Kristophe Diaz, PhD
Chief Executive Officer
325 Hudson Street, 4th Floor
New York, NY 10013
646-725-1453
diaz@curepsp.org

July 13, 2026

Docket OMB-2026-10817 (91 FR 32198), Regulation for Federal Financial Assistance

Comments submitted electronically by CurePSP via www.regulations.gov

Introduction

CurePSP appreciates the opportunity to provide public comments on the Office of Management and Budget (OMB) proposed rule, *Regulation for Federal Financial Assistance*.[1]

CurePSP is the leading nonprofit organization dedicated to improving awareness, care and research for people living with progressive supranuclear palsy (PSP), corticobasal degeneration (CBD) and multiple system atrophy (MSA). These conditions, often referred to collectively as atypical parkinsonian disorders, are rare, progressive neurological diseases that cause increasing disability and ultimately shorten life. Although they share certain symptoms with Parkinson's disease, they are distinct disorders with different disease trajectories, treatment needs and research priorities.

An estimated 50,000-60,000 Americans are living with PSP, CBD and MSA at any given time,[2] though the true number of people affected is likely higher than reported. These diseases are frequently misdiagnosed because their symptoms overlap with more common neurological conditions, diagnostic tools remain limited and definitive confirmation occurs only after death. There are currently no FDA-approved disease-modifying therapies for these disorders. Most patients experience progressive loss of mobility, speech, swallowing, cognition and independence, with average survival ranging from approximately five to eight years following symptom onset. The uncertainty and existing barriers that people with atypical parkinsonism face daily reinforce the importance of sustained federal investments in research that improves diagnosis, expands understanding of disease burden and accelerates the development of effective therapies.

[1] https://www.federalregister.gov/documents/2026/05/29/2026-10817/regulation-for-federal-financial-assistance
[2] https://www.psp.org/news/details/what-causes-rare-neurodegenerative-diseases-exploring-the-genetics-of-psp-cbd-and-msa

CurePSP works closely with people with lived experience, care partners, clinicians, researchers, academic medical centers, industry partners and federal agencies to advance research, improve care and develop treatments. Our mission is grounded in the belief that every person affected by these diseases deserves the opportunity to benefit from scientific progress. The United States has led the world in biomedical research through sustained federal investment, rigorous scientific review and strong partnerships across sectors. Preserving that leadership requires a federal research enterprise that is stable, collaborative and predictable—one that fosters innovation, attracts long-term investments and leverage opportunities to reach and serve people in every community.

CurePSP recognizes and supports OMB's overarching goals of strengthening transparency, accountability, stewardship of taxpayer resources and reducing unnecessary administrative burden within federal finance assistance programs. We also acknowledge the need to periodically reevaluate the "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (Uniform Guidance, 2 CFR Part 200) to reflect evolving needs and improve the effectiveness of federal financial assistance programs. Any government-wide revision, however, should preserve the independent, merit-based principles that have made the United States the global leader in biomedical research. We are seriously concerned that the provisions of the proposed rule, if finalized as written, could unintentionally create government-wide uncertainty and costly disruptions that outweigh the intended benefits, negatively affecting the rigorous, evidence-based federal grantmaking process on which all research depends.

For individuals living with PSP, CBD and MSA, the impact would have direct and irreversible consequences. Time is inherently limited. Patients enrolled in longitudinal studies or clinical trials often experience rapid disease progression and simply cannot afford to face diminished research study quality, unexpected research postponement, cancellations and lost research opportunities that offer the greatest hope for much needed therapies and cures.

CurePSP offers the following comments to help OMB substantively reconsider the proposed rule as written in order to preserve the continuity, integrity and collaborative nature of biomedical research that people living with rare neurodegenerative diseases depend upon.

Executive Summary

CurePSP respectfully urges OMB to withdraw the provisions that could unintentionally compromise research quality, research continuity, dissemination of federally funded science, and patient access to clinical research opportunities. Our comments are not intended to provide a comprehensive analysis of every aspect of the proposed rule that would impact our community. Rather, they focus on several provisions that we believe warrant reconsideration because of the potential direct, adverse impact on parkinsonian diseases research and the people who urgently depend upon it.

Specifically, CurePSP respectfully encourages OMB to consider the following bullets, which are also detailed in subsequent sections.

