutions with lower indirect cost rates. Indirect costs, also called facilities and administrative costs, are not peripheral. They pay for the laboratory space, data systems, regulatory compliance, and skilled staff that make clinical trials and rigorous science possible. A preference for low indirect rates would disadvantage smaller institutions and emerging research centers that cannot absorb these costs on their own, which risks concentrating headache research in a small number of well-resourced institutions and narrowing an already small field.

AHDA further notes that the proposed requirement that awards commit to achieving "Gold Standard Science" introduces uncertainty because the term is left undefined. Combined with review by political appointees, an undefined standard invites inconsistent application and leaves applicants without a clear understanding of how their proposals will be judged. Decisions about which biomedical research to fund should rest on scientific merit and reflect the priorities Congress sets through appropriations, not on standards that shift with changing political preferences.

AHDA respectfully recommends that OMB clarify in the final rule that independent scientific peer review remains the primary basis for awarding and continuing federally funded biomedical research and that post-award reviews should focus on recipient performance, scientific progress, and compliance with applicable laws and award conditions.

Comments on Proposed § 200.211 – Federal Award Information

AHDA appreciates the proposal's emphasis on communicating award terms clearly to recipients. However, to the extent agencies include additional conditions related to discretionary termination or shifting agency priorities, recipients should receive clear notice regarding the standards that may be applied during the life of an award.

Biomedical research projects often span many years and involve complex collaborations among universities, hospitals, patient organizations, and federal agencies. Clinical trials may require years of participant recruitment and follow-up before meaningful scientific conclusions can be reached. Greater transparency regarding award conditions helps institutions plan responsibly, recruit participants with confidence, and make long-term investments in research infrastructure.

AHDA encourages OMB to ensure that award notices clearly identify any circumstances under which an award may be modified or terminated and provide recipients with meaningful opportunities to respond before significant agency action is taken.

Comments on Proposed § 200.218 – Prohibition of Using Federal Awards To Promote or Support Theories of Disparate-Impact Liability

AHDA is concerned that the proposed revisions to § 200.218 could create uncertainty about whether investigators may continue to study how a disease affects different patient populations. Sound biomedical research depends on understanding these differences, and ambiguity in this section could discourage scientifically necessary work.

Migraine affects women at roughly three times the rate of men. How the disease presents, what triggers it, and how patients respond to treatment can vary by sex, age, and other biological factors (Rossi et al., 2022; NIH ORWH, 2025). Studying these differences is a matter of scientific accuracy. Research that reflects the full range of patients affected by a disease produces findings that are more precise and more useful to the clinicians who treat them.

AHDA recommends that OMB clarify that nothing in § 200.218 prevents investigators from studying how biological and clinical factors influence disease risk, presentation, and treatment response, or from enrolling the range of patients most affected by the condition under study.

Comments on Proposed § 200.300 – Statutory and National Policy Requirements

AHDA is concerned that the proposed revisions to § 200.300 could discourage scientifically necessary efforts to recruit and enroll representative study populations by creating uncertainty about which research activities are permissible.

Successful biomedical research depends on enrolling study populations that reflect the patients affected by the disease under investigation. Recruiting participants who represent the real-world patient population, and examining how disease burden and treatment response vary across patients, are fundamental components of sound science, not political activities. A clinical trial whose participants do not resemble the patients who will ultimately use a treatment produces less reliable results.

AHDA recommends that OMB clarify that recipients may continue evidence-based activities that improve recruitment and enrollment of representative study populations. Preserving these activities will strengthen scientific rigor and help ensure that advances in migraine and headache research are reliable for the full range of patients who live with these conditions.

Comments on Proposed §§ 200.432, 200.454, and 200.461 – Conference, Membership, and Publication Costs

AHDA is concerned that the proposed restrictions on conference, membership, subscription, and publication costs would raise barriers to the routine work of science. The proposed rule would make conference attendance allowable only when approved in advance in the terms of an award, would require prior approval for professional society memberships, and would make journal subscriptions and publication costs unallowable except by case-by-case agency approval. These activities are not extras. Scientific conferences are where researchers present findings, receive peer feedback, and form the collaborations that move a small field forward.

Access to journals is how investigators stay current. Publication is how discoveries reach the clinicians who treat patients.

These restrictions would fall especially hard on a field as small as headache medicine, where a limited number of specialists rely on conferences and professional societies to exchange knowledge and mentor early-career researchers. Requiring advance approval for opportunities that often arise after an award is issued would also reduce researchers' ability to respond to new developments. AHDA recommends that OMB preserve the current treatment of conference, membership, subscription, and publication costs as allowable when they are reasonable and necessary to the research.

Comments on Proposed § 200.340 – Termination and Suspension

AHDA is concerned with the proposed revisions to § 200.340 governing termination and suspension of federal awards.

The proposed rule would expand agency authority to terminate awards under broader circumstances, including when an award is determined to no longer effectuate agency priorities or the national interest. While agencies must retain appropriate oversight authority, these provisions could introduce significant uncertainty into long-term biomedical research.

Migraine research frequently involves multi-year clinical trials, longitudinal observational studies, development of novel therapeutic targets, and collaborative research networks involving multiple institutions. Patients volunteer for these studies with the expectation that researchers will complete the work and generate knowledge that may benefit future patients. Unexpected termination of awards after projects have undergone rigorous peer review and begun enrollment risks delaying scientific discoveries, disrupting patient participation, wasting prior federal investments, and discouraging future participation in clinical research.

AHDA is also concerned that broadly defined standards based on changing agency priorities could create uncertainty regarding whether competitively awarded research projects will be allowed to proceed through completion. Stable and predictable federal support is particularly important for neurological diseases such as migraine, where sustained investment has only recently begun to produce transformative advances in treatment. For 25 years, patients had few options to treat their episodic and chronic migraine – only in the past decade have innovative treatments become available.

AHDA is particularly concerned that the proposed changes would authorize termination based on an undefined "national interest," limit notice for discretionary terminations to a brief written explanation, and eliminate the administrative hearing and appeal rights that currently allow recipients to contest a termination. Ending a competitively awarded, peer-reviewed research project on shifting and undefined grounds, without a meaningful opportunity to respond, would strip away basic procedural protections that researchers and institutions rely on when they commit years of work and enroll patients into studies. The added risk could also discourage institutions from applying for awards in the first place.

AHDA respectfully recommends that OMB revise § 200.340 to provide clearer standards governing discretionary termination, require written justification for termination decisions unrelated to recipient performance or legal compliance, provide recipients with notice and an

opportunity to respond, and preserve meaningful administrative review, including hearing and appeal rights, before awards are terminated.

Conclusion

Patients living with migraine and other headache disorders depend upon continued scientific innovation to improve diagnosis, treatment, and quality of life. Federal financial assistance policies should strengthen, not destabilize, the research enterprise that makes those advances possible.

AHDA respectfully urges OMB to withdraw or revise the proposed rule to reaffirm the importance of independent scientific merit review, provide greater procedural safeguards surrounding discretionary termination authority, and preserve the predictability necessary for long-term biomedical research. These changes would advance accountability while protecting the federal investments, research partnerships, and patient participation that drive medical progress.

Thank you for the opportunity to provide these comments. We appreciate OMB's consideration of the perspectives of the headache disorders community and look forward to continued engagement throughout this rulemaking process.

Sincerely,

Alliance for Headache Disorders Advocacy