- Preserve the central role of rigorous scientific peer review in informing funding decisions for biomedical research.
- Ensure that implementation of any revisions to the Uniform Guidance supports an efficient and predictable pathway from application to award, minimizing unnecessary delays that could postpone research, patient enrollment and future therapeutic development.
- Preserve transparency, accountability and fair access by requiring written and substantive justification for award terminations, along with appropriate timeline. Clear explanations promote confidence in federal decision-making, enable recipients to understand and address concerns and strengthen future participation in federal research enterprise.
- Maintain existing administrative appeal rights for recipients whose award are terminated. Preserving appropriate procedural protections promotes transparency, accountability and continued participation in the federal research enterprise by enabling recipients to understand agency decisions and strengthen future engagement.
- Establish additional safeguards before terminating federally funded clinical trials, natural history studies, or other human-subject research where interruptions could compromise participant safety, research continuity, scientific validity, or future therapeutic development.
- Ensure that implementation of final rule is consistent with the Administration's broader efforts to accelerate biomedical innovation, including goals articulated in the U.S. Department of Health and Human Services Operation TrialBlazer initiative.

Comments on 2 CFR 200.340 and 200.342— Award Termination
[200.340] Under the proposed rule, awarding agencies would have expanded authority to terminate grants and cooperative agreements immediately when an award is determined to no longer be consistent with agency priorities or the public interest, with no notice or wind-down periods. Unlike the current Uniform Guidance, the proposal would not require agencies to provide a written substantive explanation for these determinations and recipients would generally lose administrative appeal rights.

Response:
CurePSP recognizes that federal agencies must retain appropriate oversight of tax-payer funds and the ability to discontinue awards when warranted. Biomedical research, particularly research involving rare, progressive diseases and human participants, presents unique circumstances that merit safeguards. The proposed framework does not distinguish between

routine financial assistance awards and multi-year research studies that depend on sustained participation by patients, investigators and research institutions.

For people living with PSP, CBD and MSA, the window of opportunity to participate in research is often short because these diseases progress rapidly. Some individuals volunteer to participate in research studies knowing they may never personally benefit from the discoveries but create the opportunities for future patients.

Once a patient enrolls in a research study, the scientific value of that participation depends on the study being completed. For people living with PSP, CBD and MSA, time is limited. If a federally funded study would be terminated before completion for unclear reasons, participants may lose the opportunity to contribute meaningful data as their disease progresses, no longer qualify for continued participation or die before the study resumes. These opportunities cannot simply be recreated through future funding cycles.

This challenge is especially significant for rare neurological diseases. Many people remain undiagnosed, are diagnosed only after substantial disease progression, or never reach specialty centers capable of conducting research. Longitudinal natural history studies, which follow patients over several years to understand disease progression, identify meaningful clinical outcomes and validate biomarkers that make future therapeutic trials possible, are particularly dependent on continuity. Their scientific value is realized only when studies are completed. Interruptions risk losing years of patient participation, biological samples, imaging data, and clinical information that cannot be simply replaced or repeated.

For example, there is currently no definitive diagnostic test for PSP, CBD or MSA. Longitudinal studies build the evidence needed to discover biomarkers, measure disease progression, evaluate treatment response and enable future clinical trials. Premature termination of these studies could delay not only individual research projects but also the development of diagnostic tools and therapies that people living with PSP, CBD and MSA urgently need. It would also delay efforts to better understand and identify people who remain undiagnosed, underrepresented or otherwise invisible within today's healthcare and research systems.

Beyond the immediate impact on federally funded research, uncertainty around the continuity of awards may also influence the broader biomedical innovation ecosystem. Rare disease therapeutic development frequently depends on partnerships among federal agencies, academia, nonprofit organizations and private sector sponsors. Predictable federal funding helps reduce scientific and financial risk, encouraging continued investments and collaboration. Conversely, increased uncertainty regarding whether federally supported research may be terminated for unclear reasons could discourage future investment in areas that already carry substantial scientific and commercial risk. For disease such as PSP, CBD and MSA, where research opportunities are limited and therapeutic development is inherently challenging,

preserving a stable and predictable research environment is critical to sustaining these partnerships.

CurePSP also encourages OMB to consider how these provisions align with the Administration's recently announced research initiatives such as Operation TrialBlazer.[3] The initiative seeks to strengthen America's leadership in clinical research by accelerating the development of lifesaving therapies, support informative clinical trials, advancing treatments for rare diseases, and partnering with patient organizations through the research process. Although Operation TrialBlazer and the proposed OMB rule were released within a month of each other, there is lack of clarity on how proposed grantmaking changes would interact with the initiative and potentially impede the goals and timelines expressed in Operation TrialBlazer. Efforts such as reducing unnecessary delays in clinical research may be less effective if investigators, institutions, and patient volunteers face increased uncertainty regarding the continuity of federal supported studies as cited in 2 CFR 200.340. CurePSP finds the objectives outlined in Operation TrialBlazer as a promising endeavor but respectfully highlights that this gap in coordination may have unintended consequences for the research ecosystem both initiatives seek to strengthen. We strongly encourage OMB to ensure that the final rule fully and properly aligns with broader Administration priorities.

Recommendations:

- **[200.340] Require written substantive justification** for any award termination that is not based on recipient noncompliance. Such justification should include the factual and policy basis supporting the termination decision and tangible recommendations and/or associated pathways for improving grant applications (e.g., appeals), if applicable.

- **[200.342] Preserve existing administrative appeal rights** for recipients whose awards are terminated for reasons other than recipient noncompliance. Administrative appeals strengthen accountability by providing a clear process to review agency decisions and maintain confidence in the federal grantmaking system.

- **[200.340] Establish additional safeguards for human-subject research**, including clinical trials, natural history studies and biomarker research. Before terminating these awards for reasons unrelated to recipient performance, agencies should provide an appropriate wind-down period to protect participant safety, preserve accumulated research data and biological samples, fulfill federal human subjects' protection obligations, and support an orderly transition for enrolled participants.

- **[200.340] Coordinate the implementation of the final rule with relevant department initiatives**, including Operation TrialBlazer and future administration-led research efforts. Ensure that rigorous grant administration policies and appropriate

[3] https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.html

scientific experts during peer-review are part of the shared objective of accelerating safe, high-quality biomedical innovation for patients with serious and rare diseases.

Comments on 2 CFR 200.205— Merit Review

[200.205] The proposed rule would revise the federal award review process by requiring additional pre-issuance review of discretionary financial assistance awards by senior political appointees, suggested at the agency level.[4] It would also require agencies to ensure that awards align with applicable statutes, Executive Orders, Administration priorities, and other federal policies before financial assistance is awarded. The proposal further clarifies that scientific or technical peer review informs, but does not determine, funding decisions, reaffirming that final award decisions remain the responsibility of the awarding agency political appointee.

Response:

[200.205] CurePSP recognizes that federal agencies have an important duty to ensure that taxpayer-funded research is managed responsibly, aligns with applicable law and policy, and reflects appropriate stewardship of federal resources. Through existing policy instruments, agencies within the Executive Branch have long aligned research investments with administration priorities, for example through Congressional Budget Justifications, agency strategic plans, OMB clearance of Notices of Funding Opportunities (NOFOs), and the discretionary authority of agency leadership.[5]

We also recognize that scientific peer review has never truly been the sole determinant of funding decisions. The current federal grantmaking process combines objective scientific merit review with agency programmatic judgement. Expert peer review panels evaluate applications against established scientific and technical criteria, such as structured scoring systems that promote consistency, transparency, and evidence-based evaluation. Agency leadership then considers those evaluations alongside broader public health priorities, portfolio balance, statutory authorities, and stewardship responsibilities when making final award decisions. CurePSP believes this complimentary approach has been a longstanding strength of the federal biomedical research enterprise.

Our concern is less with the appropriate agency oversight or accountability but more with the collective effect of the proposed review structure. The proposed rule introduces multiple new decision points, including pre-application screening, expanded pre-issuance review, and a framework in which scientific peer review informs but does not ultimately guide award decisions. While each of these mechanisms may serve legitimate oversight purposes

[4] Although not explicitly stated in the proposed rule, OPM Director Russell Vought clarified at the June 30, 2026, House Oversight Hearing that the responsibility would fall upon the agency-level political appointees.

[5] **OMB Circular A-110** gives agencies authority to set program priorities consistent with the President's budget and statutory objectives. **2 CFR Part 200 (Uniform Guidance)** requires agencies to conduct merit reviews of proposals and administer awards in full accordance with U.S. Constitution and applicable Federal statutes and regulations. **GPRA Modernization Act of 2010** requires agencies to align programs with strategic plans and performance goals, subject to OMB review and approval aligned with administration priorities. **OMB Circular A-11** requires agencies to submit budget justifications that reflect administration priorities.

individually, together they create additional opportunities for research proposals to be evaluated outside the context of disease-specific scientific expertise. Greater uncertainty in the award process may also increase scientific and financial risk for nongovernmental institutions whose investments often build upon federally supported research. This distinction is particularly important for rare diseases.

For patients living with PSP, CBD and MSA, uncertainty in research funding carries serious consequences beyond the research community. These diseases remain among the least understood neurodegenerative disorders. Investigators are often working with small patient populations, evolving disease criteria, limited natural history data and the absence of validated biomarkers. The scientific merit of these studies frequently depends upon nuances that are better understood by experts who have dedicated their careers to these diseases but may be less apparent through broader administrative or programmatic review.

Rigorous scientific peer review exists in its central role to provide that expertise. Peer reviewers assess whether a proposed study addresses an important unanswered question, employs appropriate methodology and is likely to generate meaningful knowledge. For diseases such as PSP, CBD and MSA, this expertise is especially important because promising research proposals may not resemble studies conducted in more common diseases. If proposals are screened out before reaching full scientific review, or if disease-specific scientific expertise sits in a diminished role in informing final funding decisions, patients may lose opportunities that cannot easily be replaced. Unlike more common diseases, there are relatively fewer investigators, specialized academic medical research centers and ongoing studies addressing PSP, CBD and MSA. A single unfunded or delayed study may represent the only opportunity to answer a critical scientific question for several years—time that people impacted do not have. Predictable federal investments also help reduce scientific and financial risk, encouraging continued participation of nongovernmental partners that are essential to advancing therapies for rare, neurodegenerative diseases.

Additional review processes should be evaluated not only for their oversight value but also for their potential effects on the timeliness and predictability of award decisions. For rapidly progressive diseases such as PSP, CBD and MSA, delays in initiating research have consequences that extend beyond administrative timelines. Delayed awards may postpone patient enrollment, slow biomarker validation, defer clinical trial initiation, and delay the development of future therapies for individuals whose opportunity to participate in research is inherently limited by their disease progression.

Building public confidence in the federal biomedical research enterprise depends on many critical factors. Patients participating in federal research studies should trust that the time, effort and risks they undertake are directed towards studies that have been rigorously evaluated by experts who understand their disease and population. Individuals living with PSP, CBD and MSA often travel significant distances to specialty centers, undergo repeated neurological examinations and imaging studies, contribute biological samples and must remain active and

engaged in the study over several years. The government doing their part in maintaining a central, meaningful role for disease-specific scientific expertise throughout the funding process helps preserve that confidence and supports the shared goal of advancing high-quality research that benefits all people affected by these devastating diseases.

Recommendations:

- **[200.205] Clearly define key terminology used throughout the proposed rule[6] and describe how scientific merit, programmatic priorities, statutory requirements, and Administration priorities will be integrated throughout pre-issuance review.** Greater transparency regarding these factors will strengthen public confidence in funding decisions and reduce uncertainty for applicants.

- **[200.205] Maintain a central, meaningful role for rigorous scientific and technical expertise throughout award decision-making for biomedical research**, particularly for complex and rare neurological disease where methodological nuance is difficult to assess without disease-specific expertise.

- **[200.205] Provide publicly available guidance describing the objectives and expectations of the pre-issuance review process before the release of a final rule.** Clear guidance will improve consistency across agencies, reduce unnecessary administrative burden for applicants and promote more efficient implementation of the final rule.

- **[200.205] Recognize the unique characteristics of rare disease research during implementation.** For conditions such as PSP, CBD and MSA where patient populations are small, diagnoses are frequently delayed, and research opportunities are inherently limited, maintaining predictable and scientifically rigorous pathways from scientific review to award is essential to ensure that every opportunity to advance research can be realized.

Conclusion

CurePSP appreciates the opportunity to submit these comments in support of an effective federal oversight framework and a biomedical research enterprise that serves all people affected by serious and rare diseases. We look forward to continued engagement as OMB proceeds and remain available to provide additional information that would assist in OMB's deliberations. For questions about these comments, please contact Kristophe Diaz, PhD, Chief Executive Officer (diaz@curepsp.org) and Nora Wong, MPH, Associate Director of Public Policy (wong@curepsp.org).

[6] For example, the proposed rule uses undefined terminology such as, "Gold Standard Science," "anti-American" and "noncompliance." The proposed rule also references the President's policy priorities but does not include a list of examples, such as the inclusion of the Congressional Budget Justifications within the President's Budget Request, agency strategic plans, department wide initiatives and other types of Executive Branch published products.